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Implementing Regulatory Sandboxes for Digital Health Innovation in Sub-Saharan Africa: Lessons from the Fintech Sector

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Abstract

Health systems in most countries in Sub-Saharan Africa face challenges relating to inadequate infrastructure, insufficient funding and shortage of skilled healthcare workers. Whereas digital health innovation has been embraced in the region to address these challenges and strengthen health systems, a delicate balance between innovation and regulation for sustainable and equitable use is imperative. However, as Africa continues to digitalise her health systems to improve healthcare, issues pertaining to data governance and privacy concerns have emerged that call for frameworks that can protect the vulnerable without stifling digital innovation in healthcare. In this article, we explore how challenges related to poor data quality and data governance in digital health innovations can be addressed through regulatory sandboxes. We draw lessons and experiences from the financial sector and how they can potentially be used in designing digital health regulatory sandboxes. Through a comparative critical analysis of the journey taken in fintech sandboxing, we highlight the challenges faced and success factors in the fintech sector that can be mirrored during the implementation of digital health sandboxes. We complement these sources with qualitative interviews and insights from engaging with different stakeholders in the Fintech and digital health sectors. Our critical analysis builds on Felix Kumah-Abiwu's extension of the Afrocentric paradigm and analyses how an Afrocentric triple helix model can enable the co-creation of regulation in digital health. We thus provide a unique empirical analysis around the opportunities, limitations and concerns of fintech regulatory sandboxes that could be used for the implementation of digital health sandboxes across Sub-Saharan Africa.

***Keywords**:* Afrocentricity; Digital Health; Triple Helix Model; regulation; sandboxes; Sub-Saharan Africa.

1. Introduction

Shaping the dynamic landscape of digital health innovation in Sub-Saharan Africa lies the imperative need to strike a delicate balance between innovation and regulation for sustainable and equitable use. Digital technologies have increasingly been integrated into different facets of the health system.[1] The increasing availability of mobile phones and internet access have led to better access to cloud technology and increased functionalities. These advances have enabled mHealth's considerable growth in Sub-Saharan Africa where health infrastructure is poor.[2] The attraction to digital health solutions spawns from their ability to harness, evaluate, manage and share health information thereby addressing some of the identified health challenges in a sustainable manner.[3]

[1] WHO, WHO Guideline Recommendations.
[2] Hampshire, "Informal m-Health"; Holst, "Sub-Saharan Africa"; Mitchelle, "Digital Technology"; WHO, WHO Guideline Recommendations; Bärnreuther, "Entrepreneurship and E-Health"; Meslamani, "Technical Regulatory Challenges"; Ameso, "Digital Entanglements."
[3] Africa CDC, Transformation Strategy; Meslamani, "Technical Regulatory Challenges"; Ameso, "Digital Entanglements."

As Africa continues to digitalise its healthcare, issues pertaining to data governance and privacy have emerged. Notably, most digital infrastructure is owned by Global North-based big tech corporations, and since African countries rely on foreign digital technologies and services, this often leads to multinational corporations that supply these technologies insisting on policies that are sympathetic to their operations and expansion. Whereas the initial arrangement would be convenient, the big techs, being large and powerful, subsequently place many of the weak communities under a 'subject and control' position. We observe this as institutional power[4] whereby the data subjects are obliged to provide data in consideration of particular services that are provided. This is manifested through data extractive patterns that would initially be baited as customer service products.[5] Subsequent to this the customer surrenders ownership of their data in a Foucauldian fashion of surveillance and subjugation. Potentially, this leads to unauthorised data access and even commodification of personal data. Granted that the nascent regulatory structures in Africa may not be able to mitigate the existent vulnerabilities on data protection and governance, this calls for frameworks that can protect the vulnerable without stifling digital innovation in healthcare.

Even though there is a large amount of literature at the crossroads of law and technology,[6] regulatory frameworks on digital health innovations in Africa lag behind other sectors and are still relatively underdeveloped and uncoordinated.[7] Moreover, the use of regulatory sandboxes in the health sector has mostly been applied in high-income countries in the context of digital health innovation.[8] Although the use of sandboxes in health context raises concerns about data privacy and security, sandboxes have demonstrated their value in validating new health technologies, accelerating their transition into the healthcare system, and enhancing the effectiveness of the healthcare system.[9] Additionally, sandboxes have been used to provide robust data support to regulators and ensure the integrity of clinical research process.[10] The closer interaction with regulators in health sandboxes brings a level of flexibility in the regulations.[11]

We draw lessons from the financial sector, which utilised technology and developed over time, and trace advancements in scholarship in fintech regulatory sandboxes in Africa to develop ideal characteristics of health regulatory sandboxes based on Afrocentric principles to counter data extractive patterns in data governance. We further explore how these lessons can be integrated in digital health regulatory sandboxes to address challenges related to poor data quality and data governance. Essentially, we analyse how the different university/industry/government entities in Sub-Saharan Africa can relate within the digital regulatory sandboxes, thus enabling the co-creation of regulation,[12] and propose contextualised insights that can be incorporated in the development of regulatory sandboxes.

The African Centre for Disease Control (Africa CDC) was created as a public health agency to support the public health initiatives of African Union member states whilst strengthening the capacity of their health institutions to mitigate health risks. The mandate of Africa CDC thus placed African health challenges at the centre of their activities. Faced with many pan-country health system challenges, the Africa CDC launched its Digital Transformation Strategy, which includes an innovation sandbox to provide 'a platform for innovators, startups, and other stakeholders to develop, test, and refine new digital health technologies and solutions.'[13] Some of the challenges which the strategy seeks to address stem from the demand for healthcare services as well as the limited ability of states to provide affordable quality healthcare.[14] Additionally, these challenges are exacerbated by poverty levels potentially leading to high disease burdens, infrastructural limitations, and weak health systems. The Africa CDC Digital Transformation Strategy was anchored on collaboration, innovation and a shared commitment by all the stakeholders whose objective was to leverage technology to address the continent's most pressing public health challenges. The strategy highlights the need for alignment with other collaborators to develop innovative technology platforms that can be scaled to address contemporary health challenges.[15]

Using an interpretivist multimethod approach, we conduct a comparative critical analysis of the journey taken in fintech sandboxing to highlight the challenges faced and success factors in the fintech sector that can be mirrored during the implementation of digital health sandboxes. We analysed available reports and published literature in English language on

[4] Dallas, "Power Global Value Chains."
[5] Zuboff, "Surveillance Capitalism," 80.
[6] Ncube, "Afro-centric Law."
[7] Setian, "One Size."
[8] Qiu, "Sandbox Expansion."
[9] Qiu, "Sandbox Expansion."
[10] Hirano, "Data Validation."
[11] Gilbert, "Roadmap."
[12] Cai, "Theorising Triple Helix."
[13] Africa CDC, Transformation Strategy, 41.
[14] WHO, Primary Healthcare.
[15] Africa CDC, Transformation Strategy, 33.

fintech digital regulatory sandboxes in Sub-Saharan Africa, focusing on literature that has been published from 2015 to date. We then complemented these sources with data from qualitative interviews and insights from engagements with different stakeholders.

We adopt an Afrocentric theoretical framework for our article. Basing our arguments on Felix Kumah-Abiwu's extension of the Afrocentric paradigm to the policy domain (2016), we analyse how the triple helix model can enable the co-creation of regulation in digital health. Grounded in innovation and entrepreneurship studies, the triple helix model converges collaboration and shares knowledge across the university academy, industry and society.[16] On the other hand, Afrocentricity relates to having Africa-centred discussions.[17] Afrocentricity is aligned with the Africa CDC's principle of ensuring that the digital health systems 'are aligned with local health priorities and needs.'[18] Our Afrocentric analysis thus focuses on four broad contexts: social, institutional, power relations, and existing legal systems. Since we propose a contextually balanced approach in digital health innovation in Africa, we use Afrocentricity theory to ensure that 'African interests, values, and perspectives'[19] inform our analysis and proposed use of regulatory sandboxes in digital health innovation. Accordingly, we seek to provide a unique empirical analysis around the opportunities, limitations and concerns of fintech regulatory sandboxes that could be used for the implementation of digital health sandboxes across Sub-Saharan Africa.

The first part of the article provides an account of how regulatory sandboxes have functioned in Africa's financial sector, in the process identifying some of the challenges experienced and how they were addressed. This allows us to map these lessons as areas of opportunity in addressing the regulatory digital health challenges in the next section. The last section analyses how an Afrocentric triple helix model can be used in the co-creation of regulation in digital health.

2. Regulatory Sandboxes in the Fintech Sector

Digital technology is fast evolving and there is always the challenge of new innovations overwriting prior ideas in a fundamental way, yet, by its very nature, real life experience may not allow time for full scale design and experimentation. Faced with challenges of marginalisation, the financial sector embraced digitisation. The need revolved around four areas, namely, compliance, consumer protection, tax collection and financial stability.[20] Fintech regulation was thus necessitated by the novelty of the new products and business models that created a lacuna in the existing laws. There may be situations where the existing laws may be completely unable to support the new set of products or the new risks may not have been identified and therefore sufficiently mitigated. There is no centralised approach in fintech regulation due to fact that fintech businesses are multi-faceted and governed by different provisions of the law. Driven by the dynamism involved, there has been an emerging interest in fintech sandboxes across different sectors.

The definition and conceptualisation around fintech has been fairly problematic and we view it from a broad perspective which refers to it in multiple ways.[21] There has been a phenomenal growth in the fintech space to address challenges associated with financial sector inclusion. This growth has similarly been accompanied by complexity in product development and functionality.[22] Further to this, fintechs offer the opportunity of furthering financial inclusion and providing innovative finance solutions to those who are digitally marginalised, and more so in developing countries.[23] Funded by growing investment, fintech has been characterised by disparate innovation product types and speed of delivery, convergence of various industries, democratised access, and increased globalised operations.[24] Such changes are potentially disruptive to any regulatory or legal system.

The decentralisation, disintermediation and ultimately democraticisation of fintech services made the regulators wary of the impact on the domestic component affected by fintechs. This led to the use of regulatory sandboxes. Sandboxes represent a hybrid, flexible paradigm focused 'on innovation as the driving principle of regulatory action.'[25] Digital regulatory sandboxes originated from within financial technology and have since spread to other sectors.[26] Regulatory sandboxes allow collaboration

[16] Cai, "Theorising Triple Helix."
[17] Asante, "Africology, Afrocentricity."
[18] Africa CDC, Transformation Strategy, 14.
[19] Kumah-Abiwu, "Beyond Intellectual Construct."
[20] Ndemo, "Digitalisation and Financial Data."
[21] Didenko, "Regulating FinTech."
[22] As of 2023, there were 678 fintech startups that had headquarters in Africa (Disrupt Africa, 2023).
[23] McCallum, "Regulatory Sandbox."
[24] Didenko, "Regulating FinTech."
[25] Muñoz, "Fintech Sandboxes."
[26] World Bank, Global Experiences; Leckenby, "Sandbox Approach"; Johnson, "Quicksand."

and experimentation between innovators, academia and regulators[27] to address a problematic concern irrespective of the existing regulations, and to derive solutions that benefit the greater public.

From a regulatory perspective, sandboxes could also be classified as advisory, adaptive or anticipatory,[28] with each of the three classifications having different levels of regulatory support and complexity.[29] Advisory sandboxes could be useful in early-stage digital health projects, where regulators act as partners rather than enforcers to encourage uptake. Adaptive sandboxes would be more suited to fast-evolving tech, like AI and genomic tools, where policy lags can harm both innovation and patient protection. Anticipatory sandboxes are crucial in Africa's leapfrogging health tech environment, ensuring that policy frameworks are ready before widespread adoption. On the other hand, from a technological lens, sandboxes can be categorised as testbed environments that can be either live labs or real-world testbeds.[30] In live labs testbeds, experimentation, mostly for novel products, occurs in controlled environments whereas in the real world testbeds, the proposed changes, mostly on existing innovations, are implemented in an uncontrolled environment.[31]

There are different types of sandboxes, and their design is largely influenced by the outcomes desired by the regulators. The design is often a function of the definitional approach whereby the regulators define their boundaries of interaction, as well as the capability approach, whereby the regulators outline what capabilities require regulation. Experience from the fintech digital sandboxes highlighted the need to consider several stages during their design which included a clear definition of the eligibility conditions, technical readiness of both the applicants' and the regulators' levels of required compliance, the test plan adopted, and ultimately the exit strategy. Several challenges were often associated with lack of clarity at the design stage. For example, multinational entities operating across different jurisdictions would pose challenges when they actually innovated and there was lack of accountability. Furthermore, existing regulatory structures may be viewed as rigid, hence calling for adjustment with every new technology that is implemented. Additionally, it was observed that some solutions might trigger multiple yet bureacractic layers of regulation once implemented.

Fintech regulation requires a balance between prudential responsibility and the desire to promote the innovation. Whereas promotion of the innovation may be essential to facilitate the reach of the innovation to marginalised communities, regulators should always be conscious of their statutory responsibilities since concerns have been raised regarding the potential for sandbox riskwashing being disguised as risktaming especially when there is lack of transparency.[32] Riskwashing occurs when 'organisations take actions to make it seem as if an asset class or technology or business model is not excessively risky, whether it is or not.'[33] The balance would thus be predicated on numerous circumstances that are consistent with the regulatory priorities. Thus regulatory priorities would be dictated by concern for systemic risk as compared to the need to address a pressing social or economic concern. Additionally, the regulators have to make a choice between immediate or deferred regulation and in both instances, the regulators may have to trade off between the benefits and associated risks. The regulators also need to be conscious of regulatory arbitrage, which may occur when innovators wish to avoid tight regulation and move into less regulated spaces. Where cross border jurisdictions are involved, this could pose quality challenges since many jurisdictions now prefer 'principle-based legal norms' in their design of fintech regulations to address their regulatory shortfalls. Principle-based regulation of sandboxes may contribute to lack of transparency since it entails a dialogue between the regulator and the regulated only and may be opaque to other parties such as consumers and other firms.[34]

3. Emerging Use of Regulatory Sandboxes in Digital Health Innovation Based on Lessons from Fintech Sector

Health regulatory sandboxes have been implemented in other parts of the world and have been valuable in anticipating the challenges in assessing innovative technologies and future techniques and improving the experiences of healthcare providers and regulators.[35] For example, in the USA the Food and Drug Administration (FDA) temporarily authorised new technologies under the Emergency Use Authorisation (EUA) program during the Covid-19 pandemic under which three vaccines for Covid-

[27] Reid, "Enforcer to Enabler."
[28] Arntzen, Testing Innovation.
[29] Armstrong, Renewing Regulation.
[30] Arntzen, Testing Innovation.
[31] Leckenby, "Sandbox Approach."
[32] Brown, "Governing FinTech."
[33] Brown, "Governing FinTech," 24.
[34] Brown, "Governing FinTech"; Allen, "Regulatory Sandboxes."
[35] Leckenby, "Sandbox Approach."

19 were developed.[36] The EUA program has the attributes of regulatory sandboxes in the fintech sector insofar as it allows industry experimentation in ways that can improve regulatory processes for new technologies.[37] These attributes include: developer experimentation and data sharing with regulatory authorities to enable ongoing transparent data collection and review; developer input that leads to a give-and-take relationship between the developer and regulatory authority; technological flexibility that allows different iterations; real-world deployment of the new technology; and limitations on the scope, duration, and identity of developers.[38]

Although there are differences between fintech and digital health, a common point of reference relates to the socially disruptive dimensions of fintech in relation to access to data, which are equally applicable to health. For example, fintech aims to achieve financial inclusion of the unbanked population to enable them access to financial services. A similar problem-solving approach is taken in digital health innovation, which seeks to enable under-resourced populations to access healthcare in hard-to-reach areas. Brown and Piroska's argument that fintech's discourse of innovation and solutionism tends to be taken at face value by regulators (thus obscuring its socially disruptive potential) is equally applicable to health innovation.[39] Consequently, the use of regulatory sandboxes in the health sector requires careful follow-up to avoid eroding public trust since, as transpired in the case of EUA, some of the products that were initially authorised later became controversial and authorisation had to be withdrawn. The controversy arose due to the likelihood of fraud in the case of the use of hydroxychloroquine and convalescent plasma for Covid-19 treatment as a result of political interference.[40]

Other notable examples of the use of sandboxes in health are the Licensing Experimentation and Adaptation Program (LEAP) from Singapore,[41] the National Health Service (NHS) Digital Sandbox from the United Kingdom,[42] and Indonesia's Health Digital Innovation Regulatory Sandbox on e-Malaria.[43] A recurring lesson learnt was the importance of adapting regulatory sandbox models to the local context thus ensuring that they are relevant and effective in addressing the unique challenges of the healthcare system.[44] Additionally, there was a need for a flexible regulatory environment to allow innovators to test new technologies while ensuring patient safety and regulatory compliance.[45] Other lessons learnt have been the need for early and iterative regulatory engagement and collaboration that would include a diverse range of stakeholders.[46] There was thus a need for continuous and transparent feedback from all concerned parties. There was definite need for establishing clear licensing pathways for digital health solutions which would facilitate smoother transitions from sandbox testing to full-scale implementation. In all instances, it was observed that there was a need to provide training and resources to stakeholders to enhance their understanding of regulatory processes and foster a more effective regulatory environment.[47] Regulatory sandboxes for digital health can thus serve as programs for testing regulatory strategies away from real-world political pressure and interference.

During the Covid-19 pandemic, countries in Africa resorted to what has been described as 'agile governance,' which can be likened to regulatory sandboxes. Agile governance entails using agile approaches by responding 'quickly to unexpected changes in meeting demands and needs of an increasingly changing society.'[48] Regulatory sandboxes are one of the agile governance tools, which enable developers of technology to test innovations under the supervision of the regulator.[49] For example, Rwanda successfully used a regulatory sandbox and built regulations in a mission-based use of airspace, which led to effective use of drones to deliver lifesaving medical supplies and Covid-19 vaccines.[50] However, agile governance is yet to gain traction in Africa due to factors such as lack of effective leadership, lack of suitable legislation, and bureaucracy.[51]

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[36] Sherkow, "Regulatory Sandboxes."
[37] Sherkow, "Regulatory Sandboxes."
[38] Sherkow, "Regulatory Sandboxes," 385-389.
[39] Brown, "Governing FinTech," 21.
[40] Sherkow, "Regulatory Sandboxes."
[41] Ministry of Health, "Licensing Experimentation."
[42] Care Quality Commission, "Regulatory Sandbox."
[43] Fuad, "Introducing Regulatory Sandbox."
[44] Care Quality Commission, "Regulatory Sandbox"; Fuad, "Introducing Regulatory Sandbox"; Ministry of Health, "Licensing Experimentation."
[45] Care Quality Commission, "Regulatory Sandbox."
[46] Tech for Good Institute, Indonesia's Regulatory Sandbox.
[47] Armstrong, Renewing Regulation; Tech for Good Institute, Indonesia's Regulatory Sandbox.
[48] Lubinga, "Agile Governance," 498.
[49] Lubinga, "Agile Governance."
[50] Signé, "Strategies for Effective Health."
[51] Lubinga, "Agile Governance."

Technology regulation and more so that which focuses on digital health in Africa needs to be contextually balanced to ensure 'that historical extractive patterns are severed and that legal frameworks do not exacerbate inequality.'[52] The Africa CDC data and innovation sandbox, which has been set up for innovators and entrepreneurs to work alongside regulatory and health sector stakeholders,[53] can be a starting point for contexualisation. Notably, experts will use the sandbox to design and develop policy, which can be harmonised and adopted by member states.[54] The Africa CDC Strategy targets a number of deliverables which include creating at least one innovation sandbox, a digital health and innovation Lab, as well as having data sharing agreements for innovation and research in place. The Africa CDC identified the need for a data and innovation sandbox[55] ostensibly to accelerate homegrown innovation solutions from seed to scale stage and synchronise policies across the member states. The sandbox is to be anchored around 'policy and regulation, innovation, and data.'[56]

To implement a regulatory framework, a number of challenges need to be addressed. Some of these may be due to the fact that fintechs mostly straddle different sectors. As a result of this, there is likely to be an overlap of regulatory responsibilities and authorities. Similarly, digital health innovation may straddle multiple sectors such as technology, medical, pharmaceuticals, consumer protection, or even Health and Safety agencies, for example, the African Medical Devices Forum and the proposed African Medicines Agency. Additionally, the financial sector is heavily regulated in most jurisdictions and as such numerous solutions often find themselves under the realm of an existing law. This is similar to digital health devices that have a transnational overlap, for instance, in interoperability, data archiving or even processing. However, the implementation of regulations may be uncertain due to either gaps or conflicts in the current regulations across the different jurisdictions. Concomittantly, smaller fintech firms, as is the case with smaller healthtech firms, often lack the capacity to comprehend and engage with the existing laws and may thus require the services of an incubator or mediators to facilitate their engagements with regulators. Furthermore, uncoordinated approaches across different jurisdictions, coupled with the fact that technological changes can be prompt, require digital techology regulation to embrace diversity which could either be new product-specific, existing product-specific or even involve new universal rules.

Other challenges observed with fintech regulations include managing the perception that the regulation was biased against certain applicants due to the fact that it may have been focused on certain segments of the population. In some instances, there were restrictions in access to banks' Application Programming Interface (APIs), and lack of interoperability between systems. This notwithstanding, the regulators may have elected to offer preferential treatment to different businesses but the criteria needs to be unambigious to avoid perceptions of bias. In the case of health technology, such perceptions may similarly apply mainly on the basis of the selected participants for the sandboxes. Thus criteria determination needs to be very clear. Lastly, digitisation has the potential to provide equity and access to basic healthcare to the marginalised communities. It could thus be seen as being potentially risky from the perspective of conventional health business models, and it is important that appropriate due diligence on technology investors be carried out prior to enrolment to the sandbox. Meslamani[57] identified additional technical and regulatory challenges that could potentially affect digital health interventions in developing countries. Some of these challenges include infrastructural limitations as well as cybercrime which remains an overarching concern across many jurisdictions that are now enacting appropriate regulations in this field.[58] Finally, enactment and operationalisation of other anciliary regulations that protect data use and privacy of the vulnerable health customers is essential.

4. Triple Helix Model in the Co-Creation of Regulation in Digital Health

The Triple Helix Model brings together the university, industry and government in interactions that seek to enhance knowledge creation and sharing.[59] Such synergistic integrations are now widely accepted as achieving better outcomes.[60] Over time, advances in the theoretical discourses of the Triple Helix model have evolved around several themes. The first theme is about the triadic interactions of the model,[61] even though it can be argued that the triadic interactions have evolved to different helical perspectives, which are generally distinguished by the role of the different actors.[62] The actors will tend to play complementary

[52] Ncube, "Afro-centric Law."
[53] Africa CDC, Transformation Strategy.
[54] Africa CDC, Transformation Strategy.
[55] Africa CDC, Transformation Strategy, 34.
[56] Africa CDC, Transformation Strategy, 35.
[57] Meslamani, "Technical Regulatory Challenges."
[58] Meslamani, "Technical Regulatory Challenges."
[59] Cai, "Theorising Triple Helix."
[60] Villanueva, "Measuring Triple Helix."
[61] Ivanova, "Quadruple Helix"; Miller, "Systematic Literature"; Lindberg, "Quadruple Helix Bridging Gender Gap"; Doh, "A Quadruple Helix Framework."
[62] Cai, "Role of University."

roles and may include expanded actors such as consumers, communities and generally civic players. This appreciates the need for technology use in health sector as the 'point of digitisation is to make this simpler so that our healthcare practitioners can focus on providing the other component that's very important for care, which is coaching and the actual care,' as stated by one of the respondents.[63]

Cognisance of the dynamic environment, the nature and form of technologies, as well as consumer awareness and demand, dictates an evolving innovation system as the fourth theme of the helix model. The integrated role of these factors thus defines organisational transformation and sectoral interactions that ultimately affect the helix models.[64] Indeed, many helices alternate between bilateral and trilateral coordination spheres of activity[65] and there is always a possibility of the dominant actor pulling in their favour. Africa is complex and is steeped in a dynamic global environment that has ever-changing determinants of innovation. Such complexities require an additional theme that addresses mediation between top-down coordination and bottom-up initiatives. Lastly, there is a focus on the antecedents for the Triple Helix model. Cai et al[66] identified a list of tangible and intangible conditions that were essential for Triple Helix interactions. Some of the tangible conditions include technical environment and capacity, whereas the intangible ones include institutional environments such as shared beliefs, culture and orientation. As we argue in the next section, an Afrocentric Triple Helix can be useful for ensuring that these intangible conditions are included in the Triple Helix interactions to co-create regulations in digital health.

Cai and Ertokowitz[67] recommend that the Triple Helix Model can be used to integrate insights from multiple approaches and possibilities in transnational contexts. This becomes very important because value is enhanced 'if data is aggregated and at the population level,'[68] as stated by one of the respondents, who goes on to add that 'data sharing across borders is very important.'[69] This brings in a pan-jurisdictional dimension that is vulnerable to global dynamics. This notwithstanding, 'there needs to be confidence in where the data is stored… (for instance) is it stored in a cloud service provider that also complies with basic accountability data protection (?)...;'[70] hence the need for multi-jurisdictional engagements to ensure consistency in data security arrangements.

As a solution to this, we consider the transnational Triple Helix model because it addresses both the micro- and macro-level mechanisms of innovation. Similarly, the global nature of digital innovation is reflected in the helix model and there have been numerous practical applications such as global innovation networks and ecosystems.[71] The transnational Triple Helix is modelled on the basis of three spheres of interactions: firstly, the transnational spheres of university, secondly, the industry as well as government cooperation that respectively achieves transnational collaboration, and thirdly the knowledge and consensus. These interactions can be demonstrated by our analytical framework, which includes a transnational university collaborative approach that is complemented by different multi-country digital developers, governmental and multi-lateral agency cooperation. Effectively, we bring together a transnational approach that bridges transnational knowledge, innovation and consensus across different actors. Consensus is often made difficult by different mindsets that can make collaboration unsustainable.

The helix model dictates that industry, government and universities can work together for the purposes of innovation. An extension of this model assigns regulatory and policy definition to the government. The Appendix provides a summary of examples of existing digital innovations in Africa and how they could potentially be catergorised across different typologies of sandboxes. In all the instances, there are distinct roles for the respective parties, with iterative engagement and collaboration leading to co-created regulation. In the next section, we explore how extending Afrocentricity into the policy domain can address this problem.

5. The Extension of Afrocentricity into the Policy Domain

The theoretical discourse around Afrocentricity has its origins in the works of Molefi Asante and was subsequently adopted by transdisciplinary researchers, who advocated for centring African values, interests and perspectives in applicable theoretical

[63] Interview with a Healthtech practitioner, Nairobi, June 2, 2021.
[64] Cai, "Theorising Triple Helix."
[65] Lawton, "Triple Helix."
[66] Cai, "Building University-Industry Co-Innovation Networks."
[67] Cai, "Theorising Triple Helix."
[68] Interview with a Healthtech practitioner, Nairobi, June 2, 2021.
[69] Interview with a Healthtech practitioner, Nairobi, June 2, 2021.
[70] Interview with civil rights activist, Nairobi, May 7, 2021.
[71] Cai, "Triple Helix Model."

discourses.[72] Afrocentricity acknowledges the need for a cultural contextualisation and an African-derived worldview and is presently widely discussed for the potential remedy it offers to African people.[73] Thus, Mazama opines that Afrocentricity springs from African ontology, cosmology and axiology. Afrocentricity emphasises the promotion of indigenous knowledge which could be useful in broader practice and research, and shifts away from Eurocentric approaches.[74] Afrocentrism is closely related to Pan-Africanism. Notably, Pan-Africanism advocates for collective action by African states to 'challenge, and possibly alter the global order in ways that can ensure a better deal for the people of the continent and the world in general.'[75] Pan-Africanism is a socio-political movement, which brought about unity in the struggle for national liberation, and later against neo-colonialism.[76] On the other hand, Afrocentrism was developed as a theory and tool to combat colonialism and support African people in their struggle against the dominance of the Eurocentric model of the world.[77] Emelianenko considers the concepts of Pan-Africanism and Afrocentrism as complementary and mutually reinforcing. The complementarity between these concepts is useful for defending policies that help African countries realise their national interests and values at individual state and continental levels. This can be realised through freedom from external influences.[78]

Though extensively used in individual and group behaviour, Afrocentricity's use in organisational theory has been somewhat muted.[79] Afrocentricity rejects social science universalism, proffering instead African perspectives, values and culture to be integrated in existing theoretical frameworks of diversity. For instance, Eurocentric approaches assume materialism, individualism, competition, power, superiority, rationality and linearity. All these influences appeal to an individual pursuing self-interest in a free market in tandem with Adam Smith's efficient allocation of resources and maximisation of social wealth. These views oppose and contrast with the Afrocentric cultural realities, which include ubuntuism, spirituality and veneration of ancestors, congruence, equality, togetherness, and interconnectedness.[80] This notwithstanding, empirical research on Afrocentricity is still at the emergent stages and mostly within social work, where Lateef et al[81] has catalogued at least seven tools that can be used to measure Afrocentricity construct. Even though it has been criticised as a racial ideology and as having potentially confusing multiple conceptualisations, the approach in these criticisms is distinct from Africology, which Asante[82] considers as a non-African centred approach that imposes Eurocentric criteria on the phenomena.

Francis and Mugabo[83] call for Afrocentric approaches to policy designs to address gaps in public policy research and practice. Hitherto, public policy has been largely influenced by local and international institutions whose worldview has been generally Eurocentric. It could be argued that European awareness led to the alteration of prevailing knowledge structures, which in turn produced additional knowledge and innovation that created discourses through which Foucauldian power was exercised over the target groups of the intended policies.[84] Indeed, knowledge power was used to shape the cognitive biases of the individuals who were exposed to Eurocentric curricula. These views suggest a need for decoloniality in our epistemological approaches.

Our approach follows precedents in Afrocentricity approaches in education, curriculum development and even social work. However, Kumah-Abiwu highlights the need for additional development of Afrocentricity in the fields of economics, health, environmental issues and other general sciences. He further reemphasises the worsening socio-economic problems that face communities in the African world. This scenario is easily replicated with the twin challenge of addressing health challenges whilst cognisant of the risks associated with digital health.

Other scholars have also investigated the role of the three actors in the Triple Helix model of innovation in the African context to determine how it can enable African countries to achieve the status of knowledge economies and industrial societies.[85] A cultural factor, in addition to economic incentives, is essential for the sustainability of the collaboration among actors since the Triple Helix Model is a manifestation of social systems, not just an innovation process system.[86] Notably, little attention is

[72] Ekiegini, "Hegemony of Eurocentrism"; Asante, "Africology, Afrocentricity."
[73] Mazama, "Afrocentric Paradigm."
[74] Schiele, "Organizational Theory"; Ekiegini, "Hegemony of Eurocentrism"; Lateef, "Measuring Afrocentrism."
[75] Oloruntoba, "(Re)Negotiating Existence," 2.
[76] Emelianenko, "Pan-Africanism."
[77] Emelianenko, "Pan-Africanism."
[78] Emelianenko, "Pan-Africanism."
[79] Schiele, "Organizational Theory."
[80] Mazama, "Afrocentric Paradigm."
[81] Lateef, "Measuring Afrocentrism."
[82] Asante, "Africology, Afrocentricity."
[83] Francis, "EXPRESS."
[84] Escobar, "Discourse and Power."
[85] Agbebi, "Afrocentric Triple Helix."
[86] Ranga, "Triple Helix Systems."

paid to socio-economic factors in African countries when adopting the Triple Helix collaboration model.[87] We thus propose an Afrocentric Triple Helix model as a way of ensuring that the model is suitable for the African economic and cultural context, which is predominantly communal.

An Afrocentric Triple Helix model entails an integration of African value systems into the conception of the Triple Helix collaboration since cultural assumptions underpin collaboration.[88] An African value system such as ubuntu, which locates power in the concept of humanness, can provide useful principles for dealing with a hierarchical style of management, power imbalances and differences in mindsets among actors in collaboration to ensure its sustainability.[89] This similar approach is useful for regulatory sandboxes to enable co-creation of regulations in ways that generate a sense of ownership to ensure compliance with the regulations. Agbebi and colleagues attribute the failure of the Triple Helix collaboration model to 'the pursuit of narrow interests at individual, organisational and institutional levels.'[90] They propose ubuntu's focus on collective personhood that also acknowledges individual agency as a solution for such narrow interests, while making it possible to focus on greater societal interests.

6. Discussion

6.1 Integrating Afrocentric Values as a Catalyst for Inclusive Development

An Afrocentric Triple Helix approach would necessitate an all-inclusive approach. During the consultative multi-stakeholders' forum[91] there was a concurrence that some of the considerations that are important when designing a regulatory sandbox include defining the scope and objectives of a regulatory sandbox for digital health applications. The scope of the regulatory sandbox needs to be clear and specific in terms of defining the types of digital health applications to participate in the sandbox, the elements to be covered or regulated (e.g. data privacy and security issues), and also the jurisdictions where the sandbox will be applicable (this is important in the context of the cross-border migration of health data). Properly designed and implemented sandboxes would ensure that innovation processes and outcomes are aligned with the values and needs of African communities. The consistent growth of innovative digital health apps, viewed with Eurocentric lenses, would often target specific 'profitable' markets whilst disenfranchising marginalised communities. In the spirit of Ubuntuism, the sandboxes should be inclusive without neglecting the marginalised individuals and neglected health conditions across Africa.

This would result in inclusive and clear guidelines on what the regulatory sandbox entails and create an appropriate and structured environment for the testing of the digital health applications within a controlled regulatory framework prior to being rolled-out for public use. Within the fintech sector, the choice of participation was often found to be critical because it was ultimately linked to the policy being considered, and helped avoid solutions that were abstracted from reality.[92] The stakeholders agreed that clarity on the objectives of the regulatory sandbox was very important. Inevitably, there will always be tension between technology and regulation: 'technology will always be ahead of regulation in terms of the innovation that happens within the technology space.'[93] Thus, any new technological change is intrinsically disruptive for any legal regime.[94] Such a phenomenon was observed during the launch and subsequent growth of Mpesa in Kenya. In this case, the regulatory frameworks for the new product had to be overhauled to accommodate the emergent risk profiles. On the other hand, virtual currencies have to walk in tandem with the regulator due to the perceived risk of the products by the financial regulators.

There is always the need to aggregate data from different sources. Indeed, one tech firm founder stated that ordinarily 'I will shop around for somebody that I can buy and utilise their data as an entry point into the market.'[95] There is thus an overarching concern that some of the extracted data should not be used in a manner that has not been consented to by the data owner. The situation is compounded by the fact that presently there are only nascent cybercrime legal frameworks, thus making data handling and protection fairly vulnerable.[96] This was best stated by a respondent who stated 'what is not healthy is when the society wants my data and gets it without any due resistance or due acknowledgement or awareness by me.'[97] This concern is

[87] Nwagwu, "Nigerian University"; Agbebi, "Afrocentric Triple Helix".
[88] Agbebi, "Afrocentric Triple Helix."
[89] Agbebi, "Afrocentric Triple Helix."
[90] Agbebi, "Afrocentric Triple Helix," 365.
[91] Inaugural Online Stakeholder Consultative Forum for a Digital Health Regulatory Sandbox. Nairobi. July 24, 2023.
[92] Didenko, "Regulating FinTech."
[93] Inaugural Online Stakeholder Consultative Forum for a Digital Health Regulatory Sandbox. Nairobi. July 24, 2023.
[94] Didenko, "Regulating FinTech."
[95] Interview with Healthtech investor, Nairobi, May 14, 2021.
[96] Meslamani, "Technical Regulatory Challenges."
[97] Interview with community mobiliser, Nairobi, May 25, 2021.

further compounded by the fact that 'one of the challenges is on having the right frameworks on data sharing.'[98] Indeed, the situation gets complicated due to the concern for data security because 'the cloud data centre, with renowned providers… may give you the best security, which you may not even afford upfront as a company when you want to invest in the right firewalls'[99] thereby necessitating data migration. This makes the technological firm, and essentially the data users, vulnerable to data migration and subsequently unconsented use. One of the core values for Afrocentricity is respect for nature and other individuals. This would entail harmony with the environment and sustainable practices for any digital health innovation that is adopted.

6.2 Bridging Global Frameworks with African Socio-Economic Realities

There are several comparisons that can be viewed between the digitalisation of health and the digitalisation of the financial sector. Prior to the digitalisation of the financial sector, access to financial services was limited and a majority of the African population was unbanked. This was due to myriad infrastructural issues like inappropriate foreign currency regimes, inadequate supply of products that could only be addressed by a disruptive business model. Similarly, the weak health systems in Sub-Saharan Africa have been plagued with myriad challenges that include inadequate infrastructure, insufficient funding and a shortage of skilled healthcare workers.[100] Desirable innovation results in promotion of economic growth that is environmentally responsible and socially equitable. Africa is unique and diverse and it is therefore essential to develop digital policies and regulations that encourage digital health innovators to prioritise social impact and environmental sustainability, reflecting the Afrocentric values of communalism and respect for nature.

A regulatory sandbox may have dual purposes either for promotion of innovation or as a regulatory standard. As such, the regulatory sandbox should ensure that the digital health applications participating in the sandbox are able to comply with the regulatory standards that are relevant to the healthcare industry. Such duality in regulation similarly afflicted fintech regulation as there were both prudential and promotional requirements for regulation.[101] Therefore, there has to be a determination as to what is the key objective of the regulatory sandbox to avoid mixed signals. In the case of fintech regulations, whenever the regulation was promotional in nature, there might have been a need for preferential treatment.[102]

To address the dilemma between regulatory and innovative objectives, a respondent was emphatic that 'we need to have a sandbox.'[103] The observation was that its use would address many of the concerns and challenges relating to the conflict between innovation and regulation. The success of a regulatory sandbox is dependent on its ability to strike a balance between ensuring regulatory compliance without stifling innovation, and protecting application users' data privacy and security. In Kenya, the inaugural financial stakeholder regulatory sandbox consultation forum expressly stated that 'regulatory nimbleness, flexibility and responsiveness provided by principle-based regulation is even more important in the fintech sector where thriving innovation is the lifeline of a vibrant business enterprise.'[104] Such a balance can be achieved through regular monitoring, evaluation, and iterative improvement of the sandbox's scope and objectives in order to ensure that the sandbox remains relevant over time. Consequently, it is important to set up periodic review processes for the sandbox to assess its progress and impact. Insights can be drawn from the review process to decide whether the digital health applications should continue in the market, be modified, or be discontinued if they fail to meet the objectives or if they pose unacceptable risks to the users. These objectives should however not be viewed in isolation as stated by one of the respondents that 'apart from the law and regulation in data protection practice around the world, there is a need for sector-based practice modes or guidelines on specific issues – which we don't have yet...'[105] This speaks to contextualisation of the sandbox practices, as 'we need to start making sure that our policies are aligned.'[106] However, this contextualisation should be broad so as not to be counterproductive as was observed in South Africa, where many observers felt that the creation of many narrow sector-specific regulatory frameworks in 2017 ran the risk of creating obstacles to bringing together technology firms and financial institutions.[107] Yet some of these changes will always prove contestable and thus regulators have an option of carrying out socio-benefit analysis through a robust, objective and verifiable ex-ante social and economic impact assessment ('SEIA') as was introduced in South Africa in 2015.[108]

[98] Interview with Insurance practitioner, Nairobi, 13th May 2021
[99] Interview with Insurance practitioner, Nairobi, 13th May 2021
[100] Ameso, "Digital Entanglements."
[101] Didenko, "Regulating FinTech."
[102] Didenko, "Regulating FinTech."
[103] Interview with Healthtech investor, Nairobi, May 14, 2021
[104] CMA, "Stakeholders' Consultative Paper."
[105] Interview with civil rights activist, Nairobi, May 7, 2021.
[106] Interview with Healthtech investor, Nairobi, May 14, 2021.
[107] Didenko, "Regulating FinTech."
[108] Didenko, "Regulating FinTech."

6.3 Synergising Digital Heath Innovation in an African Context

The emphasis on oral tradition and indigenous knowledge systems influences how knowledge is shared and disseminated within the Triple Helix, promoting participatory approaches and community engagement. This becomes vital when collaborating across the three different spheres for digital health innovations. For example, issues pertaining to data governance and privacy are emergent issues that affect the budding digital health innovations across Africa. These challenges bring to the fore the debate of public versus private interest, and one respondent opined that 'the right to privacy is not absolute, you also have to check about the public interest.'[109] There will always be tensions between the interests of the different stakeholders. Thus, the discussion flows to the need for a consensus, which requires multiple stakeholders. It therefore becomes an ever-recurring need to ask 'where do we find the balance between the interests of the individual and the interests of the society?'[110] as one of the respondents stated.

This discussion can be extended further when viewing the inherently institutional power in play, as extractive tendencies of access to data are demonstrated because individual data owners do not have a say in the post data-collection process. In the context of innovations that use electronic health records, a possible solution entails organisations that hold the records either offering innovators a service by facilitating data access, or being 'involved in the design of the software tools to facilitate access.'[111] As observed by one of the respondents, 'there is definitely a place and need for those applications.'[112] This calls for a common approach that brings all actors together, as was indicated by one of the respondents: 'we need to have a dialogue between our regulators and industry.'[113] Experience from the fintech sector indicated that regulatory feedback to the innovators was often unintelligible, unpredictable or frequently came in too late to be adopted,[114] and subsequently there was always the need to seek coherence and consensus as part of the post-implementation strategies.

Sustainable innovation integrates traditional African knowledge and practices into modern health development efforts and empowers communities to participate in the innovation process thereby benefiting from its outcomes. In the case of digital health technology – what would be the nature of preferential privileges granted to the participants? This varies and is dependent on the nature of the innovation and thus stronger ethical oversight needs to be in place. More importantly, these objectives need to be consistent with the regulatory priorities notwithstanding the fact that they should avoid "*retrofitting*" the new technological developments into the existing regulation.'[115] That notwithstanding, fintechs had to choose between domestic and international priorities whereby their immediate domestic concern was financial deepening. Similarly, prioritisation within the health sector is important due to the nature of infrastructural challenges available – for instance, a choice between something that affects the wider ill-funded public health versus a niche yet well-funded aspect of health. A case in point is the use of drone and aerial technology in Malawi and Ghana to address infrastructural challenges.[116] Whereas the introduction of drones attempted to address specific problems within the healthcare systems, there was an unintentional discovery of other underlying challenges which may not have been addressed by the introduction of drone technology,[117] pointing to the fact that African Health systems are indeed intricately saddled with legacy 'challenges of poor health outcomes, intraregional disparities, urban-rural inequalities, intra-urban differential and the intra-district skewing of care, deliberate reforms.'[118]
From the above discussion, an Afrocentric regulatory sandbox should have the attributes of advisory sandboxes and anticipatory sandboxes. As shown in the Appendix, most health regulatory sandboxes that currently exist in Africa are either advisory or anticipatory in nature. Embedding an Afrocentric paradigm in advisory sandboxes can ensure that digital health innovations for the African context are based on policies that are shaped by African values. On the other hand, anticipatory sandboxes ensure that policies that include African values can guide the adoption and uptake of digital health technologies.

7. Conclusion

In this article we have traced the need for health systems in Africa to embrace digitalisation. We have looked at similar sectoral considerations for digitalisation within the fintech sector. We reviewed how challenges in financial sector were addressed through regulatory sandboxes and how this practice could be extended to digital health innovations. Through critical analysis

[109] Interview with civil rights activist, Nairobi, May 7, 2021.
[110] Interview with community mobiliser, Nairobi, May 25, 2021.
[111] Leckenby, "Sandbox Approach," 865.
[112] Interview with civil rights activist, Nairobi, May 7, 2021.
[113] Interview with HealthTech investor, Nairobi, May 14, 2021.
[114] Didenko, "Regulating FinTech."
[115] Didenko, "Regulating FinTech."
[116] Burchardt, "Where is the Bottleneck?"; Ameso, "Digital Entanglements."
[117] Burchardt, "Where is the Bottleneck?"
[118] Ameso, "Digital Entanglements," 5.

we sought to develop an appropriate bridge to the existing policy domain. We sought to co-create regulation though design of principles that leveraged a Transnational Triple Helix Model that could be used for the implementation of digital health sandboxes across Sub-Saharan Africa. This study has not been without its limitations. Firstly, there is definitely a need for further research to establish the exact causalities and influence of different factors that would hinder the implementation of appropriate regulation. Secondly, jurisdictional heterogeneity is likely to influence the full extent of adoption of the regulations for regulatory sandboxes. There is thus a need for additional contextualisation of the recommended solutions. The existing solutions have tended to be disparate and coupled with the overarching drive to scale solutions in a Eurocentric fashion. Ultimately, the effectiveness of these recommendations can only be achieved when the Triple Helix Model is operationalised and grounded in the cultural realities that are aligned with the Afrocentric paradigm.

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Appendix 1: Typologies of Sandboxes and Possible Trials

Regulatory Function	Sandbox Approach	Sandbox Mode	Sandbox Focus	Example of possible Sandbox Trials
Promote Innovation	Advisory	Live Lab	Outcomes focused	Kenya's Telemedicine Pilot at Kenyatta National and Isiolo Hospitals aimed at extending healthcare access into remote and marginalised regions.
	Advisory	Live Lab	Outcomes Focused	Wisepill, an Electronic Adherence Monitors (EAM) with real-time feedback —This was a cellular-enabled pillbox that pings when opened and could trigger SMS reminders or flag missed doses for targeted counselling.
	Adaptive	Live Lab	Outcomes focused	Drones for medical supply delivery in Rwanda where the Civil Aviation Authority adapted airspace rules dynamically as drones demonstrated reliability in delivering blood and vaccines to remote health posts.
	Anticipatory	Live Lab	Outcomes focused	Case of minoHealth and Chestify Labs in delivering real, clinically validated AI diagnostics in Ghana**,** with peer-reviewed results to back it.
	Anticipatory	Live Lab	Data focused	Climate-informed Malaria Early Warning Systems (MEWS) for Tanzania. Regulators work with startups to test predictive outbreak models, shaping rules on algorithm transparency and public health data use before models become mandatory.
Regulatory Standards	Advisory	Real World Lab	Outcomes focused	EMGuidance Script is a comprehensive digital prescription platform tailored for South African healthcare professionals. Health regulator could partner with pharmacies to observe e-prescription adoption and draft interoperability standards based on observed patient–pharmacy–doctor workflows.
	Adaptive	Real World Lab	Data focused	Genomic surveillance for infectious diseases in Senegal - Digital intervention was primarily in data generation, analysis, and sharing through genomic sequencing combined with computational /bioinformatic analysis pipelines. The Sandbox could collect and share pathogen genome data across research institutions; data governance rules adjust in response to security and equity concerns.
	Adaptive	Real World Lab	Data focused	The Electronic Management of Immunisation Data (EMID) system in Nigeria was designed to streamline the collection, management, and reporting of immunisation data across the country. Sandbox observes varying data-sharing practices between state health systems, updating privacy and interoperability laws in real time to standardise national immunisation tracking.
	Anticipatory	Real World Lab	Outcomes focused	Cross-border digital patient records in East Africa*:* EAC health regulators simulate integrated patient record exchanges between member states to set future data governance standards before continental digital health rollouts.