Introducing Data Sovereignty Over Patient Data: Patient Data Ownership in Residence of Health Facilities in Kenya

Reginald Nalugala, Putu Hadi Purnama Jati, Samson Yohannes Amare, Maxwell Omare, Jacinta Wairimu, Charles Kahiro, William Nandwa, Seth Okeyo, Dennis Kinoti, Aliya Aktau, Albert Mulingwa & Mirjam van Reisen

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Introducing Data Sovereignty Over Patient Data: Patient Data Ownership in Residence of Health Facilities in Kenya

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Abstract

This study examines clinical patient data stewardship through the perspective of data sovereignty. Data sovereignty underscores the authority of nations, communities or entities to manage data within their jurisdiction. The study recognises the problem that digital system for patient care and preventive medicine lack data integration. Against these two major problems, the study highlights the need for a paradigmatic shift in patient data handling to solve these problems. To ensure explicit control over the data, the study identifies the new expectations of patient data stewardship and health data handling. The research highlights that federated data handling can ensure data ownership across jurisdictions. The study found that such infrastructure is best served with data curation based on localised machine-actionable metadata. The study concludes positively on the feasibility of the establishment of frameworks for localised patient data control by care providers and patients; the feasibility of systems for improved digital patient data-driven care and services, and the possibility to base analytics on conditional access to metadata. It follows that there is an urgent need to enact legislation for inclusive health data representation. The study found that the idea of the Africa Health Data Space, based on the value of data sovereignty, is a contribution to realise the required paradigm shift.

Keywords: Patient data, health information system, DHIS2, data sovereignty, health data management, DHIS, FAIR-OLR

Introduction

The inequality of access to resources to prevent, treat and protect populations in the novel coronavirus (COVID-19) pandemic was a glaring setback to making treatment of COVID-19 a universal health effort (Gleeson et al., 2023). The World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic on March 11, 2020 (WHO, 2020; CIDRAP, 2020). In 2021, Oxfam heavily criticised developed nations for hoarding vaccines at the height of COVID-19 pandemic. Pacheco (2021) pointed to the market value of the vaccine business, compounding to economic inequalities, and access inequalities. Oxfam (2021) concluded that there was a serious gap in vaccine manufacturing, ownership, distribution, and equitable sharing in Africa. Oxfam (2021) suggested supporting research into vaccine manufacture driven by Africa and to be supported by research based on its own localised data.

Following the outbreak of the COVID-19 Pandemic, the WHO (2021a) emphasised the need for all countries to collaborate in vaccine production to effectively respond to the needs of their populations, a position that coincided with WHO (2021b) proposing a new process for patient data handling to strengthen surveillance of the pandemic. This coincided with an urge that data from Africa should have greater quality to support vaccine production among others. The WHO proposed a structured procedure for handling digital patient data which is referred to as Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART) data handling guidelines (WHO, 2021b).

The COVID-19 pandemic was a watershed forcing countries to evaluate the importance of patient data and assess their national priorities to protect countries' populations with adequate health policies. The COVID-19 pandemic has changed the health sector (Robertson & Travaglia, 2020) by creating a demand for active preparedness through data production, evidence-based treatment, surveillance and prevention (Van Reisen et al., 2022). The recommendation for an innovation in data production in Africa in general (Van Reisen et al., 2020) also included an understanding that the control over the handling of patient data needed attention (Purnama Jati et al., 2022). The poor clinical health data collection

system in Africa meant that it would continue giving space for international researchers to siphon out its health data to the West at the expense of Africa (Van Reisen et al., 2021) and there was no legislation addressing this (Van Reisen et al., 2022). Africa has become disadvantaged in this regard because of poor data infrastructure and human resource expertise to handle the introduction of required technology to make sure data remains in jurisdiction (Van Reisen et al., 2022). As a result of the unpreparedness and lack of ability to respond effectively to the COVID-19 pandemic, it became evident that the overall digital health systems existing in Africa were wholly inadequate to perform data surveillance, storage, distribution and control over patient data in jurisdiction to support national strategies regarding the prevention, treatment and vaccine research (Van Reisen et al., 2022). Despite concerns over the lack of control over patient data in Africa at large and the lack of adequate national responses to the COVID-19 pandemic that were tailored to national realities, Van Reisen et al (2022) showed big discrepancies across African nations in terms of patient data handling.

Hence, to study how and in what way the COVID-19 pandemic prompted change in national policies, a case study approach on a country-by-country basis is prudent to avoid over-generalisation. Considering the problems experienced in the response to the COVID-19 pandemic, the study of Inau et al. (2022) showed that policy directions in Kenya were in line with the observation that data control in jurisdiction was necessary, however, it was unclear how such an objective could be achieved. This was particularly the case in the absence of a national policy on handling patient electronic medical records (EMR) and the Health Information System (HIS). These systems were based on the foreign donor-driven District Health Information System 2 (DISH2). In view of the findings of Inau et al (2022) the question concerning the national policy to protect patient data handling in jurisdiction, is a pressing concern. This justifies focusing on Kenya as a case study.

Concerned about the lack of patient data sovereignty on the African continent, this research addresses the question as to how Kenya is preparing to hold data in residence and contribute to future research. This study presents findings of a study approaching the data stewardship of clinical patient data from a perspective of data sovereignty.

Theoretical considerations

The conceptual framework of the study considers the sovereignty issue of countries, communities and entities, such as health facilities on the one hand, and the available operationalisation of these notions in an implementation architecture. It is argued that data sovereignty should be considered also at an individual level, and some may argue that this is the more relevant issue to consider. Value-driven Ownership of Data and Accessibility Network (VODAN) Africa is leading the advocacy for the principle of data ownership, which asserts that personal data should remain the property of the data subject.

In the scope of this study, the overall focus is on how governments can ensure adequate preparation and response to health challenges for the population they serve, and we investigate the relation of this responsibility versus those of communities and entities, in case health facilities, that produce the data. How such a framework may translate into a cross-border architecture supporting health insights is the main scope of this study. Therefore, the question of sovereignty is discussed alongside the framework that may serve to advance sovereignty in a practical way.

Sovereignty of digital data by countries, communities and entities

The principle of data sovereignty emphasises the right of nations, communities or entities to govern data within their jurisdiction (Hummel et al., 2021). Hummel et al. (2021) link data sovereignty to digital colonisation and refer to the problem of the exertion of power and influence by a dominant culture over minority cultures, a point emphasised in the literature (Wakunuma & Masika, 2017, Reuters, 2020; Cross et al. 2021). Pacheco (2021), Kukutai and Taylor (2016), Baker and Koons (2020), and Jansen (2016) focus on this power dynamic, investigating data sovereignty of indigenous communities. Citing the work of Baezner and Robin (2018), Hummel et al. (2021) observe that data sovereignty involves the ability to exercise control

over data flows, strongly basing their argument on indigenous (localised) data sovereignty.

However, Hummel et al. (2024) advance the discussion by pointing to the problem of national sovereignty over patient data. Their observations are made in relation to conclusions offered by the German Ethical Board. The German Ethical Board found that health data sovereignty should shape international opinion on where country data should be stored and made available (Ethikrat, 2017).

The tension between national sovereignty, community sovereignty and sovereignty by entities, such as health facilities, requires further consideration. Muroki and Arimi (2017) concretise this problem further, in addressing a situation in which national sovereignty may conflict with the rights of cross border (indigenous) communities concerning the control over their health data, as well as the responsibilities invested in the clinics operating in the border area. Focusing on specific challenges affecting cross-border communities, Muroki and Arimi, (2017), identified a major gap resulting to the poor handling of data of the cross-border communities with clinics not allowed and not able to share patient data across the borders. Data was collected by the researchers from 2014 onwards in borders between Kenya and Uganda and Kenya and Tanzania. The analysis showed that existing national health systems in the period investigated, did not have an integrated mechanism for tracking and tracing patients across national borders. This caused challenges to ensure a continuum of care in health facilities serving populations using health services across borders. Muroki and Arimi (2017) found that national health systems lacked mechanisms to track patients across national borders leading to loss of follow up to patients in need of ante-retroviral therapy (ART), non-adherence and multiple registration by mobile and cross-border people living with HIV (PLHIV) as they strive to access ART and other related HIV services. The East Africa Community (2017) pointed to the need to have data integration without losing control of national sovereignty in the member states of the community. The East Africa Community (2017) also pointed to the relevance of Findable, Accessible, Interoperable, Reusable (FAIR) guidelines in offering a solution to this problem.

FAIR-OLR: An operational definition of data sovereignty

The potential to operationalise the principle of data sovereignty in a cross-border set up is provided by the FAIR-OLR (Findable, Accessible, Interoperable, Reusable-Owned, Localized, with Regulatory Compliance) framework, which allows cross-border operations to be carried out on metadata of patient data, allowing full control over the data in jurisdiction (Van Reisen, et al., 2023). To realise this infrastructure, VODAN-Africa added three qualities to the principles of FAIR, namely:

- Ownership of data in the place where it is produced
- Localisation of data, to make sure provenance is retained
- Regulatory compliance is based on specific requirements in the location where data is produced and reposited.

FAIR-OLR emphasises that while data should be interoperable and reusable across borders, its stewardship and access and control mechanisms should respect local conditions, aligning with the principles of data sovereignty. These complementary principles provide a robust foundation for advancing global data sharing while respecting local governance and societal norms within national jurisdiction. In technical terms such data sharing becomes data visiting, with data visited by computational queries under strict permission conditions (Amare, Medhanyie & Van Reisen, 2024; Van Reisen et al., 2021; Purnama et al., 2022; University of Oxford, 2021; Plug et al., 2022).

Assessing the available definitions, this research operationalises data sovereignty as follows. Data sovereignty refers to the concept that data is subject to the laws and governance structures of the country, community or entity where it is collected or stored, ensuring that the control, access, and use of data align with the regulatory framework pertaining to the structure, carrying the responsibility for the data handling. Data sovereignty also includes the regulations under which data may be shared, or visited, for computational operations and analytical processes. Data sovereignty relates to the rights of the data subject, to whom the data pertains. In this study data sovereignty is operationalised in the principles of FAIR-OLR data curation.

Context: The legal embedding in Kenya

The Kenya Constitution (2010) and Vision 2030 development blueprint require Kenya to provide the highest attainable standard of healthcare. The Ministry of Health developed the Kenya Health Policy to fulfil this mandate. This comes at an important time when the health sector is implementing far-reaching reforms to achieve universal coverage. This concept is anchored in Vision 2030, which sets the overall goal in health to have "equitable and affordable healthcare at the highest achievable standard" for her citizens. It is informed by the strategies and results emanating from the implementation of the Kenya Health Policy Framework, 1994-2010, the health sector strategic plans, and the e-Government and Shared Services Strategies implemented through the e-Government Directorate and the ICT Board respectively.

The Kenya Health Policy, 2014-2030 gives directions to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030, and global commitments. It demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population. This policy is designed to be comprehensive and focuses on the two key obligations of health: realisation of fundamental human rights including the right to health as enshrined in the Constitution of Kenya 2010; and the contribution to economic development as envisioned in Vision 2030 (Republic of Kenya, 2014).

The Kenya Government also set up an authority to monitor and direct all data information especially health data. The Kenya Information and Communication Technology Authority was created in 2019 to lay out a platform for better policy implementation and monitoring. Under this authority, it is understood that the specific mandate is to ensure coherence and a unified approach to the principles that govern the acquisition, deployment, management, and operation of data production in Information and Communication Technology (ICTs) across the public service, state agencies, to promote service integration, adaptability, and cost savings through economies of scales in ICT investment. Compliance with the national policy will bring about an efficient and effective service delivery to citizens.

Working within the framework of the Health Act (2017, revised in 2019, 2021) the Health Act Section XV, article 104, directs the Ministry of Health to administer health information banks, including an interoperability framework, data interchange, and security (Republic of Kenya MOH, 2021; Republic of Kenya, 2015 & Republic of Kenya, 2019). Another survey conducted by the Ministry of Health and Kenya Bureau of Standards (Republic of Kenya MOH, 2014) and released in 2022, brought out the difficulty of retaining health data at the place of production. Despite good data produced by different research agencies, that data is not retained nor easily accessed due to poor data interoperability systems, and there remains a serious risk of data loss (Republic of Kenya, 2014, Republic of Kenya, 2023).

Research approach

This is an exploratory case study research, a branch of research that tends to assist in investigating a problem that is still emerging and under-investigated. Data from exploratory studies tends to be qualitative.

Implementation of the study: The VODAN research group

A group of researchers involving nine countries in Africa came together in 2020 to address the curation of patient data from COVID-19 for future use and storage in local health facilities. The researchers grouped under the programme of the Virus Outbreak Data Network (VODAN), established as a response to the pandemic, in 2024 rebranded as the Value-driven Ownership of Data and Accessibility Network (VODAN).

The mission of VODAN-Africa is to create open-source innovation by African engineers and health workers to enhance health data interoperability problems in Africa. The VODAN-Africa works closely with researchers from Europe, Asia, and the Americas and is linked to the research carried out at Leiden University on the use of FAIR-Data for improved health outcomes. The group of researchers in Africa became well-organised and established country teams in eight countries, supported by a technical team working across countries. In addition, there were categories of support teams, namely, a technical data curation team, a team working on access and control and regulatory compliance, as well as a team for deployment for testing in real life. The research was implemented in existing health facilities with real patient data to increase the ecological validity and reliability of the approach.

In Kenya, four health facilities were selected. The administrators of data clerks were included in the Kenya team. The Kenya team also had the support of good links to the Ministry of Health and the Nairobi Metropolitan Health Bureau. The team communicated regularly, in person, and in writing. The core team members attended the weekly Zoom meetings of the Africa-wide research team. Separate meetings were also held with the Kenya team, to tackle issues relevant to the Kenyan context.

The VODAN-Africa Kenya team was led by Tangaza University, Nairobi, which led the study, supported by the VODAN-Africa technical teams, Leiden University Medical Centre (LUMC), and Stanford University.

Preparation for implementation of the study

The Kenya team conducted a study in 2020 to assess the alignment between the FAIR data principles and Kenya's regulatory and policy framework for digital health data (Inau et al., 2022). The findings demonstrated a strong congruence between the FAIR data principles and the Kenyan government's regulatory and policy framework. Furthermore, the study revealed that the aspirations underlying both approaches were closely aligned, highlighting the potential for seamless integration of FAIR principles into Kenya's digital health strategies.

The findings were presented to the staff of the Ministry of Health, and the approach for implementation research was discussed. The Ministry of Health and Nairobi Metropolitan Bureau offered approval for the implementation of the study, provided that the research was carried out in grassroots led approach, meaning that the results should pertain to positive results within the health facility and benefit the clinical service provision in the facilities. The research group obtained a letter to support the work. The four health facilities included in this study were Zambezi Hospital (a private hospital) and Pumwani Hospital (under Nairobi County Ministry of Health), Beacon of Hope (private in Kajiado County), and the Kenya Medical Research Institute (KEMRI). Pumwani Hospital is one of the largest hospitals specialised in maternal health. KEMRI is closely associated with the Ministry of Health as its research arm.

The health facilities provided the necessary support required for the deployment of a semantic machine actionable data system aligned with the FAIR-OLR Data Principles and Kenya's regulatory and policy framework for digital health data production. It included the various stakeholders and took an interdisciplinary approach. The hospital teams included the ICT technical teams, electronic and computer network engineers, medical doctors, nurses, social scientists, policymakers, social workers, and health data stewards.

Study period

The study started in 2021, following an evaluation of a Proof of Concept of the use of FAIR data for data-visiting under full data sovereignty. The study was completed in 2022 when the four facilities in Kenya deployed the infrastructure for patient data capture, recognising the need for full data sovereignty and produced patient data during that time, in the installed software.

Legal and ethical considerations

For this study a letter was received by the Ministry of Health in Kenya that it authorised the study. The study coordinator reported to the Nairobi Metropolitan Bureau of Health. The study coordinator signed four Data Use Agreements, with the health facility concerned, with the Bureau of health representative and the VODAN executive coordinator. The Data Use Agreement identified specific operations that would be authorised over the data of the four facilities and facilities outside Kenya. These were aggregates, mostly intended to test the capacity of the system to develop insights without transporting any data outside the health facility and the country by aggregating and computing only from the metadata. The purpose of the Data Use Agreements was to give very clear insights in the operation, with the aim to allow maximum understanding of all involved in the scope of the operation, and to test the feasibility of the operations. The purpose was for the Data Use Agreements and the test of the operational structure to build confidence and trust that sovereignty aspects were fully adhered to.

Data collection

The study started with an in-situ exploration of how data sovereignty was discussed in the Kenya health system, with emphasis on the Nairobi metropolitan area. Next, four facilities were selected based on their interest to participate, their strategic position - in the case of the KEMRI and to have some variety in the settings of each facility. The participation was entirely voluntary and there were no benefits associated with the participation in the study. The four health facilities received (i) training to data clerks and data stewards; (ii) information sessions to management of the health facilities (iii) team management support by the Country Coordinator; (iv) technical support by the VODAN technical team; (v) one computer (vi) a software installation pack and manual and (vii) technical support back up. In the second study component, data was derived from a series of discussions, based on open questions and individual communications and group engagements. The focus was on the four facilities where the study was implemented, the administrators, clinical doctors, health workers, and digital support staff in those facilities.

The data for this second study component was collected prior to installation, during the implementation and after the study was over. At first, the Country Coordinator engaged with all the teams in the four health facilities, and made notes of the observations. These were also discussed in the weekly Zoom meetings, which were all recorded. During the deployment, the Country Coordinator engaged with the technical teams to understand their observations on the system. After the implementation, semi-structured questions were given to all of the participants. Additionally, observations and communications in engagements with the policy staff of the Bureau and Ministry of health were recorded and these were separately analysed. Finally, a series of group meetings were held to discuss the consequences of the study for the team, the outcome of which is presented in the final section.

Data analysis

The processing of the data followed an interpretative analysis. The data was analysed by the first author, in vivo, with a view to identify main themes that were addressed in the responses. The observations were regularly discussed in team meetings of the Kenya team and in the VODAN Zoom meetings. These discussions served as a means to validate the interpretation and to develop understanding on the overall assessment and conclusions. As a result of this process, the findings presented, reflect a consensus developed over time by the participants. The findings as presented in this chapter were shared with all the participants to validate the consensus that emerged, and the Kenya team members engaged collectively in the writing of this chapter to present the collective results of their experiences and discussions.

Findings

This research is divided in four parts: (i) reported problems with data handling prior to the implementation; (ii) the understanding of the architecture that was implemented; (iii) the appreciation of the installation by the technical team and (iv) the perceptions of the results after the implementation was concluded.

The legacy of DHIS2 and KHIS

Early on in the research the participants point to the DHIS2 system as the main problem. The four facilities all used the district health information science (DHIS2), since this was a requirement. During the period of the research, Kenya changed DHIS2 into the Kenya Health Information System (KHIS), to emphasise its control—or national sovereignty, over the system. The change of name pointed to a control by Kenya over the data.

However, according to the participants in the research, the change from DHIS2 to KHIS was largely cosmetic. In their view as they experienced it, the problem remained the same: DHIS2 did not give control over the patient data to the health facility. In fact, according to the participants, KHIS does not recognise ownership over the data by the Ministry of Health. They understood that the data was transported outside the country for the exercise of carrying out operations over the data.

The participants in the four health facilities in Nairobi, Kenya where the DHIS2 was used, found it to be very inadequate. The data is aggregate and gives little information for the clinicians and health workers. In the communications, DHIS2 was reported as an avenue for transporting patient data outside the country for analysis conducted outside Kenya. The overall conclusion among participants was that DHIS2 has not rendered control to the Kenyan government with regard to patient data management.

The participants in the study reported that the Kenyan policy lays a good foundation for making sure data is stored in Kenya for better use and support to the wellbeing of the country. However, the weak area not addressed with this ICT Authority mandate is the discussion of FAIR data and curation. According to participants, it remains vague on how health data can be stored, controlled, and shared, for research while allowing any independent agency to access, control, and also for the patient data. The examples that were given are the tech start-ups that are not under an organised government health data infrastructure. Hence the gap remains how to make sure that data is controlled by the government through the respective Ministry of Health and local health facilities.

DHIS2 and KHIS were heavily criticised by the majority of participants for not providing data that would lead to better health outcomes in the health facilities. The concern that the ownership of digital patient data was unclear and that the health facility did not benefit from data insights to improve health services, provided a fertile ground for participants in health facilities to agree to carry out the implementation study.

The participants in the four health facilities were interested in understanding whether data could be held under control of the facility while contributing to better health outcomes. The participants were also interested in discussing other features of the data; particularly the economic aspect of where the data is produced and how to ensure value of the data comes to Africa and wanting to understand whether (self)-employment and benefits is generated - in Africa.

Implementation of the FAIR-OLR infrastructure

VODAN-Africa proposed an intervention to the four facilities in Kenya, together with 84 facilities in other African countries. The infrastructure could be implemented by the health facilities for them to test whether the problem of low rendering of digital data could be solved.

The solution proposed by VODAN-Africa was that data is created and held in the facility where the data is produced under the regulatory framework of the county and national state jurisdiction. This delivers a resource in which the data remains an asset for the health facility, both in terms of providing improved insights to help health care services improve as well as contributing to other uses of the data which may also help services (surveillance, pharmacovigilance and clinical studies).

The installation of the data infrastructure required a lot of preparation. There was a need to develop software to allow a new application which would test how data can be collected, stored and curated within local health facilities and remain available and interoperable with data held in other facilities elsewhere. Therefore, VODAN-Africa built a platform that comprises a network of systems fitted with sets of tools to produce, use, and reuse FAIR data. This system builds on the globally known and widely used standards that allow FAIR-data management, expanded with the OLR principles, to localise the data sovereignty to the health facilities. By the time the project was finished in 2022, 88 health facilities had been accessed and 74 were producing data in eight countries across Africa, including in the four facilities in Kenya.

Figure 1 gives a synopsis of an elaborated architecture for data ownership and retention in places where data is produced. The data is retained in the health facility, and through computations data is visible or searchable for visualisation or querying. The FAIR Data Point provides the elements necessary to make the data findable and discoverable, while access is mediated by stringent permission controls, which can be managed from the health facility directly. The data does not leave the health facility.



Figure 1. VODAN-Architecture for a One-Data Entry Machine-Actionable Semantic Curation for a Multiple Functionalities Architecture Based on Queries through Data-Visiting of Federated Local Depositories in AllegroGraph

Source: Van Reisen et al., 2021, Vodan website ref. 10.1002/ggn2.10050

The architecture has the following features:

- One-time data entry
- Multiple functionalities are run over the same data
- The data instance is reposited locally
- The data instance is curated with semantic meaning
- The data instance is expressed in triples (subject-predicateobject) and retained in machine-language that retains the triple format
- The metadata instance is reposited in a triple store
- The metadata instance can be visited for computations within and across the triple stores, with Query Language and Resource Description Framework (SPARQL) queries
- Visiting of the data preserves stringent conditions for privacy preserving computations that aggregate the data and that can be exported
- The metadata instance is exposed in a FAIR Data Point, that identifies the datasets and data-catalogues

- The metadata instance is harvested for insights visualised in the health facility for use by health workers in the health facility
- The metadata instance is harvested for surveillance purposes, visualised in a dashboard showing aggregate computations of all participating health facilities
- The metadata is exposed in aggregate format to KHIS

The features relate to core objectives: (i) the data is entered only once and does not add to pressure of health workers to fill out multiple data entry tools, (ii) the data remains under full control of the health facility; (iii) the data contributes to the value of better health insights at point of care, translating into better health services in the health facilities and (iv) the data contributes to surveillance, pharmacovigilance and better contextualised clinical trials to further improve preparedness, prevention and treatment.

The system was installed in the health facilities in 2022, following an introductory training, to help the installation of the software prepared for each health facility. The software was deployed on a dedicated computer.

Technical assessment of the deployment of the FAIR-OLR system

During the deployment and implementation, the Kenya technical team met regularly, to discuss the experiences. The following topics were the most prominent.

Control over the data

Following deployment and having full access to the technical specification of the architecture, the technical team from Kenya was able to ascertain that the patient data did not leave the health facility. The technical team ascertained there was no 'back door' in the infrastructure and that they had full control over the system.

It was concluded from the study that a patient data architecture with data visitable for analysis by the health facility and by external actors (under permission), could promote data ownership localisation and regulation compliance (OLR), which is described as FAIR-OLR within the FAIR specifications, while allowing external parties to run operations over the data. In this case a specific permission procedure was run to adapt the Data Use Agreement.

Control over data visiting

The technical team also ascertained that the specific permissions required for data visiting that were asked outside the scope of the Data Use Agreements required handling through additional and new permissions. In such cases, the Country Coordinator had to ask specific permission from the health facility to amend the original agreement for the new process carried out over the data.

Feasibility in low-resource settings

The implementation of a bottom-up approach enabled the Kenya team to assess the feasibility of deploying the intervention in health facilities across various contexts, including low-resource settings. All four facilities were able to deploy the infrastructure, under different operational circumstances. The low costs associated with installation, coupled with the training provided by VODAN Africa, granted young data clerks and stewards access to innovative knowledge on data stewardship. These conditions demonstrated the practicality and potential of the proposed direction, offering promising prospects for the future. The team realised that the VODAN Africa training component is integral to fostering data sovereignty, and there was excitement that it would empower Kenya's youth to contribute to shaping the future of computational technologies, such as artificial intelligence (AI), and to enhance the inclusion of African data in AIdriven solutions.

Conclusions by the technical team

The Kenyan technical team concluded that the data sovereignty promoted by the intervention could have a positive impact on the realisation of digital innovations that are tailored to and benefit Africa. The team in Kenya learned from the deployment, particularly through conversations on the set up of the system, the team was able to understand why data interoperability is not enough and why the full FAIR-OLR principles were needed to optimise an architecture, in which all the objectives were achieved.

Perceptions of results from health facilities

After the intervention, the research team conducted a review among the stakeholders, who had participated in the implementation of the intervention.

Control over the data

The researchers found that the intervention by VODAN-Africa was widely acknowledged by the directors of the four health facilities where the architecture was installed, as a timely and critical initiative. It provided an essential framework through which patients could maintain control over their data, ensuring ownership and localisation at the point of data production. The results of the implementation study highlighted the profound concerns expressed by hospital directors and data stewards who participated in the exercise. They were notably dismayed upon recognising the deficiencies in technology available for patient data handling, and the lack of adequate skills available in their teams regarding machine learning and machine-actionable data. As a result of the intervention, the participants realised how little control they had over their patient's data.

Reconsidering DHIS2

An unexpected finding of the researchers was that the deployment of the VODAN infrastructure triggered a reconsideration of the DHIS2, which was the system in use during the intervention. The following comments were received in a reflection on DHIS2.

Lack of local data storage of data generated in the health facility:

The participants understood that DHIS2 can be configured to store data locally, primarily within the country or region/district) where the data is generated. In principle this supports the doctrine of data localisation, ensuring that sensitive health data remains within the geographical boundaries of the country as localisation at the facility level is concerned, this is largely unavailable. However, since DHIS2 does not operate based on a FAIR-OLR premise, the data-visiting in localised repositories would require difficult data-mapping exercises, and it seemed unlikely that interoperability would be retained in the current format. Therefore, none of the health facilities was using the possibility to localise the data, because it did not appear to participants as serving any functional purpose.

Difficulties in using the data generated at the health facility within the health facility

Difficulties concerning the deployment approaches of creating infacility repositories for DHIS2 data management contributed further to a sense of helplessness concerning the complexity of choosing this option. Since DHIS2 uses an online deployment approach raised the issue of in-country server hosting and app management which in most cases is applied as internal hosting within the Ministry of Health (MOH) or at a government-operated/sanctioned data centre. An offline deployment style also presents significant challenges around advanced hardware requirements, accessibility, and maintenance, data exchange barriers as well as localised human capital capable of handling bug fixing and upgrades.

Lack of patient-centred data curation

A further concern, highlighted in the conversations following the FAIR-OLR-based intervention, is that DHIS2 is not specifically designed as a patient-centred system and its primary functionality serves public health actions related to disease surveillance, programme monitoring, and reporting on health indicators. As a tool for the collection, validation, analysis, and presentation of both individual and aggregate data, it provides the capability to authorised users to access facility-level data through the built-in pivot table tool and Geographic Information System (GIS) features as well as allowing users to compare data across facilities and districts and to view trends in data over time. However, the data does not inform clinicians on individual patient data analytics, as an EMR does, nor does it provide interoperability for analytics across the EMR, as data based on FAIR-OLR principles can generate.

Bias of data use at higher echelons of the health system

In the reality of the health service practice, often the analytical capabilities are limited to only the higher levels of the national health reporting hierarchy. These serve to aggregate data for reporting on programme outcomes and this has administrative relevance. However, this system of offering this capability to the higher level (in the reality of how DHIS2 is used), is not supporting the health service delivery by clinical physicians and health workers.

Concerns about data quality

The participants reported an ongoing concern on the DHIS2 data quality. Data quality issues also remain a significant problem with regards to DHIS2. These issues include incomplete, inconsistent, and duplicate data that may require varied data-cleaning strategies. The issues may be multifactorial arising from human error in entry, system errors, poor recording, and poor data collection systems, which if unremedied can distort the analysis derived from the data and can lead to misleading results and interpretations.

Lack of recognition of data concerning patients as data subjects

A further concern that was raised was that patients are not recognised as data subjects, and concerns of how this would translate into them having ownership or control over the handling of their health data.

Concerns regarding the DHIS2 system are closely tied to the need for a robust data localisation strategy that ensures health facilities maintain control over patient data handling. Such a strategy should establish clear mechanisms for patients to exercise authority over permissions, specifying who can access their data and for what purposes. Ethical considerations emphasise the minimisation of data access, as broad approvals for general access fail to provide patients with genuine control over the granting of permissions.

The concerns that were expressed highlight issues related to privacy preservation, particularly when disparate digital health data points are interconnected. Without appropriate safeguards, such linkages can lead to the easy identification of private identities. This potential for future patient identification underscores the necessity for stringent privacy controls to prevent misuse and ensure data security on any modus operandi for data-sharing, including aggregate data.

Due to the rapid evolution of digitisation of patient data, including aggregate data, the patients' rights, it was argued, should be central to any system that re-uses their data, including in aggregate form. Any system that reuses data derived from patients should entail granting and revoking access, anonymisation as well and profound privacy preservation measures when data is reused for clinical research requests with consent from management and patients with the specific health facility.

As far as upgrades of patient data recording systems, it was suggested by the health facility administrators that interventions are necessary to push the sector closer to enacting data ownership policies and to come to agreements that emphasised the responsibility of the clinic over the handling of the health data.

It was acknowledged that this ideal system may not be achievable overnight, but a roadmap that provides a pipeline for this to become a reality must continue to be explored as is being facilitated by VODAN Africa and other groups. The intervention by VODAN-Africa was timely in giving a necessary pipeline through which the idea that patient data could be controlled and owned in residence and locality of production, seems a realistic option.

Towards an African Health Data Space

Upon the positive assessment of the VODAN-Africa FAIR-OLR intervention, the Kenya implementation team engaged in a consideration as to why data needs to remain in residence of its production. The shortcomings of DHIS2 have prompted the Kenyan team to consider what alternatives are available. Based on the outcomes obtained regarding the feasibility of data held in location, the Kenya team concluded this was feasible, and that advocacy for data sovereignty in Africa is necessary. The innovation of digital health solutions with FAIR-OLR principles is expected to improve health outcomes in Kenya.

According to the deliberations in the Kenya team, the following aims must steer future developments in health data architectures:

- Bringing an end to the lack of data ownership on the African continent and the migration of patient data away from care providers and data subjects.
- Overcoming the lack of data use and reuse, including for quality of care at the level of health facility.
- Legislating to put an end to poverty-based bias in health data from Africans which leads to further exclusion of people

living in poverty, who are poorly represented in the development of digital AI-based health tooling innovation.

- Developing feasible and concrete pathways to resolve the problem of inadequacy and lack of representation as well as the poverty-based bias of data from Africa in global health analytics, impeding pandemic preparedness and impeding a concern for neglected diseases.
- Strengthening regulation to avoid the lack of interoperability of data for the use of health care providers, due to vertical digital upstream solutions that do not integrate at the level of point of care and preventative medicine.
- The expansion of expertise which will bring in data stewards, and unemployed youth and support the government's concern for reaching in Technical and Vocational Education Training (TVET) in data infrastructure development and knowledge transfer.

The Kenya team concluded that the establishment of an Africa Health Data Space is the best way to respond to these urgent needs. According to the Kenya team, the Africa Health Data Space will be the next concrete and achievable step that should be realised to improve the health infrastructure in Africa. So far health facilities from eight countries in Africa have joined the call to create an Africa Health Data Space.



Figure 2. Patient Data reposited in Health Facilities, visitable under permission for computations carried out in the Health Data Space

Source: Curation of federated patient data, VODAN Federated Data Space presentation https://doi.org/10.1016/B978-0-443-13897-3.00013-8 The Kenya Team has concluded it will join the development of the concept of the Africa Health Data Space as a transnational space that connects data curated as FAIR in an ethical African health data quality of care and surveillance. Based on the experiences, the team believes the Africa Health Data Space can serve the entire population, especially as it can easily involve vulnerable populations.

The Africa Health Data Space is inspired by the aspiration of the development of a European Health Data Space which aims to regulate the transmission and sharing of health data across the EU. According to the Kenya team, there is no reason why Africa should not develop its patient health data management to the same standards, particularly since the implementation in Kenya was successful. It considers that it is only logical that the Africa Health Data Space will have a similar role for Africa.

To unleash the full potential of health data for individuals and society in Africa, a Health Data Space should aim to ensure patient data is safe within health facilities, can be visited under clear permission for health research, and will reduce healthcare costs while the quality data produced in Africa following FAIR-OLR principles can add new value to the health sector in Africa. This will decrease the independence of the health sector from external donors. It will contribute to data sovereignty, strengthening the role of the Kenyan government in realising its aims to achieve universal access to health, and it can balance the sovereignty of the country, communities, entities, such as health facilities, and even individual patients, since the permission workflow can have granular variation to meet any concerns, in line with regulatory frameworks.

The African Health Data Space will lay the foundation to ensure that the services are contributing to better-informed health care. Health facilities will benefit from the use of data in the health facilities and the data analytics across the facilities. The objective is to create a better representation of patients in remote and vulnerable settings. It stimulates a data space that is set up with inclusiveness (including data from facilities in remote and vulnerable settings).

Ecosystem APIs								
Intelligence		User Experience						
Infrastructure services			Generic Data Capabilities - services					
Data storage and hosting		Federated data management						
Hosting & operations	Hybrid in location & local cloud		Regulatory Compliance, Privacy & Access Control	Data Sharing & interoperability	Digital IT & Customer service			
Data layer-single copy, machine actionable data creation								
Machine-actionable and semantically linked clinical, operational & research data at point of creation (produced for instance : in point of care, point of service, or at research data collection)								
	Generic connective ca Int rastructure services Data storage Hosting & operations Data layer-single copy, Machine-acti	Generic connective capabilities - use intelligence rastructure services Data storage and hosting Hosting & operations Hybrid in location Data layer-single copy, machine action Machine-actionable and semantic	Generic connective capabilities - users Ecosys Intelligence Tastructure services Data storage and hosting Hosting & operations Hybrid in location & local cloud Data layer-single copy, machine actionable data c Machine-actionable and semantically linked clinic (produced for instance in part of care, p	Generic connective capabilities - users Ecosystem APIs Intelligence Trastructure services Data storage and hosting Hybrid in location & local cloud Augulatory Compliance, Privacy & Access Control Data layer-single copy, machine actionable data creation Machine-actionable and semantically linked clinical, operational & research data sol point desvise, or a treasch data sol	Generic connective capabilities - users Ecosystem APIs Intelligence User Experience rastructure services Generic Data Capabilities - service Data storage and hosting Federated data managemen Hosting & operations Hybrid in location & local cloud Data layer-single copy, machine actionable data creation Data research data at point of creator for stores: in point of care, point of at research data collection Machine-actionable and semantically linked clinical, or start research data collection Start collection			

Figure 3. VODAN architecture of a Federated Health Data Space

An African Health Data Space is based on health data curated as Findable, Accessible (under well-defined VODAN-Africa conditions), Interoperable, and Re-usable (FAIR) that is machineactionable and creates a space for strong high quality and ethical data for analytics, with the following characteristics that are better adapted to patients in these settings. This will ensure that:

- Data can reside in the health facility where the data is produced (just as the patient records do), or held under the control of the facility.
- Data is useable for analytics within the health facility and can contribute to quality health services at the point of care.
- Data can be visited for de-identified computational analytics across health facilities and across borders through algorithmic data visiting, contributing to studies for improved treatments, pharmacovigilance and clinical studies.
- The creation of an inclusive data pipeline across larger and smaller areas and facilities in connected and remote areas which will increase the representativeness of the data, remove poverty-based bias, and assist in pandemic preparedness.
- The creation of interoperable health data will increase the relevance of digital health innovations and assist in the horizontal integration of all of these innovations.

The technical experts of the Kenya team have observed that there are various ways proposed to realise this space through digital innovations that are coming up, and that this will be a source for a new generation of economic opportunity. The Kenya chapter of VODAN-Africa concluded that it should support this as a conduit for the channelling of support to local universities in Africa and help build the expertise necessary to create and build relevant ethical and locally owned data infrastructures.

Discussion

The VODAN-Africa approach showed the curation of comprehensive data that were supportive of Kenya government policy on the interpretation of Sustainable Development Goal (SDG) 3 within the wider health sector. A case in point is the need to identify a proper health infrastructure tool that would store data within all hospitals to strengthen the Kenyan capacity for research, vaccine and medicine development, and patient treatment.

This study has analysed that the continent of Africa will no longer be a spectator excluded from representation and will be strongly represented at the global health level. Without data being curated at its point of production most developing countries, would continue in their poverty perpetuity. Africa is now ready to lead in the emerging tech community. It means that growth in data intelligence should open opportunities for innovations that can help developing countries dig into this untapped healthcare economic empowerment of its unemployed youth.

This research has validated fundamental points by challenging existing paradigms on value creation for the health sector. The findings by the Kenya team of VODAN-Africa show that developing countries have the potential to have a competitive advantage in digital health data production and sharing with the international community. By controlling their digital health data, the shift in the paradigm of economic development in countries of Africa and Asia has just started, where now, the value of health data can be invested in health services and exchanged for money as a resource owned by the health facilities who produce and curate the data.

Conclusion

This study explored the findings of an investigation into clinical patient data stewardship, approached through the lens of data sovereignty. The study was implemented in Kenya.

Data sovereignty denotes the principle that data must comply with the laws and governance structures of the country in which it is collected or stored. This ensures that the control, access, and use of data is aligned with the regulatory framework in the country and related to communities and entities concerned in a workflow. It underscores the authority of nations, communities and/or entities to regulate data within jurisdiction, particularly concerning issues such as cross-border data flows, data privacy, and the management of digital infrastructure.

VODAN-Africa is leading the advocacy for the principle of data ownership, which asserts that personal data should remain the property of the data subject. This data is then managed by the data producer (health facility) as a fundamental and non-negotiable principle. This raises an essential question: how are African countries preparing to maintain patient data residency while contributing to future health research initiatives?

This study, conducted by the Kenya team of VODAN Africa, highlights the critical role of patient data stewardship and health data handling in ensuring data ownership as a foundational principle for access and control. This necessitates the use of semantic machineactionable metadata within repositories located at the point of data production. The preliminary findings outlined this is feasible, and it also offered awareness of the limitations of current systems in place in Kenya, such as DHIS2.

While data ownership may vary across countries due to differing regulations, the researchers advocate that ultimate ownership of personal health records should rest with the data subject and the health facility where the data is produced, ensuring consent-based reuse for purposes such as research or vaccine production.

The research resulted in the following proposals for affirmative action to build an inclusive, equitable, and effective health data ecosystem:

• The establishment of frameworks to guarantee patient data ownership on the African continent, ensuring that patient data remains under the control of care providers.

- The promotion of systems and practices that enable the effective use and reuse of patient data to improve the quality of care at health facilities.
- The enactment of legislation to ensure the inclusion of people living in poverty in health data and analytics, ensuring equitable representation in the development of AI-based digital health tools.
- The creation of actionable and sustainable strategies to address representation gaps, and poverty-based biases in African health data, enabling its effective use in global health analytics, surveillance, pharmacovigilance, clinical studies and pandemic preparedness, including on maternal health, and promoting a focus on neglected diseases.
- Implementation of robust regulatory measures to promote patient data interoperability, ensuring integration of data visualisation and decision-making support at the point of care and within a priority of prevention and avoiding siloed digital solutions.

By taking control of digital health data, Kenya is initiating a paradigm shift. Managed under the concept of data sovereignty, health data, is now recognised as a valuable resource, which can be invested in enhancing health services and valued as an asset owned by the health facilities that produce and curate it for the benefit in Kenya and of the African continent.

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Authors' Contributions

Reginald Nalugala conceptualised the first draft, he was the leader of the research in Kenya and coordinated the research group. He edited subsequent versions of the chapter. Putu Hadi Purnama Jati was a co-lead of the research carried out in Kenya and conducted interviews and gave overall research support. He edited the chapter. Samson Yohannes was the technical lead of the research project in Kenya, and engineering lead, and responsible for technical developments and deployments that were tested in this research. He provided text for this chapter and gave comments to all drafts. Maxwell Omare, Jacinta Wairimu, Charles Kahiro, William Nandwa, Seth Okeyo, Dennis Kinoti, were responsible to guide and conduct part of the implementation of the research. Aliya Aktau provided leadership support on the data mapping of the Kenya patient data Albert Mulingwa, provided general comments as a medical expert, Mirjam Van Reisen edited various versions of the chapter and provided suggestions.

Ethical Considerations

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