



Advocating for Digital Health Legislation in Kenya

December 2024

This report was commissioned by **Transform Health** through funding from **Fondation Botnar**.

The case study was carried out and authored by James Gathogo and edited by Tariq Tobias Omarshah Ambrose.

The views expressed in this report reflect the independent assessment of the author and do not necessarily represent the views of Transform Health or its affiliates.

The study drew from a series of semi-structured interviews and focus group discussions conducted between September and October 2024 with eight members of Transform Health Kenya.

The study was managed and facilitated by Danielle Mullings, Mandy Govender and Frank Smith from Transform Health

For any questions related to this report, please contact:

Transform Health is a coalition of 200+ organisations that advocate for equitable digital transformation of health to achieve health for all in the digital age.

Find out more: https://transformhealthcoalition.org/

One South is an international development consulting firm working to support organisations to understand and deliver social change. Our vision is a world where social change is experimental, incremental, and driven by a shared experience.

Table of Contents

Table of Contents	3
Acronyms and Abbreviations	4
Executive Summary	5
Successful strategies	
Key Impacts	8
Conclusion & Lessons Learned	9
1. Background	10
1.1. The challenge	11
1.2. Addressing the challenge: Transform Health Kenya	12
2. Key strategies	13
3. Impact	19
4. Lessons learned and best practices	20
Annexes	24
Kenya's Digital Health Act timeline	24
Transform Health Kenya's logical model	30
Study methodology	31

Acronyms and Abbreviations

Acronym/Abbreviation Full Name

CIHIS Comprehensive Integrated Health Information System

DHA Digital Health Act

ICF Inner City Fund (often used for demographic surveys)

KeHIA Kenya Health Informatics Association

KELIN Kenya Legal and Ethical Issues Network on HIV & AIDS

KNBS Kenya National Bureau of Statistics

KP Consortium Key Populations Consortium KTN Kenya Television Network

MoH Ministry of Health

MSM Men who have Sex with Men PHCA Primary Health Care Act

PHDAF Partners for Health and Development in Africa

PS Kenya Population Services Kenya SHIA Social Health Insurance Act

SRHR Sexual and Reproductive Health and Rights

UDA United Democratic Alliance
UHC Universal Health Coverage
WHO World Health Organisation
WRA White Ribbon Alliance

Executive Summary

Transform Health is committed to building a global movement that leverages digital technology and data to accelerate progress towards Universal Health Coverage (UHC) by 2030. In alignment with this mission, the coalition has actively engaged in digital health policy advocacy across multiple countries, including Kenya.

This report documents the journey and impact of Transform Health Kenya in advancing digital health reforms, mainly through its advocacy for the recently enacted <u>Digital Health Act</u>. Transform Health Kenya supported the process by leading key activities, including workshops, stakeholder engagement, community mobilisation, technical assistance, and administrative coordination. These efforts ensured the Act's inclusivity, technical robustness, and alignment with Kenya's universal health coverage goals.

Drawing on interviews with key coalition members, this report aims to assess the national coalition's efforts, providing a case study highlighting both the successes and challenges.

The assessment consolidates several learnings from Transform Health Kenya's advocacy initiatives and guides future programming and donor engagement. By showcasing best practices, unique coalition dynamics, and practical advocacy approaches, this report provides insights into Transform Health's impact in Kenya and is a resource for other national coalitions.

Successful strategies

"If KELIN was there alone, we would just be seen as a human rights lawyer. But we showed up with researchers, young people, and advocates on digital technologies, which gave us more credibility. It was critical for us to include diverse voices, making our advocacy efforts more impactful." - KELIN representative



Transform Health Kenya adopted a structured, multi-stakeholder approach to support the drafting and enactment of the Digital Health Act. These key steps aligned closely with the national coalition's overarching strategies for policy influence:

- Engaging government stakeholders: Courtesy visits, from the onset, and sustained dialogue with the Ministry of Health positioned the national coalition as a trusted partner and ensured alignment with national priorities.
- Contributing to drafting workshops: Coalition members participated in technical and
 consultation sessions, offering expert input on data governance, interoperability, and
 compliance with existing laws, such as the Data Protection Act. These participatory
 workshops facilitated direct collaboration with policymakers and ensured that the Act
 reflected the needs and concerns of all stakeholders, particularly marginalised and key
 populations.
- Mobilising public participation: Webinars, grassroots forums, and digital campaigns
 led by members like Youth Alive Kenya and Love Matters amplified marginalised voices
 and fostered broad-based support for the Digital Health Act. The webinars, organised
 by KELIN, were a four-part series designed to raise public awareness and gather

- feedback on the Digital Health Bill before its enactment. These webinars targeted a broad audience and attracted approximately 100 participants per session, contributing to the bill's inclusivity and responsiveness to public concerns.
- Integrating global standards: The national coalition worked with the Ministry of Health to incorporate international health data governance principles into the legislation, enhancing the legislation's credibility and robustness.

These steps laid a strong foundation for the strategies outlined below, demonstrating how targeted actions contributed to the successful enactment of the Digital Health Act.

- 1. Issue-linking for policy change: The national coalition aligned its advocacy efforts with Kenya's national development goals, such as UHC, and international commitments like the Sustainable Development Goals (SDGs). By linking digital health to these priorities, the national coalition positioned digital technologies as critical enablers for bridging healthcare gaps, enhancing data governance, and improving service delivery. The national coalition effectively reinforced the belief that digital technologies are essential for achieving universal health coverage, as they can expand access to healthcare, improve quality of care, and lower healthcare costs. Advocacy efforts leveraged a policy window created by government commitments, including the Kenya Kwanza Manifesto, which prioritised UHC, and renewed interest in stalled legislation like the e-Health Bill.
- 2. **Building alliances with government:** The national coalition collaborated with key government departments, such as the Directorate of Health Policy, to ensure the Act aligned with existing health priorities. Targeted workshops facilitated direct engagement with policymakers, integrating consent, data governance, and privacy provisions into the legislation. This approach enhanced the Act's credibility and accelerated its enactment.
- 3. Leveraging relationships and expertise: Transform Health Kenya successfully advocated for the Digital Health Act by combining technical expertise, human rights advocacy, and community insights. KELIN, the National Coordinator, played a crucial role in aligning the national coalition's efforts with Kenya's health priorities and facilitating government engagement. By leveraging its strong relationships with the Ministry of Health, KELIN ensured the Act incorporated human rights and technical standards.

The national coalition strategically recruited diverse members, including KEHIA, Love Matters, and Youth Alive, to address critical gaps and ensure inclusivity. Despite initial challenges, the national coalition adapted and refined its approach, ultimately evolving into a cohesive platform for effective collaboration. This enabled meaningful policy influence and ensured the Act addressed Kenya's diverse healthcare needs, advancing universal health coverage through digital transformation.

4. Generating public demand: Public consultations, digital campaigns, and grassroots forums mobilised support for the Digital Health Act. Youth Alive, Love Matters, and the Key Populations Consortium were critical in raising awareness, amplifying marginalised voices, and fostering public trust. However, a High Court ruling later highlighted gaps in public participation, underscoring the need for more extensive consultations to ensure legitimacy.

Key Impacts



The national coalition's strategic initiatives significantly shaped Kenya's digital health landscape. Notably, the national coalition achieved the passage of the Digital Health Act in 2023, ensuring its alignment with Kenya's Universal Health Coverage goals through strategic stakeholder engagement. This success underscores the national coalition's influence in accelerating policy change.

Beyond national policy, the national coalition influenced county-level initiatives, such as the Kisumu Digital Health Transformation Roadmap, which serves as a local ownership and implementation model.

Conclusion & Lessons Learned

The Transform Health Kenya initiative highlighted several key insights:

- Inclusive coalition-building and advocacy: The national coalition's success stemmed from diverse collaborations, ensuring the Digital Health Act addressed the needs of underrepresented groups, including youth, women, and marginalised communities.
- Effective resource allocation and investment: Limited resources constrained the breadth of public participation, underscoring the need for increased investment to enhance legitimacy and avoid legal challenges.
- Sustained engagement with government stakeholders: Building and maintaining solid relationships facilitated the swift passage of the Digital Health Act, demonstrating the importance of political goodwill and consistent advocacy.
- Navigating government-led legislative changes: The bundling of the Digital Health Act with other legislation highlighted the importance of evaluating risks and opportunities when aligning with broader legislative reforms.

To replicate the national coalition's success, future initiatives could consider:

- Establish clear governance structures to align diverse members and streamline decision-making.
- Prioritise inclusive engagement to ensure underrepresented voices are integrated into policy discussions.
- Invest in robust public participation to enhance legitimacy and mitigate risks of legal challenges.
- Maintain consistent communication with government stakeholders to sustain advocacy momentum and foster trust.
- Explore hybrid funding models that balance central coordination with member autonomy, fostering ownership while maintaining strategic focus.

1. Background

In October 2023, Kenya took a bold step toward transforming its healthcare system by passing the <u>Digital Health Act</u> (Kenya Digital Health Act, 2023). This legislation seeks to promote the safe, efficient, and effective use of technology in healthcare while enhancing health data privacy, confidentiality, and security. The Act aims to integrate digital health technologies in support of UHC. It establishes the Digital Health Agency (DHA), which will oversee and guide the digital transformation of the health sector. It mandates the creation of the Comprehensive Integrated Health Information System (CIHIS). This system will connect all digital health platforms, ensuring seamless data exchange. Additionally, the Act emphasises the protection of personal health information and sets standards for data governance. It encourages telemedicine and mobile health technologies to improve healthcare access and delivery. By advancing these priorities, the Digital Health Act plays a key role in achieving Kenya's UHC goals and enhancing the efficiency and effectiveness of healthcare delivery.

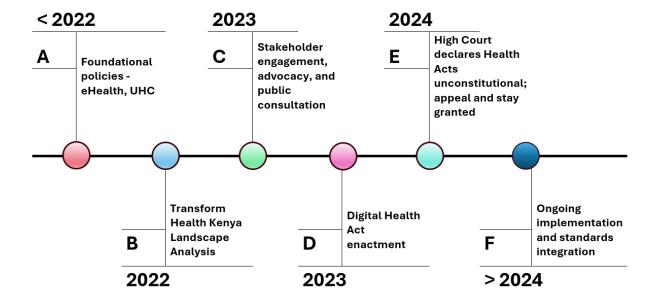


Figure 1 Kenya Digital Health Act timeline (2010 to future)

Transform Health Kenya has played, and continues to play, a key role in shaping this legislation at both national and sub-national (county) levels through an inclusive, multi-stakeholder process. By engaging diverse voices - including youth, marginalised groups, and health professionals - the national coalition ensured that crucial issues like

data governance, privacy, and systems interoperability were central to the legislation, making the Act a progressive step aligned with Kenya's UHC targets.

1.1. The challenge

Kenya has made progress in improving its healthcare system, as outlined in the Kenya UHC Policy (MoH Kenya, 2020). This policy, aligned with Kenya's Vision 2030 and global health goals, aims to ensure all Kenyans can access quality healthcare without financial hardship. Progress is evident in the rise of the UHC service coverage index, which rose from 28% in 2000 to 53% in 2021 (WHO, 2024).

However, pointed gaps persist in access to essential health services for all, especially for marginalised groups such as youth, women, and rural populations (KNBS & ICF, 2023). Lack of health insurance remains a significant barrier, leading to high out-of-pocket expenses and deepening healthcare inequalities.

Digital health technologies offer a promising solution to bridge these gaps (WHO, 2021). These tools can make healthcare more accessible, affordable, and inclusive by reducing the need for in-person visits, lowering treatment costs, and improving data management.

Despite the potential of digital health, Kenya faces obstacles to its widespread adoption. A fragmented legal and policy landscape hinders effective implementation, creating data protection, system interoperability, and standardisation challenges. This has led to uneven adoption across the country, with limited coordination between health systems and a lack of awareness among marginalised groups about their digital health rights and opportunities. Furthermore, insufficient funding and resources, particularly in rural areas, constrain the development and scaling of these vital technologies (Transform Health Kenya, 2022).

1.2. Addressing the challenge: Transform Health Kenya



Transform Health Kenya is driving the adoption and integration of digital technologies into Kenya's healthcare system by 2030 to advance UHC. Through targeted advocacy, strategic partnerships, and capacity-building, the national coalition focuses on three core objectives outlined in its Logical Framework (see Annexes):

- Develop and advocate for robust legal and policy frameworks: This includes
 promoting the enactment of a national E-health Act (now Digital Health Act) and
 county-level laws, focusing on standardisation, and empowering marginalised
 groups to advocate for an enabling legal environment.
- Drive the adoption of digital health technologies: This involves advocating for
 policy implementation, raising public awareness to increase demand for, and
 supporting community-led monitoring and accountability systems to track
 progress in.
- 3. Increase resource allocation for digital health: This includes conducting resource gap analyses, advocating for digital health budget inclusion at national and county levels, and building the capacity of marginalised groups to engage in the budgeting process.

2. Key strategies

"If KELIN was there alone, we would just be seen as a human rights lawyer. But we showed up with researchers, young people, and advocates on digital technologies, which gave us more credibility. It was critical for us to include diverse voices, making our advocacy efforts more impactful." - KELIN representative

Working as a coalition offered several benefits compared to ad-hoc partnerships or working alone, particularly in the context of policy, advocacy and legislative processes. One advantage is the diversity of voices and expertise a coalition brings together, enhancing credibility and enabling the national coalition to address complex issues from multiple perspectives. Coalitions also foster collaboration and shared learning, strengthening their ability to influence policy and advocate for change. Furthermore, coalitions enhance the visibility and impact of advocacy efforts by amplifying the concerns of different stakeholders, increasing the likelihood of influencing policy decisions.



The strategies employed by Transform Health Kenya to leverage these benefits are outlined below.

1. Issue-linking for policy change

The national coalition aligned its advocacy efforts with existing government and development sector priorities to create a conducive environment for policy change. This approach tied the expansion of digital health to government commitments outlined in

the Third Medium Term Plan (MTP III) and the Kenya Health Policy 2014-2030, which emphasised achieving UHC, enhancing access to healthcare for women and girls, and supporting key populations. These national commitments were further reinforced by Kenya's adherence to international agreements, such as the Sustainable Development Goals (SDGs), particularly Goal 3 on good health and well-being. This calls for ensuring healthy lives and promoting well-being for all. Digital health was positioned as an enabler to achieve these national and international health objectives, bridging gaps in healthcare access, enhancing data governance, and improving service delivery for underserved communities.

The national coalition capitalised on a convergence of three streams - problems, policy opportunities, and political support - to leverage a policy window that enabled the swift passage of the Digital Health Act.

Under the **problem** stream, the national coalition identified the fragmented legal and policy landscape around digital health technologies and the need for more government leadership to address this challenge. A <u>landscape analysis</u> commissioned by the national coalition in 2022 also highlighted the pressing need for digital health technologies to be people-centred and consider the issues of vulnerable, marginalised, and criminalised populations to ensure access to health services for all.

Recognising the **policy opportunity**, the national coalition noted unfulfilled commitments made under previous government pledges. For example, the MTP III 2018-2022 outlined the government's commitments to achieving UHC through a multi-pronged approach, including improving the synchronised uptake of digital health technologies. Although the e-Health Bill 2020, in line with the Health Act 2017, had provisions for digital health, it required renewed momentum as the process had stalled due to limited political will. Transform Health Kenya engaged the Ministry of Health through targeted courtesy visits, advocating for the swift enactment of regulations around data governance and interoperability.

The **political climate** also played an essential role in advancing the national coalition's agenda. During the legislative process, President William Ruto's incoming administration had outlined its commitment to achieving UHC through its <u>Kenya Kwanza Manifesto</u>, creating an opportune moment for policy advocacy. One coalition member noted, "This was a fairly fast process compared to other legislative efforts. The government was eager

to show progress on its UHC agenda, and the Digital Health Act fit right into that narrative."

By aligning with national priorities, the national coalition positioned itself as a credible partner, enhancing its influence through technical support and strategic engagement on this issue.

2. Building alliances within the government and creating a venue for sustained interaction



The national coalition strategically identified key staff within departments responsible for developing the Digital Health Act and established strong working relationships with them throughout the legislative writing process. The national coalition worked closely with the Directorate of Health Policy, Monitoring, and Evaluation within the Ministry of Health, which oversees the development, implementation, and evaluation of health policies and systems in Kenya. This directorate also includes the Department of Health Sector Monitoring, Evaluation, and Informatics, which focuses on developing and managing national health information systems, including digital and eHealth platforms. The expertise from this unit was crucial in aligning the Act's provisions with ongoing digital health initiatives, making it a valuable ally for the national coalition.

Transform Health's funding supported targeted workshops that included staff from various government departments to streamline the drafting process. These sessions facilitated direct collaboration, ensuring that contributions from the national coalition, including consent, data governance, and data management, ensured that the Act reflects the needs and concerns of all stakeholders, particularly marginalised and key populations. The funding was also vital in sustaining momentum, enabling the national coalition to organise focused engagements with government stakeholders, ultimately accelerating the Act's enactment.

Digital health is a nascent policy subsystem in the Kenya context. Given recent regime changes and the fact that this is a new area, the national coalition model had significant scope to become a dominant player in agenda-setting by banding together a diverse group of policy actors around an issue with considerable convergence and little competition for alternatives.

3. Leveraging relationships and expertise for policy influence

The national coalition effectively capitalised on the diverse expertise of its member organisations to strengthen advocacy for the Digital Health Act. This collaborative approach was instrumental in shaping the Act to address the real-world needs of Kenya's healthcare system across various health policy priorities. By pooling their strengths, coalition members enhanced the Act's credibility and impact.

Key contributions by stakeholders

- i. Legal and human rights advocacy: KELIN, as the National Coordinator, ensured the Act adhered to a rights-based framework. It bridged gaps between civil society and government while promoting inclusivity and equity in policy development. KELIN's coordination facilitated the inclusion of marginalised voices in the legislative process
- ii. Technical expertise: KEHIA provided critical technical guidance on health informatics, data governance, and interoperability. It also ensured that the Act aligned with global best practices and included robust data privacy and interoperability standards. Love Matters Kenya also contributed its SRHR expertise by addressing the digital communication needs of youth and marginalised groups, ensuring that the Act incorporated provisions to improve access to health information for these populations.
- **iii. Youth engagement:** Love Matters Kenya, and Youth Alive Kenya mobilised young people, conducted workshops, and amplified youth voices in policy discussions. Their efforts ensured the Act addressed the needs of youth as primary adopters of digital technologies.
- **iv.** Marginalised community representation: The Key Populations Consortium represented groups such as LGBTQ+ individuals, people who use drugs, and sex workers. Their advocacy for data privacy and equitable healthcare access ensured the Act included strong protections for vulnerable populations.
- v. Community data governance: Partners for Health and Development in Africa (PHDAF) focused on safeguarding sensitive health data, particularly for HIV-related information. Their contributions ensured the Act incorporated comprehensive data security measures in alignment with Kenya's digital transformation priorities.

4. Generating public demand through consultation and mobilisation



Public mobilisation was a critical component of the national coalition's advocacy for the Digital Health Act. It combined public consultations, digital campaigns, and targeted outreach to engage Kenya's diverse communities. These efforts aimed to achieve three key objectives: increasing awareness and understanding, amplifying marginalised voices, and building public trust and support.

The national coalition sought to educate key demographics—particularly young people—on the Act's significance, addressing widespread gaps in awareness, including among healthcare workers. Love Matters spearheaded these efforts through digital media campaigns on platforms like Instagram and Facebook, reaching millions with accessible content that simplified complex legal concepts and encouraged participation.

Public engagement also prioritised amplifying marginalised voices, recognising the Act's implications for groups such as key populations, persons with disabilities, and the LGBTQI community. The KP Consortium played a pivotal role, organising sensitisation meetings and empowering digital health ambassadors to involve these groups in discussions and community-led monitoring, ensuring their needs were integral to the legislative process.

Another critical objective was building trust between the government and citizens, especially on sensitive issues such as data privacy. This was achieved through grassroots forums such as Youth Alive's, where youth leaders shared priorities and helped shape the national coalition's advocacy. Meanwhile, KeHIA's capacity-building efforts strengthened county teams' understanding of the Act and prepared stakeholders for its implementation at the local level.

Partner activities were strategically integrated to align with the national coalition's overarching goals. As one Youth Alive representative observed, "Our county-level engagement was a critical piece of the national effort to secure public support and advocate for the Digital Health Act." By leveraging the strengths of its members, the national coalition ensured diverse voices contributed meaningfully to its advocacy efforts.

The timing of these activities coincided with the government's renewed push for the Digital Health Act, amplifying public demand and reinforcing the Act as a collaborative effort between stakeholders and citizens. However, a recent High Court ruling highlighted gaps in public consultations, emphasising the need for more extensive digital and in-person outreach in future legislative processes. These lessons underscore the importance of sustained grassroots engagement to legitimise policy efforts and ensure long-term impact.

5. Continuous feedback and adaptive strategy

The national coalition employed continuous feedback loops in its advocacy efforts to remain agile and responsive to the shifting policy landscape. Regular internal consultations allowed the national coalition to refine its strategies based on stakeholder input and changing circumstances. This adaptive approach proved crucial when unexpected challenges arose, such as the need to pivot from developing a county-level digital health bill to supporting the creation of a county-specific digital health roadmap.

The national coalition's flexibility was further demonstrated during periods of economic and political unrest, when it strategically paused activities and later accelerated its efforts to align with the government's fast-tracked timeline for enacting key UHC bills. This continuous feedback and adaptation ensured that the national coalition's strategies remained relevant and effective in navigating the complexities of the legislative process.

3. Impact

The strategic initiatives outlined in the previous section played a crucial role in shaping Kenya's digital health landscape. This section will explore the specific impacts of these strategies and demonstrate how the national coalition's efforts translated into tangible outcomes.

- 1. **Policy impact:** One of the national coalition's most significant accomplishments was the successful passage of the Digital Health Act in October 2023. The national coalition ensured that the legislation was inclusive and aligned with Kenya's UHC goals through strategic engagement with government stakeholders, civil society, and underrepresented communities. Several respondents observed that this bill progressed relatively quickly through the legislative pipeline compared to other legislative processes. This suggests that the national coalition's concerted efforts and strong political goodwill were crucial in accelerating its enactment. However, this swift process also raises questions about whether the speed may have impacted the depth of public participation, an issue later highlighted in legal challenges.
- 2. Strengthening legitimacy, establishing a digital health policy subsystem, and building enduring relationships through collaborative drafting: The national coalition led several drafting workshops and consultations with government officials, healthcare professionals, and key community representatives, funded by Transform Health. These workshops were instrumental in refining the Digital Health Act's provisions on data governance, privacy, and interoperability. The national coalition aligned the Act's content with global best practices through sustained collaboration, ensuring it responded to local needs. According to respondents, this participatory approach provided critical legitimacy to the legislation.
- 3. **Kisumu digital health initiative as a model for county-level implementation**:

 Beyond national policy, the national coalition's influence extended to county-level digital health initiatives, such as the Kisumu Digital Health Transformation

 Roadmap, launched in October 2024. This initiative was informed by a Transform Health-funded resource gap analysis that identified critical areas for the county's digital health investments. The Kisumu initiative is now a model for other counties, emphasising local ownership and implementation.

4. Lessons learned and best practices

The Transform Health Kenya initiative provided valuable insights into coalition-building, advocacy, and policy development in digital health. This section highlights key lessons learned and best practices that emerged from the initiative and offers guidance for similar endeavours.

1. Inclusive coalition-building and advocacy: Transform Health Kenya's experience demonstrates the power of inclusive coalition-building and advocacy to influence policy. Their success stemmed from strategic collaborations across diverse sectors—civil society, private sector entities, and community-based organisations—ensuring the Digital Health Act was responsive to underrepresented groups and tapped into key health priorities in Kenya.

A key takeaway was the emphasis on inclusive engagement, bringing youth, women, and marginalised communities into the policy development process. This ensured that the Act reflected the real-world needs of those most affected by healthcare disparities. For example, partnerships with Youth Alive Kenya empowered young people to advocate for their health rights. At the same time, collaborations with the Key Populations Consortium ensured key populations, such as LGBTQI communities and sex workers, had their privacy concerns addressed. These targeted engagements reinforced the importance of a rights-based approach to digital health policy.

2. Effective resource allocation and strategic investment: The national coalition's ability to strategically allocate Transform Health's funding was instrumental in achieving its advocacy objectives. However, one lesson learned was that limited resources can constrain the breadth of public participation, as demonstrated by the High Court's suspension of the Digital Health Act due to insufficient engagement. This underscores the need for future initiatives to consider increased investment in public consultations to ensure comprehensive buy-in and mitigate legal challenges. Perhaps future efforts should include lobbying Parliament to take the public consultation process more seriously, as gaps in this area can result in costly setbacks for the exchequer. Moving forward, investing

- more resources in expanding public engagement could be essential for preventing legal challenges and securing broader support for legislative reforms.
- 3. Navigating policy influence and sustaining momentum: The national coalition's ability to build and maintain relationships with key government stakeholders was vital in the swift passage of the Digital Health Act. Courtesy calls to the Ministry of Health and continuous engagement through workshops allowed the national coalition to influence legislative priorities effectively. Compared to other legislative efforts, the relatively expedited process indicates that political goodwill, combined with consistent advocacy, can significantly accelerate policy change. However, the suspension of the Act following concerns about public participation reveals the need for sustained engagement beyond legislative approval. For coalition members, this suggests the importance of securing policy wins and ensuring long-term implementation through continuous dialogue with policymakers.
- 4. Navigating government-led legislative changes: The bundling of the Digital Health Act with other health-related legislation was a government-led process. While the national coalition capitalised on this momentum to advance its advocacy efforts, the approach also underscored challenges. Increased scrutiny of fiscal measures in the accompanying acts highlighted the importance of evaluating the risks and opportunities of such policy bundling. Although not directly orchestrated by the national coalition, the experience underscored the need for strategic navigation when aligning policy priorities within broader legislative reforms.
- **5. Recommendations for replication:** The experience of Transform Health Kenya offers valuable insights for similar initiatives in other countries. Key recommendations include:
 - Establishing clear governance structures to streamline decision-making and maintain alignment among diverse coalition members.
 - Prioritising inclusive engagement strategies to ensure that marginalised voices are heard and integrated into policy frameworks.

- Investing in public participation to avoid legal setbacks and enhance the legitimacy of policy initiatives.
- Maintaining consistent communication with government stakeholders to build trust and sustain advocacy momentum.

Exploring hybrid funding models to balance central coordination with member autonomy, which can help foster ownership while maintaining strategic focus.

Advancing influence: recommendations and opportunities

Building on the lessons learned, the national coalition has a unique opportunity to enhance its influence and effectiveness through strategic recommendations and innovative approaches. The national coalition can solidify its position in the digital health landscape by expanding partnerships, strengthening decentralised support, and prioritising data-driven decision-making. While many of these recommendations reflect ongoing efforts by Transform Health Kenya, they are included here as guidance for other coalitions that may benefit from similar approaches. These recommendations provide actionable steps to sustain and amplify advocacy efforts, ensuring continued impact while addressing the evolving needs of diverse populations.

- 1. **Expand coalition membership and partnerships** to include persons with disabilities, technical experts, innovators, and diverse voices. Ensuring representation from marginalised groups will help build broad-based support.
- 2. **Strengthen connections with key government officials**, particularly those focused on digital health, to secure advocacy allies and high-level endorsements.
- 3. **Integrate digital health within broader goals**, such as UHC, to demonstrate its relevance and value to diverse stakeholders.
- 4. **Focus on decentralised support** by engaging county health management teams and the Council of Governors to encourage policy adoption at local levels.
- 5. **Prioritise advocacy for digital health investments** at both national and county levels to address sustainability challenges. This will be a critical focus in Phase 2, ensuring adequate resources for implementing and scaling digital health technologies.

- 6. **Leverage data for decision-making,** using evidence to showcase the positive impact of digital health initiatives and strengthen advocacy efforts.
- 7. **Engage government stakeholders early at the county level** to minimise bureaucratic barriers and support consistent advocacy efforts.
- 8. **Emphasise digital rights and data security**, particularly in high-stigma environments, to build trust and foster safe engagement across all populations.
- 9. **Enhance accessibility and inclusivity** by tailoring content to meet the needs of marginalised groups, including persons with disabilities.
- 10. Raise awareness and foster community involvement through online and offline public engagement strategies that encourage feedback and participation.
- 11. **Invest in ongoing training** for healthcare professionals, government staff, and coalition members, with a focus on digital health sensitisation and cross-sector knowledge-sharing.
- 12. **Establish clear objectives and structured roles** within the national coalition to maintain alignment and facilitate efficient decision-making across diverse member organisations.
- 13. **Ensure consistent funding for advocacy efforts**, improving financial coordination among coalition members to prevent delays in resource disbursement.
- 14. Address concerns highlighted by legal challenges, such as the recent constitutional petition (Aura v Cabinet Secretary, Ministry of Health & 11 others; Kenya Medical Practitioners & Dentist Council & another (Interested Parties), 2024). Although outside Transform Health Kenya's direct control, this case underscores the importance of proactive advocacy for practical, public-oriented policies. Anticipating legal, social, and infrastructural challenges early on can build public trust and facilitate smoother implementation.

Annexes

Kenya's Digital Health Act timeline

1. 2010: Constitution of Kenya, 2010

The 2010 Constitution of Kenya introduced key legal frameworks crucial for advancing digital health. Most notably, it guaranteed the right to health (Article 43) and access to information (Article 35), laying the groundwork for a citizen-centred approach to healthcare. The Constitution's devolution provisions also decentralised health services to the counties, encouraging localised solutions and digital integration. This legal foundation established a basis for reforms and paved the way for future policies concerning digital health technologies.

2. 2016: Kenya National eHealth Policy 2016-2030

2016, the government launched the Kenya National eHealth Policy 2016-2030. This policy was a roadmap for integrating digital technologies into healthcare delivery and established key priorities such as electronic medical records, telemedicine, and health information systems. Its goal was to improve service delivery, promote health data interoperability, and create a foundation for scaling up digital health initiatives. The policy emphasised universal access to health information, thereby enabling the gradual transformation of the healthcare sector through digital innovations.

3. 2017: Health Act, 2017

The Health Act of 2017 was another step toward realising Kenya's structured digital health environment. It provided comprehensive guidelines for health service delivery and emphasised the need for structured health information management systems. The Act mandated the development of health data management, privacy, and interoperability frameworks, setting the stage for later legislation like the Data Protection Act and the Digital Health Bill. This Act formed a legal basis for regulating and standardising digital health systems across Kenya's healthcare sector.

4. 2019: Data Protection Act, 2019

Enacted in 2019, the Data Protection Act was a milestone for securing personal data, including sensitive health information. This law established a framework for collecting, storing, and using personal data while emphasising the protection of citizens' privacy rights. It set specific guidelines for health data management, underscoring transparency and security. The Act aligned with global standards on data privacy and laid a strong foundation for subsequent digital health legislation, ensuring trust in digital health systems and protecting patients' sensitive health information.

5. December 2020: Kenya UHC Policy

In December 2020, Kenya introduced its UHC Policy, a key pillar of the government's Big Four Agenda. The policy aimed to provide affordable and accessible healthcare for all Kenyans, emphasising health equity. It identified the need to leverage digital health solutions to expand access, improve efficiency, and enable data-driven decision-making. This policy aligned digital health initiatives with the broader national objective of achieving UHC, making digital health a critical enabler for health reforms.

6. April 2022: Transform Health Landscape Analysis of Digital Health and UHC in Kenya

In April 2022, Transform Health Kenya produced a comprehensive landscape analysis (Timothy Wafula & Steven Wanyee, 2022) of digital health and universal health coverage in Kenya. The report identified critical policy, infrastructure, and capacity gaps and provided strategic recommendations to enhance digital health initiatives. The analysis offered insights into existing legal frameworks, data governance challenges, and stakeholder roles in advancing Kenya's digital health ecosystem. This analysis laid the groundwork for the national coalition's engagement in developing the Digital Health Bill.

7. Pre-2023: Drafting and consultations for Digital Health Bill

7.1. Early engagement and relationship building (August 2022)

The drafting and consultations for the Digital Health Bill began with early engagements in August 2022. The Kenya Legal and Ethical Issues Network on HIV & AIDS (KELIN), as the coordinator of Transform Health Kenya, identified gaps in the existing digital health policies, particularly the lack of government leadership. Transform Health and KELIN initiated relationship-building efforts with the Ministry of Health, specifically with the

Directorate of Digital Health. Courtesy visits were conducted to familiarise with ongoing initiatives and to align the national coalition's work with government plans.

7.2. Development of E-Health Bill to Digital Health Bill (End of 2022)

By the end of 2022, the national coalition learned that the Ministry of Health had been working on an "E-Health Bill." KELIN's landscape analysis revealed the fragmented nature of digital health policies. The national coalition's efforts shifted towards collaborating with the Ministry to refine the bill's focus and scope. As a result, the bill transitioned from an "E-Health Bill" to a more comprehensive "Digital Health Bill." Key participants in this phase included the Directorate of Digital Health, KELIN, Palladium, and KeHIA (Kenya Health Informatics Association).

7.3. Workshops and stakeholder engagement (November-December 2022)

The national coalition facilitated stakeholder workshops in November and December 2022, bringing representatives from partners like Palladium, Safaricom, healthcare institutions, and research organisations. These workshops provided a platform for discussing the bill's provisions and aligning coalition efforts with government priorities. The aim was to solidify the national coalition's goals with the broader policy direction and leverage political goodwill under the Kenya Kwanza Manifesto.

7.4. Key drafting workshops supported by Transform Health (March 2023)

In March 2023, the national coalition led a key drafting workshop supported by Transform Health. The workshop involved members from organisations like White Ribbon Alliance (women's engagement), Youth Alive Kenya (youth engagement), Love Matters Kenya (media engagement), and the Key Populations Consortium. The result of this workshop was the formal inclusion of health data governance principles and guidelines into the draft bill. This milestone helped ensure that critical standards were integrated into the legislation.

7.5. Drafting process and consultations (March-August 2023)

From March to August 2023, the national coalition continued the drafting process through a series of consultations. Partners like Intellisoft and Health IT supported these consultations, which focused on refining the bill's language, setting telemedicine

standards, and solidifying health data governance. By August 2023, a final draft of the bill was ready, marking the culmination of months of intensive stakeholder engagement and policy refinement.

7.6. Public participation and awareness (September 2023)

In September 2023, KELIN organised a four-part webinar series to ensure public participation and increase awareness about the Digital Health Bill. Each session attracted approximately 100 participants, who provided valuable feedback that was incorporated into the bill. These webinars helped bridge gaps between policymakers and the public, aligning the bill with citizens' needs. The public participation period was extended to accommodate additional feedback, ensuring compliance with legal requirements.

7.7. Presentation to parliament and fast-tracking (September-October 2023)

The bill was presented to Parliament for debate in September 2023. The government prioritised it as part of its UHC agenda, accelerating its legislative process. The bill underwent all necessary readings and committee deliberations before being scheduled for presidential assent.

8. October 19, 2023: Digital Health Act, 2023

On October 19, 2023, the President of Kenya signed the Digital Health Bill into law, officially enacting it as the Digital Health Act No. 15 of 2023. This Act was part of a unified legislative effort to realise Article 43(1)(a) of the Constitution, which guarantees the right to health. It was enacted alongside the Social Health Insurance Act (SHIA) and the Primary Health Care Act (PHCA). These statutes address interrelated aspects of healthcare in a cohesive, modern framework: SHIA (integrated health coverage), DHA (modernising health data management), and PHCA (strengthening primary health services).

9. November 2, 2023: The Digital Health Act comes into effect

The Digital Health Act came into effect on November 2, 2023. This commencement set in motion the operationalisation of the Act's provisions, including establishing the Digital Health Agency and the rollout of an integrated digital health information system. The new law aimed to streamline the provision of digital health services and ensure the confidentiality and security of health data.

10. Post-2023: Implementation of Digital Health Act

Following the Act's commencement, efforts are underway to implement its provisions. These include setting up the Digital Health Agency, drafting regulations, and developing telemedicine guidelines. The Act's implementation focuses on building digital health infrastructure, creating standards for health data management, and fostering collaboration among stakeholders. These ongoing efforts aim to establish a robust digital health ecosystem in Kenya, emphasising access, security, and data-driven healthcare solutions.

10.1. July 12, 2024: High Court ruling declares health acts unconstitutional

In the case(Aura v Cabinet Secretary, Ministry of Health & 11 others; Kenya Medical Practitioners & Dentist Council & another (Interested Parties), 2024), the High Court ruled that the Social Health Insurance Act (SHIA), Digital Health Act (DHA), and Primary Health Care Act (PHCA) were unconstitutional due to insufficient public participation and violations of constitutional rights. While the petition focused primarily on SHIA, arguing that it limited healthcare access by making it conditional on mandatory registration and contributions, it also raised concerns with DHA. Specifically, DHA's unique identification and biometric data collection requirements were deemed intrusive, violating privacy rights without adequate safeguards. The court suspended all three acts for 120 days, mandating Parliament to ensure comprehensive public participation before re-enacting the laws.

10.2. September 2024: Appeal filed and stay granted

In September 2024, the MoH appealed the High Court's ruling. The Court of Appeal granted a stay(*Cabinet Secretary, Ministry of Health v Aura & 13 others* [2024] KECA 1195 (KLR), 2024), allowing SHIA, DHA, and PHCA to remain operational while the appeal proceeds.

10.3. October 16, 2024: Kisumu Digital Health Transformation Roadmap launched

On October 16, 2024, Kisumu County launched the first-ever Digital Health Transformation Roadmap at the Lake Region Digital Health Conference with support from Transform Health Kenya. This roadmap addresses fragmented IT systems and uncoordinated patient data by setting functional standards for digital health across primary care, lab services, and pharmacy management. The roadmap, a collaborative effort involving stakeholders

from local government, the private sector, and international partners, aims to enhance data quality, reduce errors, and improve real-time data access. Kisumu County's leadership, led by Governor Professor Anyang' Nyong'o, positions this initiative as a model for achieving UHC through digital health innovation.

Transform Health Kenya's logical model

Universal Health Coverage (UHC) will be achieved in Kenya by 2030 by hamessing digital technology and the use of data TRANSFORM HEALTH KENYA COALITION: LOGIC MODEL 2022 - 2023 Increased resources at national 2. Increased adoption and use of digital health Objectives technologies at the national and county and county level for 1. Laws and policies on digital health technologies to government for access to equitable, affordable and achieve UHC commitments are developed and adopted strengthening digital health quality health care; at both national and county level by 2030 technologies to achieve LIHC Sub-Objectives 1.1. Advocate for enactment of 1.2. Advocate for people-3.1. Generate evidence and advocate for 2.1. Advocate for implementation of E-Health laws (national and in centered digital health national government policy commitments the inclusion of digital health 2.2: Increase public demand for counties) that advances the Standards and for to adopt and use digital health technologies technologies in the budget allocations standardization of digital adoption and use of digital development, adoption and as well as for formulation of policy health technologies use of digital health health services and commitments at county level technologies to achieve UHC applications to achieve the commitments. goals of UHC. 1.1.1 Develop a Human Rights Centered 1.2.1 Conduct research to identify and 3.1.2. Conduct a resource gap Legislative Guide of best practices adopted 2.1.1. Identify government digital analyze the existing digital health 2.2.1. Engage in media campaign to analysis to identify the resources under international, regional and domestic health champions (national and services and applications across the raise public awareness on required to achieve efficient use and legal frameworks; for use in advocacy country and make recommendations county health informatics officers) to adoption of digital health fundamental role of digital health 1.1.2 Champion for the enactment of the champion policy formulation and on bests practices technologies in achieving UHC; and technologies. national E-Health Act through both technical implementation on adoption and use 1.2.3 Conduct research to analyse the create demand for use and adoption 3.2.1. Engage national and county assistance to government as well as of digital health technologies 2.1.2. Support and facilitate roundtable dialogues with Ministry of standards and guidelines (national on digital health technologies government officials using the mobilization of communities to take part in and/or international) that informed 2.2.2. Develop a community-led evidence generated above on the public participation forums development and operation of existing monitoring and accountability inclusion of digital health 1.1.3 Champion for the development and Health Technical Working Groups digital health services and applications system and engage adolescents, technologies in budget allocations. enactment of a county-specific e-Health law in (UHC & Health Informatics), Ministry in the country and make youth, women and KP champions to. 3.3.3 Enhance capacity and support Kisumu County through technical assistance of ICT, Media and Private Sector recommendations on ideal standards through use of score-cards, track youth, women, vulnerable and to the county government 2.1.3. Host an annual multi-1.2.3. Engage state actors and private commitments and assess the marginalized groups champions to 1.1.4. Identify and build capacity of women, stakeholders conference during the sector actors in the national and adoption and use of digital health engage in budget making processes youth, vulnerable and marginalized Digital Health week as an county government on the need for and advocate for prioritization of community champions to actively advocate people centered standardization of accountability conference on the resources for digital health for an enabling legal environment. digital health technologies. policy commitments technologies GROWTH, GOVERNANCE AND DEVELOPMENT: (a) Identify and invite new members to the coalition; (b) Annual capacity building of coalition members on emerging issues; (c) Conduct Quarterly Meeting

Coalition; (d) Develop a website and social media platforms for coalition

(i) eHealth projects mostly implemented in urban centres creating inequalities and inequities in access to health care in rural areas; (ii) Lack of government stewardship and leadership, with most eHealth initiatives not aligned to the Ministry of Health priorities; (iii) Lack of a comprehensive legal framework conducive for the adoption and utilization of eHealth in Kenya; (iv) New digital tools and products are entering the market all the time, but regulatory systems have not kept up with the influx of technologies; (v) Privacy as a legal and ethical barrier to the adoption of eHealth applications; (vi) Lack of awareness of digital rights by the population; (vii) Little investment in quality healthcare; (viii) Digital divide, where access to digital space is gendered, with most women not being able to use mobile apps at the same level as men.

Study methodology

Scope

This study's primary objective is to document and analyse Transform Health Kenya's influence on digital health policy, specifically in advocating for the Digital Health Act. By detailing the national coalition's strategies, advocacy efforts, and lessons learned, this methodology offers a replicable model for similar coalitions navigating policy influence in diverse settings.

Study approach

- 1. **Case study method:** A case study approach was chosen to examine Transform Health Kenya's advocacy in-depth, covering coalition structure, stakeholder engagement, and specific tactics used to shape policy.
- 2. **Multi-source evidence:** The methodology draws on multiple sources: document reviews, stakeholder interviews, and secondary data. Documents, including coalition strategy papers and the Digital Health Act, provided context on the national coalition's alignment with national priorities. Interviews with coalition members added personal insights, while secondary data offered a broader context on Kenya's digital health ecosystem.

Sampling and participants

A targeted sampling approach was employed to select key coalition members and stakeholders, each chosen for their unique contributions to Transform Health Kenya's advocacy efforts and influence on the Digital Health Act. These participants represent diverse expertise across legal, youth engagement, digital health, and key populations, offering a broad view of the national coalition's approach and impact.

Coalition partner	Representative	Date of interview	Role
KELIN	Martha Ogutu	26-Sep-24	Provided insights on coalition governance and inclusivity, fostering collaboration and transparency.
PHDA	Antony Kariri	08-Oct-24	Focused on digital health for key populations; provided insights on healthcare access for vulnerable group

Coalition partner	Representative	Date of interview	Role
Key Population Consortium	Solomon Wambua	08-Oct-24	Worked with marginalised groups (e.g. MSM, sex workers); critical for insights on inclusivity and human rights.
Youth Alive	Moses Dianga	09-Oct-24	Led youth engagement in digital health; offered perspective on policy impact on young people in Kenya.
Love Matters	Terry Gachie	17-Oct-24	Drove awareness via digital media, which is key for understanding outreach and public engagement strategies.
KeHIA	Sylvia Mwelu	18-Oct-24	Led research on digital health standard and guidelines; provided technical expertise in health informatics.
KELIN	Alan Maleche	25-Oct-24	Led Transform Health Kenya Coalition; key in legal/policy advocacy and Digita Health Act drafting.

Data analysis

Data from document reviews, stakeholder interviews, and secondary sources were analysed using thematic analysis. Key themes, such as coalition governance, advocacy strategies, and stakeholder engagement, were identified and synthesised to provide insights into Transform Health Kenya's influence on digital health policy.

Limitations

This case study uses a qualitative, non-experimental approach, which limits its ability to establish causation. Instead, it provides plausible conclusions based on thematic insights. Additionally, potential data gaps may exist due to limited access to certain stakeholders or incomplete documentation, which may affect the depth of some analyses. However, the multi-source approach mitigates these limitations by ensuring a comprehensive view of the national coalition's activities.