



FINDINGS REPORT

MHEALTH INTERNATIONAL WEBINAR ON THE REGULATION OF DATA IN SUB-SAHARAN AFRICA

South Africa, 29 June 2021



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BACKGROUND

On 29 June 2021, Dr Sharifah Sekalala of the University of Warwick, UK supported by the Wellcome Trust, and in collaboration with the University of Nairobi, Kenya and the University of the Witwatersrand, South Africa, hosted the second event in an international webinar series to explore with government regulators, public health researchers, medical licensing boards and app innovators/users their perceptions of the regulatory problems of health apps, particularly within the Sub-Saharan African context, with a view to produce a public policy paper that evidences the problem and identifies possible solutions. The webinar was part of a larger project on mHealth apps that seeks to map the strategies currently in use to protect data subjects' privacy in Kenya, Uganda and South Africa.

OVERVIEW

The webinar was attended by participants from, Kenya, Uganda and South Africa. The keynote presentation, from Professor Tom Kariuki, was on *Priority Themes in the Governance of Health Data in Africa*, and there were also three plenary presentations entitled: *'The Promises and Pitfalls of Health Apps in Sub Saharan Africa'*, *'Embracing 4IR to Ensure Safe and Secure Digital Data Regime in mHealth Applications'*, and *'Comparative Overview of Regulatory Frameworks for Health Data Migration in Kenya, Uganda and South Africa'*.

Panel discussions covered the following topics:

- Setting the Agenda for Transnational Regulation of Health data migration in Sub-Saharan Africa;
- Co-development of Regulatory Tools; and
- Towards Equitable Frameworks for Regulating Health Data Migration.

CONTRIBUTORS

PROJECT FACILITATORS AND PLENARY PRESENTERS



Dr Sharifah Sekalala, Associate Professor of Law, University of Warwick

Sharifah is an interdisciplinary researcher working at the intersection of international law, public policy, and global health. Sharifah holds a PhD in Law from the University of Warwick, an LLM in Public International Law from the University of Nottingham, and an LLB Hons from Makerere University, Uganda; she was called to the Ugandan Bar in 2005. Sharifah Sekalala teaches Global Health Law, Law and Ethics, and she has contributed to Public Health modules in Warwick Medical School. She also teaches Tort Law.



Professor Pamela Andanda, University of the Witwatersrand

Pamela teaches Intellectual Property Law and Research Methodology. Her research interests are in the areas of intellectual property, biotechnology, health law, bioethics, policy analysis and governance of biomedical research. She was a member of the European Commission's Expert Group on Global Governance of Science, strategic advisory committee member of UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, and executive member of Ethics, Law and Human Rights Working Group of the African AIDS Vaccine Programme. She regularly acts as an expert and evaluator in the Ethics Review procedure of the European Commission and EDCTP. Pamela is a member of the UNESCO's International Bioethics Committee, the African Academy of Sciences - Data and Biospecimen Governance Committee, Academy of Science of South Africa (ASSAf) Standing Committee on Biosafety and Biosecurity, the Ethics Advisory Council of the International COVID-19 Data Alliance (ICODA), and she chairs Wits University's advisory committee on ethics.



Professor Bitange Ndemo, Professor of Entrepreneurship, University of Nairobi

Bitange's research centres on the link between information and communication technologies (ICTs) and small and medium enterprises, with emphasis on how ICTs influence economic development in Africa. Bitange chaired the Kenya Distributed Ledgers and Artificial Intelligence Taskforce that developed the country's a road map for digital transformation. He is an advisor and board member of Safaricom (a leading telecommunication company in Africa), a member of both OECD Expert Panel for Blockchain, and World Economic Forum Global Blockchain Council. Formerly Permanent Secretary of Kenya's Ministry of Information and Communication, Bitange has also been a senior advisor to UN's Global Pulse (Big Data initiatives) and the UNCDF's Better than Cash Alliance and UNICEF's Innovation Council.



Dr Ben Mkalama, University of Nairobi

Ben undertakes scholarly research in innovation, digitisation, economics and enterprise development. A business consultant with over 25 years of senior leadership and management positions with international financial and local organisations in Africa, Ben is also a part time lecturer at the University of Nairobi, researching entrepreneurship and digital innovations with an emphasis on SMEs. Ben has a PhD in Business Administration from the University of Nairobi, MSc degree in Agricultural Economics from the University of Oxford, BSc degree in Agricultural Economics from Egerton University, Kenya.

WEBINAR MODERATOR



Larisha Bedhesi, University of the Witwatersrand

Larisha is a doctoral researcher in the School of Law, University of the Witwatersrand and practises law as a member of the Johannesburg Bar.

KEYNOTE SPEAKER: PRIORITY THEMES IN THE GOVERNANCE OF HEALTH DATA IN AFRICA



Professor Tom Kariuki, Director of Programmes at The African Academy of Sciences

Tom leads the Alliance for Accelerating Excellence in Science in Africa (AESA Platform), which was launched in 2015 by the AAS and the New Partnership for Africa's Development Agency (now known as the African Union Development Agency). An internationally recognised immunologist, Kariuki leads the Academy's programmatic activities to accelerate world-class research, foster innovation, and promote scientific leadership on the continent. He oversees the funding of research, development and commercialisation of novel, high-impact STI solutions for the continent, and is cultivating strategic partnerships with academic institutions, governments and industry globally to transform Africa's future through science-led, knowledge-based economies.

PANEL SPEAKERS: SETTING THE AGENDA FOR TRANSNATIONAL REGULATION OF HEALTH DATA MIGRATION IN SUB-SAHARAN AFRICA



Siobhan Green, Digital and Data Governance and Transformation Portfolio Manager at IMC Worldwide

Siobhan is a digital development professional and data social scientist, with expertise in digital inclusion, data ethics, and responsible data, Siobhan is a managing associate at IMC Worldwide, Lead of Global Digital and Data Governance and Transformation practice. She has been working with various countries, Kenya, Uganda, Zimbabwe, Zambia to look at how data can be used for decision making including the use of mHealth tools.



Dr Nicki Tiffin, Associate Professor at CIDRI-Africa/Computational Biology Division, University of Cape Town

Nicki holds a PhD in molecular oncology at the University of London and a postdoctoral fellowship in endocrinology research at UCSF. She focused on computational approaches to disease gene identification and the genetics of disease in African populations and addressed ethical issues relating to genomic studies undertaken in African populations. Nicki holds a Masters in Public Health

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(Epidemiology), and worked in the field of health informatics and data governance at the Centre for Infectious Disease Epidemiology and Research (CIDER), contributing to the development of the Provincial Health Data Centre.

PANEL SPEAKERS: CO-DEVELOPMENT OF REGULATORY TOOLS



Eunice Namirembe, Innovation Specialist at Kampala Capital City Authority

Eunice is based in Kampala and works with the team at the Innovations for WASH in Urban Settings Bootcamp to define problems and needs, and conduct assumption-mapping. Eunice is also Country Director at Text to Change, a mobile for development organization which designs and implements mobile for development programs around Africa. She holds a Bachelor's Degree in Economics and Statistics from Makerere University and has over eight years of experience in formulating and implementing ICT for development programmes in Uganda and Africa.



Martin Weiss, Lead Solutions Engineer at Jembi Health Systems

As well as being Lead Solutions Engineer at Jembi Health Systems, Martin also undertakes research in Public Health Information Systems, and recently published 'Blockchain as an enabler for public mHealth solutions in South Africa'. Jembi Health Systems is an African not-for-profit organisation improving global health by developing and improving information systems, growing partnerships and building local capacity, with a focus on developing countries.

PANEL SPEAKERS: TOWARDS EQUITABLE FRAMEWORKS FOR REGULATING HEALTH DATA MIGRATION



Dr Harriet Etheredge, Ethics and Regulatory at Wits Donald Gordon Medical Centre and Wits Department of Internal Medicine

Harriet is a medical bioethicist and health communication specialist based in Johannesburg, South Africa. She shares her wide-ranging expertise across a spectrum of bioethics topics, including research ethics and health communication. Harriet is a Co-Chair of the Wits Human Research Ethics Committee (Medical) and she also serves on the South African Medical Research Council Human Research Ethics Committee.



Moses Mulumba, Executive Director, The Center for Health, Human Rights and Development (CEHURD)

Moses is Head of CEHURD Uganda, and is a lawyer with special interest in international human rights, global health and sexual reproductive health and rights. He has a Bachelor of Laws (LLB), Post Graduate Bar qualification, Master of Laws and Master of Philosophy in health sciences. Mulumba has widely researched, published and taught in the various areas of global health and international human rights.

THE AFRICAN CONTEXT FOR DATA COLLECTION, SHARING AND USE

Africa has a high disease burden; this remains one of the major areas of priority for the continent. There are also challenges around food, poverty, urbanisation, weak health systems, climate, and displacement/migration. All these issues set the context for how scientific research is positioned for Africa, and also how institutions who are driving science and innovation engage—both across the continent and at the global level.

To date, there has been a lot of work done on areas such as maternal and neonatal health, food security, epidemic preparedness, and the specific SDGs that target these and other areas for human development. There is a growing focus on governance, and on gender, mental health and the Fourth Industrial Revolution agenda. The engagement, research and production for all these areas is being driven by data. For every level of every organisation there is a journey to consider in how such data is collected, shared and used.

WHICH PROBLEMS CONCERNING DATA MIGRATION OF HEALTH APPS IDENTIFIED IN THIS PROJECT ARE THE MOST WORTHY OF FURTHER EXPLORATION?

Data privacy regulation is increasing. For instance, Kenya, Uganda and South Africa all have new data regulation acts attempting to cover the challenges associated with privacy violation, and how states/people should protect themselves, although in practice this is not very easy.

In many cases, while the state might want to make changes, it may be very limited in its ability to do so. That's something that we want to explore much further in the project looking specifically at the contexts of Uganda, Kenya and South Africa.

Typology of apps

A scoping analysis has created a typology of the kinds of apps that we see in the project regions; each of these app types have different challenges:

1. **Digital Health Surveillance Applications:** produced by either states/organisations and researchers mainly in the form of epidemiological data. e.g. COVID-9 tracing apps are running in all three countries. These apps may share health data from Sub-Saharan African countries to researchers in the Global North. In some cases, there may also be the potential for commercialisation of data. For example, a potential US\$45 million partnership agreement between the World Food Programme and Palantir would allow Palantir to exploit data from 90 million people.
2. **Merchandise Applications:** rendering goods and services, e.g., diagnostics and health services. For instance, in Uganda, the Dokitari app helps people to access health services at home from experienced primary care doctors. The data from many of these apps is valuable if it is commercialised and integrated into bigger data sets.
3. **Lifestyle Applications:** embedded health-tracking apps, which are included in day-to-day items, such as phones and devices such as watches and trackers. Many of these contain third-party apps, which may lead to the migration of data. It is impossible to know the scale of these apps, as for many of these countries, this information is

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considered proprietary and even states themselves often have very little knowledge of how these apps operate.

4. **Connected Network Applications:** some digital tools may be linked to health outcomes. Although the apps themselves are not health apps, they are leveraging popular apps in order to provide health services. For example, digital IDs, transport systems, and communication systems. Again, this has increased during the COVID-19 crisis. The project highlighted attempts to link digital IDs to vaccine access, and mobile phone companies using their apps to deliver public health messaging.

Tackling the ethical design of health application development requires consideration and input from a broad spectrum of stakeholders: health app investors, health app developers, insurance companies, health professionals, civil society, and other people in the technology space.

The proliferation of health apps

The benefits

Big data: health apps move data from third party users to third party actors, sometimes over different jurisdictions—this supports collecting more data to find solutions to problems, and allows progress in areas where a lot of analytics are required to move forward, to support data driven policymaking/development (e.g., infectious disease—for example, in COVID-19, where track and trace data has mapped the way in which the COVID-19 virus mutates and moves, and how we react to it—and in food security, poverty, urbanisation, weak health systems and displacement/migration.) Big data is allowing scientific priorities to advance through partnerships and collaborations across the continent of Africa. Sharing data and science globally is now critical to tackling the climate emergency. In moving forward, areas such as gender, mental health, and the Fourth Industrial Revolution agenda will require attention.

Working smart: health apps can also make the delivery of services easier: making efficiencies in stretching resources further and helping to target and map vulnerable populations—these apps have been pivotal in addressing the health needs of vulnerable populations, for example, sexual reproductive rights for young people, or victims of sexual violence.

The challenges

Data collection parameters: data exists in a dynamic environment—at the outset, investors/developers may not have a clear idea of how much/what type of data they want. This creates incentives to collect huge amounts of data.

Data handling parameters: app investors don't always have a clear idea of what the end-product is likely to be. However, many investors are collecting data on the basis that they will be able to profit from it in the future.

Data sharing/storage: data moves across borders for a variety of reasons, including back up storage. A major constraint is reliance on external servers to back up data; a lot of app data is stored in third countries, primarily in the Global North, due to capacity. Once the data is

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outside the jurisdiction of African states, in many cases they lose all control and oversight over the ways in which it can be used. For example, in data collection challenges in another sector, the Supreme Court of Kenya asked to see some of the electronic logs from the Kenyan election, but the judges were simply told that the servers were in France, and therefore they could not have access—entirely frustrating judicial oversight.

Data repurposing: cross-border data can be repurposed and used, in violation of data users' privacy—it may later come back to harm users, because insurers may refuse to insure them, or data may be used as the basis of discrimination, users may later be denied health services etc.

Data ownership: the primary owner is the person who collects the data, which is then acquired and processed; it may be then used for a secondary purpose. There are various views on what happens next—does the data ownership sit with the person who finances the collection of the data, or the primary or secondary collector?

Spotting the gaps: sometimes data needs to be tracked for security purposes, but in other cases this is unnecessary, and the design of the app's data collection is illegal—detailed guidance would be helpful for app developers, who can then build in alignment with regulatory areas.

Data transfer: it is difficult to ensure privacy of people once their data is moved to third party actors—whether they be states, private entities or international organisations. All of these actors can create ethical conflicts when they access private data. For example:

- **State actors:** some behaviours of people in key populations (including young people, women and girls, people living with HIV/TB/STIs, sex workers, men who have sex with men, the LGBTI community, refugees and internally displaced persons, and people who use drugs) are illegal, and these groups can be highly stigmatised. Is this data that should be in the hands of some governments? Donor-funded NGOs/private sector companies may not necessarily have very strong regulatory infrastructures; are they able to protect the privacy of the data subjects against states?
- **Private actors:** in Uganda earlier this year, a company called Safe Border (a commercial company that provides transport services on motorbikes) launched an 'add on' to an existing health app, to help app-users locate nearby pharmacies and health services, in conjunction with Marie Stopes International. This data was being shared with a third-party data user in the USA, CleverTap, which was doing behaviour analysis without users' consent. When referred to the regulator, Set Border merely changed its terms and conditions in a way that users had no choice but to consent to the new data-sharing agreements.

User incentives: a lot of data is captured and shared on free applications (WhatsApp, Gmail, Facebook, etc.). While these apps are free to use, users are usually paying in the form of their

“When I worked with key populations, they are not necessarily worried about international hackers, but they are worried about law enforcement, and members of their own community finding out that they are a member of a key population.”

Dr Nicky Tiffin

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data. There is a trade-off being made to access tools that are now considered essential; the incentive to share data may become overwhelming.

Lack of informed consent: currently, consent is a complex area and there are so many terms and conditions framed in opaque ways that users are unable to make properly informed choices. Users may feel a strong incentive to agree to data-sharing, but it may be also that they are unaware of the implications of such agreement.

Multiple risks in privacy violations: when considering data privacy and consent, there are a range of different risk factors, at international, national, local and community levels. Vulnerable populations are at risk of palpable socioeconomic harms when their data is shared.

Trust failures affect behaviours: given the risks involved, members of vulnerable groups use multiple strategies to avoid exposure; e.g., false names, using someone else's ID, SIM cards registered to a proxy, travelling even across borders to access health. These strategies have an impact on the usefulness of the data collected.

HOW CAN EQUITABLE FRAMEWORKS INFORM THE DEVELOPMENT OF IMPROVED REGULATION FOR HEALTH DATA MIGRATION IN SUB-SAHARAN AFRICA?

In order to continue to move forward with all of the gains to be made in health data collection, there must be fair access to data—responsible data access, sharing, and use—which also addresses privacy-related issues.

Proactive health data management by government (such as that which may be found in the Western Cape) with stringent processes and oversight for launching health apps can be really helpful. This approach can provide some roadblocks to getting useful apps into use—but these frustrations are worth it, in order to have apps that are fit for purpose out there in the community.

Technology development is ahead of regulation

The new 'Wild West'

"You can do whatever you want in some places because the regulatory infrastructure hasn't been there... How do you handle that?"

Siobhan Green

A lot of investment is happening in the private and donor sectors in new technologies (drones, the Internet of Things, GIS, Fourth Industrial Revolution), but the regulatory space is not keeping up—in places being as much as a decade behind the technology.

When examining data legislation drawn up by legal experts (for example, South Africa's Protection of Personal Information Act 2013 (POPIA) and the Ugandan Data Protection and Privacy Act 2019), from a technologist's perspective, there are gaps in the details (such as in addressing needs to track data for security purposes) that experts in app development could help to address.

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Similarly, practical ‘checklist’ style guidelines could be created, advising both app developers, and legislators, that uses technical expertise to work in conjunction with legal expertise—that informs the law and app development about the ethical and legal requirements of designing functional health apps. This collaboration can produce a virtuous circle of expertise.

Researchers, NGOs and CSOs—working with good intentions—don’t always understand the legalities of the tools they are using, such as data scraping to create disease profiles for a region, for example, are unaware that their activity is infringing privacy rights, because the information appears to be available online. There is a clear requirement to translate legal regulatory requirements into practical guidance for all stakeholders—not just developers, but for users and policymakers.

Researchers nurture great ideas which can be built into an app—and there is a strong incentive to ignore the possibility that there are restrictions which would prevent them. For example, consider the COVID-19 app collecting clinical data in Africa, where data was hosted in Europe. Exporting identified clinical data without appropriate consents is illegal, but this obstacle was ignored/sidestepped in order to quickly produce an app perceived to be more important than the legal considerations of cross-border data storage. Addressing this philosophical/pragmatic position will require advocacy, clear communication of rules and regulations, and strong back up from the relevant authorities/governing bodies.

A good start would be by identifying where the processes are already working well: good data-use agreements, good local storage of data, and good adherence to laws. Working with health and thematic, and routine health data, POPIA-compliance is important. When this is not the case, learning what is working well and where sectors are complying can provide answers about to improve compliance generally.

Health Services and Health Apps: A Parallel Ecosystem

There is a tension and mismatch between health services providing health facilities and provision of health to the population, running alongside a parallel health data economy, using independently developed health apps, and research programmes facilitated through app-based and online-based services. These two ecosystems have never yet come back together, raising many problems of ethics and economics: missed opportunities for integrated data/analysis, data protection issues being run over roughshod, and research driven by special interests rather than public health needs, to name a few.

To counter this problem, we need to look at systems already in use, or at enrolling people into new systems through government-funded health facilities and services. The data should remain in the health service ecosystem and should be used for the better provision of health care.

In this way, Department of Health/health environment regulators can have oversight on whether apps are performing due diligence, have the right consents and appropriate border controls in terms of where the data goes.

When regulation is in place, how can it be enforced?

With regulation, monetary fines are considered the cost of doing business. Why change your behaviour when you can budget the fine into your expenses? The most effective approach to punitive consequences for data misuse seems to be to enforce custodial sentences at high levels of management; a financial penalty is not enough to enforce compliance, if the financial reward of selling/exploiting data is higher.

REGULATORY FRAMEWORKS GOVERNING THE MIGRATION OF HEALTH DATA IN KENYA, SOUTH AFRICA AND UGANDA

Below is a brief outline of the regulatory environment governing health data migration in the region—this is an emerging area which requires coordination and empowerment. The coordinating body '[Collaboration on International ICT Policy for East and Southern Africa](#)' has actively commented on some of the regulations covered here—a collaborative approach which builds confidence and allows for regional regulatory development.

Kenyan regulatory framework

The Kenyan Data Protection Act of 2019 explicitly states that it aims to give effect to the Constitution, it applies to data processing and data controllers or processors that are established both in country and outside of the country. Therefore, apps developers outside the country are actually covered under this particular provision (specifically section 4 of the Act), speaking to international movement or cross-border data transfer.

The Act also covers those processing data who are located beyond Kenya's geographical borders (sections 48-49): sufficient safeguards must be in place, and the data subject's consent must be obtained. This regulatory framework has pinned down a regime for all Kenyan data, even when it is handled out of the country.

Section 18 of the Act specifically targets the registration of processors or data collectors that process sensitive and huge volumes of data. This allows for an ethical guideline to be designed into a regulatory framework. Any person or organisation developing and introducing apps affecting citizens in Kenya is subject to oversight by some authority within the country. This is the key element missing in the South African and Ugandan frameworks.

A limiting factor of the Kenyan framework is the definition of 'health data'. It is actually limited to the healthcare context and does not cover the broader spectrum of apps that are collecting sensitive personal data, such as fitness apps—there is scope for further development on that definition.

Ugandan regulatory framework

The Uganda Constitution also includes a broad provision on privacy protection and the right to privacy. Uganda's Data Protection and Privacy Act 2019 protects data and privacy and applies to the processing of data within and outside Uganda, addressing transboundary aspects. Storing or processing data outside Ugandan borders requires, as a minimum, an

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equivalent framework—although critics have argued that this is somewhat general in comparison to the more cogent draft regulations in Kenya. Further regulation is required in this area: for example, covering who oversees the activities of these processors. Article 28 speaks to the need for adequate measures and appropriate safeguards, and this general guidance also needs to be unpacked further with greater detail; for example, an accreditation or registration process that also brings on board ‘ethics by design’, as in the Kenyan model.

South African regulatory framework

In a similar way, South Africa has a general right to privacy contained in its Constitution. The Protection of Personal Information Act 2013 specifically deals with the processing of health data. Section 26 prohibits health data processing unless it falls under the requirements listed in section 32 (healthcare and social services—which are broad categories and might benefit from further definition—and insurance, schools, educators, and medical schemes). This regulation also governs transborder flows of information, which includes provision for transborder processing (section 72), again requiring an equivalent level of protection in whichever country the data is moved to, and the consent of the data subject.

In South Africa, the focus on regulation is largely aimed at administrative processes, and an area for more development is support for educating and supporting the individual to give or withhold informed consent—there are approaches in Uganda and Kenya that could be instructive here.

How can regulatory tools be developed with participatory processes?

Given the fast pace of technological change and the varied actors involved in the design, application and regulation of health apps, how does regulation stay current and meaningful? And what role do multi-stakeholder partnerships have in the process?

Custodial responsibility for data—A new model of working

Data science in Africa must be driven by addressing the governance agenda, providing guidelines and practical accommodations for biospecimen data governance.

Considering the intrinsic values of the biospecimen data agenda, the best ethical practice and standards are those based on putting the participant’s interests first, and establishing social contracts that ensure protection for the rights of the patient. When it comes to dealing with sensitive data, particularly medical records or data, these social contracts can be upheld, or violated—thereby demolishing trust and confidence in an organisation or project.

“a paradigm shift from data ownership to custodial responsibility of the data”

Professor Tom Kariuki

By upholding the social contract, we move the research forward, and improve the ability to prevent disease or reduce health disparities by measuring disease, pathogens, exposure or even behaviour, and developing highly targeted programmes to improve health using data-driven decisions.

This is a critical area of focus over the coming years—to lay a foundation for using the data being mined in various laboratories and institutions across the continent—which can then position science within Africa towards precision medicine.

In the context of COVID-19, using this custodial responsibility lens to view the field of data collection has become very important. Access, regulatory ethics and regulatory issues, and even innovation and intellectual property rights are all aspects of the discussion, and in thinking about the future for genomic and precision medicine—how we govern biospecimens—this shift from community engagement and sharing information, to inclusion in discussion and decision-making is a priority.

There are well-embedded African values to protect the vulnerable and those who can be easily exploited, through:

- fostering research integrity and equity to ensure protection of privacy and confidentiality;
- ensuring responsible dissemination of findings and giving back to communities once we have been given the leeway to work with them; and
- continuous engagement, back and forth, to build better informed consent and respect for autonomy, integrity, upholding respect for privacy, and promoting equity etc.

Creating equitable partnerships involves getting people ‘in the room’—participating in the discussion—from the very beginning, to ensure strong oversight: equal partnerships between researchers and institutions, for stakeholder benefit sharing, and with strong legal frameworks in place where required.

LOOKING AT THE REGULATORY LANDSCAPE, HOW CAN WE ENSURE THAT WE HAVE EQUITY AND A PROCESS THAT CAN WORK FOR EVERYBODY?

“What is ethical is not necessarily legal, and what the law tells us to do is not necessarily ethical”

Dr Harriet Etheridge

In the African context, it is important to facilitate open science and data sharing as much as possible, because we have a population that has been so underrepresented historically. The data of the African population must be shared in order to facilitate participation and better health outcomes for the people. POPIA’s provisions for cross-border data transfers, and the proposed case-by-case assessment of data protection levels of other countries could potentially take years—if the General Data Protection Regulation (GDPR) process in Europe is any guide.

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This approach is legal, but it may hinder data sharing—so is it ethical and equitable? An equitable framework must be one that has leveraged every aspect of the legislation to find ways to facilitate what is ethical within that framework. There is a need for a dialogue about the best interests of the population and its representativity.

Innovation can be fragile, and regulatory oversight should not act as brake on development, but rather to create an enabling environment to advance research via internal oversight and policies, utilising global policies where helpful, to support innovation within an ethical framework.

Failure to prioritise equity in innovation-led development for health

A number of weaknesses were identified in the way innovation of emerging tech does not consider issues of equity, such as:

- energy in the African health context tends to be focused on finding solutions and fixing health systems—these approaches are embraced without any assessment of human rights and social impact, and so equitable issues are missed;
- innovation is embraced by the private sector, which becomes the lead team in developing these solutions—rarely, if ever, independently considering vulnerabilities and equity;
- those involved in developing the technological solutions are not working in or with government. The state—which should be regulating—becomes disempowered. Governments don't understand the solution, and they don't hire the right people to implement the solution;
- the state views data collection as a security issue and critical to national health—once it is framed as a security issue, equity concerns don't hold much weight in policymaking;
- NGOs involved in advocacy over equitable issues appear to have been reticent about data collection;

Public availability of data

Once data has been shared initially, and then makes its way somehow into the public domain, how then do we address responsible sharing? There needs to be a holistic conversation about data—from the time it is generated, to what then happens to it, and what it is used for—much more accessible to everyone: simplifying the terminology and giving the public more of a place at the table.

Responsible collecting, processing, storing, and sharing of data

In some donor projects, a safeguarding approach is that whoever is repurposing or using publicly available data must put in place measures when disseminating findings of that dataset to ensure that their outputs do not enhance vulnerabilities or put people in a light that is harmful to them. This 'ethics by design' approach takes responsibility for how we

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collect, access and process data—not waiting for a regulator to oversee you, but being human-facing in designing the work; thinking about the humans behind the datasets that you’re handling.

Consent is an ongoing process

When data is repurposed, what are the implications for the consent given for the original use of the data? In the regulatory frameworks examined earlier, for all three of Kenya, Uganda and South Africa, there is strong emphasis on initial consent—but equity calls for a continual process of involvement and understanding by the data subject on their data use. The data subject must be empowered to continue to voice their concerns, and agree or disagree to the proposed repurposed use of the data.

New tech

There are technologies that can support this process—for example, blockchain can be used to ensure consent for data—however, in considering the emergence of the Fourth Industrial Revolution, emerging tech (such as AI, blockchain, and big data analysis) is making a vast, and as yet not fully known, impact on our privacy.

AI is widely used in Africa. Whether or not a regulatory regime should be initiated for AI is still a contended point—we don’t know what kind of innovations are coming. We need to develop the capacity to enable us to understand how data has been processed and who has it.

What is falling through the cracks?

Using the regulatory frameworks of Kenya, Uganda and South Africa as case studies, we can consider the possibility that there are apps collecting health-related data but falling through the cracks in regulation. For example, a smart blood pressure app may not fall within the definitions of the Kenyan Data Protection Act, or the South African or Ugandan regulations or provisions—and yet, the data collected is health-related, and may be shared with healthcare providers.

Apps tracking sleep patterns are another example of a ‘grey area’ of data collection—reports have been generated from these apps making comparisons about the national sleep patterns of various countries: who wakes up earliest, which people sleep less—what’s the purpose of gathering such data? Process and practices around health apps need special attention, and call for a more robust regulatory framework which includes ethics by design in designing these apps, with empowered data subjects, regulators, developers and wider stakeholders.

“If you just talk about collection of physical or mental health-related data... what about fitness apps? That is a crack through which issues can arise...”

**Professor Pamela
Andanda**

The ‘Triple Helix’: Research, Private Sector and Government

Whilst collaboration is certainly in process, stronger alignment between the private and academic sectors would be beneficial. Academic innovation could be fuelled by activity in private industry—although commercial confidentiality/competitiveness tends to restrict information sharing.

There are significant challenges in the interactions between these three groups:

- driven by the need to perform, private sector research tends to out-compete academic research in terms of speed;
- it is a continual and significant challenge within the public health sector to find the right decision makers, which slows down innovation;
- donors are prepared to fund development for mHealth applications, but often government priorities are not aligned to the innovation/don't have the required capacity or funding streams/would be duplicating a similar project—and therefore after a pilot, there is no scope to scale up;
- private companies and donors tend to host data themselves—away from government servers—restricting access and oversight; thus, these apps don't meet existing regulation and data cannot be used for national purposes; and
- complexities in integrating new tech apps with legacy public health service platforms leads to inoperability and wasted opportunities, and is another reason for private donors / companies to refuse central data hosting.

AREAS TO CONSIDER FOR MOVING FORWARD

There are a number of areas to consider moving forward in order to improve data regulation in Sub-Saharan Africa:

- Can we work with stakeholders from government and the private sector, to explore partnerships/an MOU, based on government access to data for planning, and private sector opportunity to use the data? What are the ethical implications to consider in such an agreement?
- Can we theorise a space and approaches by which to tackle the ethical design of health application development, with consideration and input from a broad spectrum of stakeholders: health app investors, health app developers, insurance companies, health professionals, civil society, and other people in the technology space?
- Can we examine data legislation drawn up by legal experts (for example, POPIA and the Ugandan legislation), and working with technology experts, identify gaps in the details?
- Can we further identify where the regulatory processes are working already well (good data use agreements, good local storage of data, and good adherence to laws), and where sectors are complying, and from this learning, develop findings on how to improve compliance generally?
- Can we work with community groups and members of civil society to consider equitable frameworks, leveraging every aspect of legislation to find ways to facilitate what is ethical

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within that framework; facilitating a dialogue about the best interests of the population and its representativity?

- Can we facilitate the brokering of a holistic conversation about data—from the time it is generated, to what then happens to it, and what it is used for—increasing its accessibility, and building an ‘ethics by design’ approach of taking responsibility for how we collect, access and process data?

CONCLUSION

Being ‘human facing’ and thinking about the humans behind the data sets that are being handled will inevitably lead to more responsible conduct in the collection, storage, processing and use of data. Process and practices around health apps call for a more robust regulatory framework which includes ethics by design during app development. Data subjects, regulators, developers and wider stakeholders all need to be empowered to understand the issues that we have identified to not only appreciate how valuable their own personal data is, but to also understand what they are consenting to, where consent is obtained during data collection. Addressing weaknesses in the way innovation of emerging tech does not consider issues of equity will also lead to fairer outcomes for data subjects. It is clear from the rich discussions that took place during the webinar that continued collaboration and continuous collective thinking with stakeholders from diverse backgrounds around the issues identified will shape the solutions we need to improve the regulation of health data in Sub-Saharan Africa.