Title: Governance of Health Research in Four Eastern and Southern African countries

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Abstract

Background: Health research governance is an essential function of national health research systems. Yet many African countries have not developed strong health research governance structures and processes. This paper presents a comparative analysis of national health research governance in Botswana, Kenya, Uganda, and Zambia where health sciences research production is well established relative to some others in the region, and continues to grow. It aims to examine progress made and challenges faced in strengthening health research governance in these countries.

Methods: We collected data through document review and key informant interviews with a total of 80 participants including decision-makers, researchers, and funders across stakeholder institutions in the four countries. Data on health research governance were thematically coded for policies, legislation, regulation, and institutions and analyzed comparatively across the four national health research systems.

Results: All countries were found to be moving from using a research governance framework set by national science, technology and innovation policies to one that is more anchored in health research structures and policies within the health sectors. Kenya and Zambia have adopted health research legislation and policies, while Botswana and Uganda are in the process of developing the same. National level health research coordination and regulation is still hampered by inadequate financial and human resource capacities, which present a challenge for building strong health research governance institutions.

Conclusion: Building health research governance as a key pillar of national health research systems involve developing stronger governance institutions, strengthening health research legislation, increasing financing for governance processes, and improving human resource capacity in health research governance and management.

Key words: Health Sciences; Research; Science, Technology and Innovation; Governance; Africa
Introduction

Scholars and experts define research governance as an overarching responsibility of government to ensure effective oversight, coalition building, system design, accountability, and regulation of research for health in both the public and private sectors (1). The WHO Regional Office for Africa identifies research governance as a core function of a national health research system (NHRS), alongside others of developing and sustaining resources, financing, and producing and using research (1,2). The World Health Report 2013 emphasizes that every country needs an effective NHRS to set research priorities, develop research capacity, define norms and standards for research, and translate evidence into practice (3). In Africa, strengthening NHRS is particularly essential to generate research that would inform interventions as well as the new tools to tackle emerging and reemerging diseases (4).

Initiatives to improve NHRS in African countries generally focus on strengthening governance mechanisms, capacity building and funding (5–8). These are frequently short-term initiatives, lacking sustained engagement and support. Studies show that face challenges in health research governance for African countries including inadequate funding for governance activities, misalignment of research funding with national research priorities, lack of optimal coordination among stakeholders, and limited health research capacity (9–11). This paper comparatively examines what health research governance arrangements are in place in four Eastern and Southern African countries and discusses the lessons and challenges to strengthening them.

Strengthening national health research governance is a long-term investment that requires political commitment and sustainable action, which includes public institutions and policies to regulate and coordinate research institutions and research conduct. Robust and high-performing NHRS have typically integrated governance elements such as national research policies and regulations, institutional structures and systems to guide and support researchers, and funding mechanisms (12). For example, Yasamy et al. argue that lack of mental health research governance is one of the reasons for the inadequate research outputs from low-income countries in the past years (13). However, many low- and middle-income countries have
historically faced challenges in the development of research governance and management of these elements (9). This has been attributed to several factors, such as models of research capacity building that focus primarily on developing individual skills without the necessary national and institutional structures and systems to support the trained individuals or inadequate funding for research systems strengthening (14,15). In Africa, the Republic of South Africa stands out as having established well-regarded research governance structures and policy mechanisms, however, even countries that have established governance structures still face major challenges like inadequate human resource for health research and financial capacity that would enable the governance structures to function well in the countries (5,16).

A number of frameworks have been developed to support the design and evaluation of health research governance for NHRS, for research institutions, or for health research funding institutions. The frameworks of Pang et al. (17), WHO Afro NHRS Barometer (1), and the Council on Health Research for Development (COHRED)(18) are oriented towards needs of the national systems level, to describe and guide the governance of NHRS. Smits and Champagne (19) adapted their synthesis framework for the governance needs of health research funding institutions. Table 1 summarizes key features of these frameworks related to governance functions. Looking across these frameworks, some governance functions appear common, such as policies and legislation; strategic vision and planning; prioritization; coordination; management; and ethical regulation. The Smits and Champagne framework was the only one to include accountability and resourcing within governance functions, perhaps related to its intended use by research funding agencies. The Pang et al. framework is the only one to explicitly include monitoring and evaluation of the NHRS as governance functions, although this is implicit in the COHRED and Smits and Champagne frameworks embedded in management and system optimization.
Despite the existence of these frameworks, majority of which directly target national level research governance, there have been limited studies of national health research governance in African countries. According to the latest review of NHRS in Sub-Saharan Africa using the WHO African NHRS barometer published in 2019, African countries have made some progress on health research governance indicators in the 5 years since the previous assessment (2). More recently, results from a survey of WHO/AFRO member states specifically reported on which countries have the health research governance structures in place that are recommended by the WHO / AFRO regional strategy on research for health with data from 35/47 countries (20,21). But neither paper provides qualitative analysis of how these governance arrangements function to support NHRS, nor how they were decided and implemented in NHRS. However,
Sombie et al. provide some insights on how the West African Health Organization’s collaboration with COHRED influenced health research governance changes in four West African countries through a participatory project to build NHRS capacity (7).

Information on the existence of policies and institutions is insufficient on its own to inform us of how governance is developed and carried out within a NHRS. Most literature on research governance in African countries focuses instead on the organizational level, such as research institutions and universities (14,22,23). These studies have looked at governance elements such as presence of institutional research policies, strengthening research management offices, and development of ethics review systems as important functions of governance, while some examine specific research areas, such as governance of clinical trials and mental health research (13,24). The studies have found improvements in strengthening of ethics regulation systems and technical research capacity in the African countries with support from external experts. While various initiatives have focused on supporting African countries to strengthen their health research capacity in terms of human resources and skills development (2,25,26), the establishment of health research governance structures within NHRS does not appear to be advancing at a similar pace or in a similar manner across the continent (20).

In this paper we analyze and compare health research governance functions in Botswana, Kenya, Uganda, and Zambia to highlight insights and challenges in developing health research governance arrangements and structures. In the next section we describe some of the main pillars of NHRS across the countries to contextualize our comparison of the governance functions within these systems.

Country background

We selected the four cases from a larger research project examining health sciences research (HSR) capacity across the African continent because of their similar histories as former British colonies with shared influences on models and methods of governance in public sectors. Although some states are members of the same regional blocks and research hubs, they perform differently according to standardized metrics of national research performance and
capacity, and vary in numbers of public and private research institutions in their NHRS landscape. That said, they all have reasonably well-established health research activities and infrastructures compared to some other countries in the Region.

Acknowledging that Kenya and Uganda have a much larger population than Botswana and Zambia, there are similarities and differences in generally accepted per capita indicators of HSR performance (see Table 2). Botswana and Kenya produce more publications and first authored publications on health per million inhabitants relative to those of Uganda and Zambia. Botswana and Kenya also spend more on research and development (although gross expenditure on research and development, or GERD, is not specific to health) as a percentage of GDP and per capita. Botswana also has a notably higher number of clinical trials per million inhabitants than the other countries, supported by the strong history of HIV/AIDS research collaborations since the early days of the epidemic. While these indicators provide a static snapshot of the state inputs and outputs for HSR in the four countries, they do not capture the dynamic processes at play behind these metrics, nor the research governance underpinning knowledge production.

The institutional landscape of research institutions in each of the countries is also relevant to the exploration of governance functions because they are the settings for the training and conduct of HSR day to day. Table 3 lists the main public and private research institutions, universities, and centres of excellence for health research in each country. In all four countries, public universities conduct health research, and in some instances, the universities have also established autonomous institutes through international collaborations. Specialized research institutes, particularly in areas of infectious diseases, also constitute important knowledge producers in the institutional landscape. While Kenya and Uganda have similar health research and development portfolios, Zambia and Botswana are considered to have smaller research and development portfolios mainly focused on clinical trials for infectious diseases (27). Researchers in institutions from all four countries rely on international funding institutions to support health research, such as the European Commission, the Medical Research Council, the
National Institutes of Health, or the Wellcome Trust, which are among the top public funders of institutions of health research in the world (28) (see Table 4). However, the external research funding in the Kenya and Uganda from these agencies is comparatively higher than for Botswana and Zambia.

While these indicators provide a static snapshot of the state inputs and outputs for HSR in the four countries, they do not capture the dynamic processes at play behind these metrics, nor the research governance underpinning knowledge production. Studies of the governance functions of NHRS are needed to gain insight into the story behind performance to better understand the relationship between governance and health research capacity and output. This paper will draw on our qualitative work in these countries to explore the key governance factors that may help to explain the differences in performance, and through comparative analysis help draw lessons from their experiences in developing governance of NHRS and promoting HSR.

**Table 2: Indicators of health sciences research performance**

| Country | GDP (million, current US$, 2016) | Population (thousand, 2016) | GDP per capita (current US$, 2016) | # of publications per 1 million inhabitants | # of first author publications per 1 million inhabitants | # of trials per 1 million inhabitants | GERD as a % of GDP | GERD per capita (in current PPP$) | Total R&D personnel per million inhabitants (full-time equivalent [FTE]) |
|---------|---------------------------------|----------------------------|-----------------------------------|--------------------------------------------|----------------------------------------------------------|--------------------------------------|-------------------|----------------------------------|-------------------------------------------------------------|
| Botswana| 15,581                          | 2,250                      | 6,924                             | 784.80                                     | 335.96                                                   | 41.33                                | 0.53728           | 86.56169                         | 570                                                          |
| Kenya   | 70,529                          | 48,462                     | 1,455                             | 294.79                                     | 125.27                                                   | 13.19                                | 0.78578           | 19.06104                         | 1029                                                         |
| Uganda  | 24,079                          | 41,488                     | 580                               | 198.85                                     | 84.27                                                    | 15.69                                | 0.17043           | 2.93947                          | 42                                                           |
| Zambia  | 21,064                          | 16,591                     | 1,270                             | 166.23                                     | 51.89                                                    | 15.79                                | 0.27819           | 7.7016                           | 163                                                          |

*Source: World Bank*

**Table 4: Funding awarded to researchers in each country (2008-2017)**

| Country | Wellcome Trust | Medical Research Council | National Institutes of Health | European Commission |
|---------|----------------|--------------------------|------------------------------|---------------------|
| Botswana| 184,186.00     | -                        | 7,356,998.00                 |                     |
| Kenya   | 120,959,548.23 | 762,618.20               | 23,965,606.00                | 2,532,293.26        |
| Uganda  | 17,943,085.72  | 40,607,133.72            | 35,999,665.00                | 17,641.05           |
| Zambia  | 15,720.00      | -                        | 13,073,179.00                |                     |

*Source: Funding institutions’ websites. Figures reported in this table are 2017 U.S. dollars based on consumer price index adjustments to account for inflation.*
Methods

Data were collected in 2019 through a combination of document analysis and semi-structured interviews aiming to explore what has supported or challenged the strengthening of HSR capacity in African countries and to learn what could be done to improve it. We reviewed scientific and grey literature, policy documents, and websites of HSR institutions to identify the HSR actors and to inventory the governance mechanisms. A stakeholder mapping identified potential informants in key organizations who we invited to participate in the study, and additional names were identified through snowball sampling of key informants. Key informants were from government ministries (health, education and/or science), universities, regulatory bodies, national and international funders, public and private research institutions, international organizations, and non-governmental organizations involved in HSR. We conducted 80 interviews with key informants from institutions that fund, conduct, and/or govern HSR in the countries (Table 5). Interviews focused on participants’ experience in governing or regulating HSR, the facilitators and barriers or other factors that influence their work, policies and regulatory practices in place to support their work, and the challenges in improving HSR governance in their country.

| Participant Category          | Botswana | Kenya | Uganda | Zambia | Total |
|------------------------------|----------|-------|--------|--------|-------|
| Regulator/Decision Maker     | 1        | 4     | 6      | 5      | 16    |
| Researchers                  | 17       | 17    | 7      | 12     | 53    |
| Donors                       | 0        | 4     | 3      | 4      | 11    |
| **Total**                    | 18       | 25    | 16     | 21     | 80    |

Interview data were transcribed and imported into Dedoose software for thematic coding. The data were coded independently by each case researcher using a collaboratively developed coding framework based on the key themes for HSR development under categories of capacity, governance and context. For this paper we analysed elements related to health research governance from the data coded under the governance category of our larger coding framework, namely policy, regulation, legislation, and institutions. The definitions of our codes include key common functions of health research governance from the frameworks reviewed.
above such as policies and legislation; strategic vision and planning; prioritization; coordination; management; and ethical regulation.

Results
This section presents insights and challenges according to four themes in health research governance that we found in our interview data, which are part of those commonly identified core elements in the reviews of conceptual frameworks above. These included: legislation, coordination, regulation, and prioritization.

Prioritization of health sciences research
A first point emergent from the analysis is the importance of ensuring that health research aligns with local needs. Participants in all the countries raised a general concern that their governments had not done enough in shaping national health research priorities and consulting in-country stakeholders. Many informants mentioned that the HSR agenda is often imported from international organizations, or foreign research and funding institutions. This may distort research focus on external priorities when local needs may be different, as explained by a researcher from Kenya.

The global health agenda is decided at high-level, like WHO assemblies. Most researchers tend to respond to the recommendations at that level, which [...] poses a challenge because locally we may have priorities that don’t fit into the global and are sometimes ignored. K17

Each country has attempted to address this in different ways with different structures. In Kenya and Uganda, institutions in the STI sector have lead health research prioritization processes. While the health sector institutions in both countries also conduct similar processes in parallel, there has been little coordination and integration of health research prioritization efforts between the two sectors. In Zambia there is a much longer history of health research priority setting by health sector institutions than in the other three countries, with the first national health research agenda produced in 1999.
Stakeholder engagement is also a key challenge for priority-setting highlighted by interviewees across the countries. This is important both to define the most relevant health research priorities for the country and to foster endorsement and understanding among stakeholder of the priorities for their use. While there were examples of engagement in a number of these exercises in Zambia, we were not able to identify any NHRS within the countries which appeared to have solved this problem. In Botswana, it also remains a frustration as expressed by one researcher:

*In my opinion, there wasn’t much consultation in developing the [health research] agenda. If we had more consultation to develop that, then maybe we [could] say, “Yes, this is what the country needs.” But I think it was sort of one-sided thing. B10*

While including stakeholders in establishing national health research priorities that reflect local realities is important for their adoption, it can also help to support how the priorities are used by stakeholders. For instance, the strategic research areas in Zambia have facilitated researchers’ entry to communities in regions which are difficult to access for data collection because of the government’s interest in priority questions such as understanding a high prevalence of tuberculosis in the regions.

We did not find any NHRS among these countries with arrangements for prioritization that stood out as exemplary which could offer lessons to others. Yet, one insight which emerged is that integrating responsibility for leading prioritization processes into institutional mandates appears a promising means to begin formalizing expectations and accountability around health research priorities. Informants highlighted those institutions such mandates - including the Uganda National Health Research Organization, the National Health Research Authority in Zambia, and the National Health Research Committee in Kenya - as being critical to advancing this function of health research governance.

*Regulation of health sciences research*

A second element that informants highlighted was the importance of regulation, in particular that of the ethics, of health research. One of the main concerns noted for the ethical regulation of health research is whether there is a clear definition of the institutional mandate for this, and
the extent of authority of regulatory bodies. The ethics review systems for HSR vary across the countries (see Table 7). Without a clearly mandated body for the national oversight of ethical regulation, the fragmentation of regulatory systems for research ethics can be problematic for a NHRS according to participants. Zambia was the only NHRS with a separate health sector statutory institution, the National Health Research Ethics Board (NHREB), that is centrally mandated for national oversight of ethics policies and guidelines. This differs from Uganda and Kenya, where the responsibility for regulatory oversight is carried out through STI regulatory institutions which accredit the IRBs in universities, research institutions, or hospitals. In the case of Kenya, the National Bioethics Committee is also responsible for dispute resolution, monitoring and evaluation. Botswana differs from the other cases in that ethical review of all health research is regulated by a committee under the auspices of the Health Research Unit at the Ministry of Health and Wellness.

The differing arrangements for ethics review and oversight could create a number of challenges for coordination. For example, although all of these countries conducted ethical reviews, none of our interviewees identified a centralized repository to monitor all health-related studies being carried out. Kenya, Uganda, and Zambia have specific institutions mandated to review and approve of clinical trials specifically. However, informants expressed that a registration system for all HSR studies (including non-trial research) would be a useful resource for stakeholders and the public; and it could further improve oversight of health research by tracking research project status (i.e. ethics decisions, results, dissemination) over time.

Interviewees stressed the importance of legislation to strengthen ethical regulation. Zambia and Kenya have laws that provide standardized ethical codes for the conduct of health research, including clinical trials (29) In countries without such legal protections, however, serious concerns could be raised. One decision-maker from Uganda expressed a number of “black holes” for which there are no legal frameworks for ethical regulation, such as biobanking and biological material transfer of samples from the community. Uganda has the longest standing regulatory institution (UNCST) of the four countries, which is actively advising
government on policy and managing intellectual property for innovation with other
departments, but the gaps in regulations to provide authority for institutions to regulate
specific issues was highlighted by a researcher as follows:

Those regulations help to facilitate or to make the environment research friendly. Some of
them do not exist, and yet they should be in place. As a country, we need to look at that
area very carefully, what are the necessary research regulations? U5

Informants in Botswana relayed similar concerns, where despite its long history of HIV clinical
trials, there appeared to be no legal frameworks for ethical regulation of research involving
human participants or to protect intellectual property.

One of the central challenges that informants shared for regulation are the capacity issues for
ethical review within IRBs. Participants from Zambia and Botswana reported slow ethics
processes due to inadequate capacity of reviewers and limited resources to support IRBs.
Capacity for ethical review requires specialized experts with knowledge of health research
across disciplines, and compensated time or buy-outs for the service of IRB members to
participate. One Zambian researcher (Z04) expressed that things were improving in this area
with the NHREB but “we still have a long way to go.” Informants relayed that training of
committee member in scientific and ethical review and monitoring of studies with a variety of
research designs and methods (including, but not only, for clinical trials) is currently missing to
improve this function of health research governance.

**Coordination of health sciences research**

Coordination emerged as a vital third element for health research governance, but informants
raised it as a somewhat neglected aspect of health research governance as most reform efforts
have focused on regulation. Ministries of Health are often the authorities with the remit for
coordination of health sciences research and our findings indicated that coordination of health
research could be most effective when there are designated statutory institutions with
authority for coordination within legislation.
The situation in Zambian stands out, in that the National Health Research Authority operates as an independent body in the health sector that is responsible for both health research regulation and coordination. Local informants explained that this arose as a result of a long-term process of advocacy. First by research leaders, in collaboration with international partners, encouraging the Ministry of Health to develop legislation on health research that would include coordination as a priority function of governance. This was followed by further advocacy of senior civil servants and policy-makers in the Ministry of Health to other ministries across sectors (including finance) to obtain sufficient budget to implement the statutory bodies. While it has been a long road for the NHRA to come to fruition since the process began in 1997, one Zambian researcher expressed how important this has been:

*The regulatory environment has improved tremendously in 20 years from nothing to a very rigid system, to a system now that is trying to facilitate and encourage research.*

Although informants highlighted that dedicated statutory bodies for health research governance should ensure that mandates include both regulation and coordination, these do not necessarily need to be carried out by the same institution. For instance, the Zambian experience contrasts with that of Kenya and Uganda where the national STI bodies in the education sector are primarily responsible for the regulation of HSR (as discussed in the previous section), while coordination of HSR has been mandated by law to statutory bodies in the health sector. However, some informants mentioned that the ambiguity of roles and responsibilities between the STI institutions and the health research institutions sometimes leads to duplication of efforts or gaps in leadership. So, for instance, in Kenya, the National Health Research Committee was only established in 2019 to coordinate health research with stakeholders, develop research priorities, and advise the government on HSR policies. A lack of intersectoral collaboration to regulate and coordinate health research was thus a concern of many informants for those countries where governance arrangements were moving from regulation provided through STI institutions (under the auspices of Ministries of Education or Science and Technology), towards the inclusion of coordination by the Ministries of Health or other health sector institutions (see Table 7).
Many informants suggested that coordination of health research by the Ministry of Health is less than ideal for NHRS because a ministry’s core mission is policy-making. There was a general sense across the countries that Ministries of Health often lack capacity to coordinate research stakeholders within the evaluation and planning units where this function generally sits. Rather statutory bodies, located arms-length from the political arena with specialist research expertise, were seen by informants to be more fit for purpose. Thus, coordination was felt to be less effective when it is an additional or secondary responsibility of an agency as it necessitates dedicated and trained staff without competing with other internal organizational priorities.

Coordination was reported as one area of governance that Botswana has struggled to develop and institutionalise within the Ministry of Health and Wellness, primarily due to lack of dedicated capacity for this role. Thus, while countries might officially mandate coordination to key institutions, performance may be limited without capacity reflected in budgets and human resources.

*Legislation for health sciences research*

Health research legislation is the final area of governance that emerged from the interviews as important. Multiple respondents highlighted legislation as the point where there could be an opportunity to comprehensively improve many of the elements of governance mentioned in preceding sections. Informants underlined two key potential benefits of legislation in particular – first how it can formalize institutions and regulations, and second how it can improve their harmonization.

The first key aspect is the formalization of regulation in a legal framework. Indeed, many informants viewed formal legislation as a gold standard of regulatory practice. We found that many health research governance functions in the included countries did indeed operate on the basis of norms and guidelines. Multiple informants also expressed the view that legal frameworks provide clarity on authority and accountability mechanisms, and they can offer some protection from political threats to the regulatory environment. Formalization of regulation in law can also bring high-level support for institutionalizing governance and national
The second key aspect is the harmonization of various regulations within law. Informants from countries with health research laws expressed that legislation can also serve a purpose of clarifying the connections and relationships between the legacy of the STI regulatory institutions and the more recent health research statutory bodies (see Table 7). For example, the law in Kenya helped to spell out the links between institutions and stakeholders in the regulatory environment and streamline the regulatory process for researchers, according to one decision-maker.

*The Health Act tries to bring all these regulations dealing with research together, clinical trials being one. [T]here are many different laws and regulations that a researcher has to adhere to when they are carrying out research, and ... one of the key complaints they have is that they don’t know [where] they have to go [for what]... NACOSTI, ethics committees... K21*

Thus, the experiences of countries like Zambia and Kenya have shown that health research legislation is both useful for constructing dedicated institutions and for consolidating the rules in regulatory frameworks. But informants also raised the fact that ensuring this coherence so that law covers the key issues for health research governance that are at stake in the countries (e.g. ethics, intellectual property, data sharing, bio-banking, etc.) as well as provide the mandate to institutions for health research financing, coordination, and regulation is a considerable challenge for the process of developing law.

We found laws in Zambia and Kenya were most emblematic of these two key aspects and had the most comprehensive formal health research legislation of the four countries, while the draft of Botswana’s Health Research Bill (as of 2020) in Parliament reflects a similar comprehensive approach. Zambia appears to have achieved the earliest success of all four countries, being the first to have a national health research policy in 2010 and a Health Research Act in 2013. This process began early with the formation of the National Health Research Advisory Committee in 1997, which gained authority as the proponent of health
research legislation. Their success was progressively achieved through sustained advocacy and support from partners. The Zambian experience is unique in our case study countries in terms of having strategically used support of international collaboration for this.

Advocacy, however, is critical to improving regulatory environments for NHRS in part due to the need for resource allocation. One Ugandan respondent explained that while funders often gave money for research, they rarely did for regulatory development. The trajectory of Zambia shows how incremental change through advocacy for a health research agenda, strategy, policy, and health research governance institutions contributed to achieving the adoption and implementation of a comprehensive health research law through building the support and coalitions over time. Key individuals (research leaders and policy-makers occupying senior roles in government and research institutions) also facilitated this at critical moments, shaping the policy context to build an enabling environment for HSR through legislation. Table 7 presents a summary of the health research governance elements seen across the four countries emerging from our data.

Table 7: Health research governance elements

| Function                          | Botswana          | Kenya                                 | Uganda                                             | Zambia                                           |
|-----------------------------------|-------------------|---------------------------------------|----------------------------------------------------|-------------------------------------------------|
| STI Legislation                   | None              | -1977 1st STI Act (amended in 1979)   | -1990 National Council for Science and Technology (UNCST) Act | -1997 National Science and Technology Act       |
| National STI Policies/Plans       | -1998 STI Policy  | -2008 STI Policy                      | -2009 STI Policy                                   | -2009 STI policy (revised in 2006 and 2009)    |
|                                   | -2005 STI Plan    |                                       | -2012 STI Plan (2012-2018)                         |                                                 |
|                                   | -2012 Research, Science, Technology and Innovation (RSTI) Policy | |                                                    |                                                 |
| Health Research Legislation       | None              | - Health Act of 2017 (contains legislation pertaining to health research) | -2011 Uganda National Health Research Organization (UNRO) Act | -2013 National Health Research Act             |
| National Health Research Policy   | None              | -2019 Research for Health Policy      |                                                    | -2010 National health research policy           |
| National Health Research Strategic Plan | None          | - National Research for Health Priorities (2019-2023) | -2012 UNRO Health Research Policy                  | -2008 National health research                 |
| Oversight of National Research overall | - Ministry of Infrastructure, Science and Technology (Department of Research, Science and Technology) | - Ministry of Education (Directorate of Research Management and Development) | - National Council for Science, Technology, and Innovation |
|---------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Oversight of Health Research          | - Ministry of Health and Wellness, Department of Health Research, Policy and Development, Health Research Unit | - Ministry of Health, Research and Innovation Division, Health Research Office | - Uganda National Health Research Organization |
| Ethical review systems                | Health Research and Development Committee (HRDC)                                               | 27 IRBs accredited by National Bioethics Committee (under NACOSTI); KEMRI Scientific Ethics Review Unit (SERU) | 23 IRBs are accredited by the UNCST |
|                                       | IRB, University of Botswana                                                                      | IRB, AMREF & IRB in some hospitals                                                               | - National Health Research Ethics Board |
|                                       | IRB in some hospitals                                                                            |                                                                                                   | - ERES-Converge |
|                                       |                                                                                                   |                                                                                                   | - IRB, University of Zambia |

**Discussion**

The findings show that even though similar in some ways, they have different approaches to and experiences with the governance of health research. These countries may have some similar historical contexts (e.g. inheriting institutions from a British colonial experience), they have differences with regard to political, economic, legal, education, and health care systems which are all part of the larger context for the governance of health research. The findings highlight where countries have made progress, such as ethical regulation, along with areas like prioritization and coordination which remain areas needing ongoing reflection. Through the findings we see that legislation appears as a standard to which countries may aspire to formalize their regulatory frameworks and health governance arrangements, and which may
help to raise awareness and status of HSR issues within the broader regulatory environment. However, while health research legislation is seen as a benchmark for governance of NHRS, the process to develop and implement legislation is long and resource intensive, as examples from our data show this takes generally a decade or more to achieve.

All four countries have established structures and guidelines for ethics review. Zambia and Kenya have legislated the ethical regulations, while Uganda and Botswana utilize guidelines. Countries differ in their arrangements for health research ethics and IRB oversight at the national level, whether as a statutory body for health research ethics (Zambia), under the STI regulatory institution (Uganda and Kenya), or within the Ministry of Health (Botswana). Likewise, other sub-Saharan African countries including South Africa and Nigeria have established national ethics committees to guide establishment of IRBs (23). However, many IRBs are under-resourced and the institutional capacity for coordination of these regulatory bodies, IRBs, and research institutions is a persisting challenge that countries across the various arrangements.

Even though there is some prioritization of HSR in government policies, there are concerns whether national health research priorities are aligned to community health needs and national health and development policies in all the countries. The findings point to stakeholder engagement in priority settings processes as a fundamental concern for how priorities are developed, defined, and used. Frequently, we see prioritization as an exercise that happens on paper without government or donor funding aligned with national health research priorities. In addition, when researchers use donor priorities to guide their work, they may risk failure to align their studies with the population health and health system needs. The Council for Health Research on Development has argued that countries cannot steer research expenditure, promote science and innovation for health, strengthen health research capacity, support research institutions to use the priorities, or negotiate with partners for funding without clear national health research priorities (12,30). We found that there have been various initiatives to support health research priority setting in developing countries such as Zambia and Tanzania.
and four West African countries (7,12) – but overall reviews of national research priority setting have demonstrated that these processes requires political will, funding, and a monitoring system to track progress (31).

Our findings also show that advocacy efforts by local leaders and international partners can be influential for efforts to strengthen HSR governance when sustained over time and linked to individual NHRS needs in context. Many African countries have received external support to strengthen their NHRS through improvements in national HSR governance including policy development, research coordination structures, and capacity building as seen in Zambia and some West African countries (7,32). Our findings confirm the lessons from these initiatives that local/external advocacy and international partnerships can be favourable to strengthening research governance.

One of the main similarities seen across our countries is the intersectoral nature of mandated authority in HSR governance - although the division of responsibility for HSR governance between the education and health sector has evolved over time in each of the countries differently. While Zambia moved earlier to develop health research law with a mandated standalone national health research authority and national ethics board within the health sector, the other three countries have been slower to develop health sector research policies and legislation. There were strong impressions shared by informants in multiple countries that research units within Ministries of Health generally do not have sufficient capacity for national oversight and coordination of HSR, however, and such a role may be better suited to a statutory institution with technical and administrative expertise for this function.

**Conclusion**

Health research governance is an essential component of a strong health research system as it plays vital role in the enabling environment for HSR. This study was not designed to evaluate whether the improvements in national health research governance arrangements have directly led to increased research productivity. Furthermore, efforts to improve elements of HSR
governance are relatively recent in comparison to efforts to strengthen HSR capacity. However, the international calls to improve governance of research is based on an assumption that over time improvements to health research governance can also shape research production and utilization when they are part of a systemic approach to NHRS strengthening.

We have highlighted some of the lessons and examples from countries in improving important elements of health research governance at national levels. Improving legal frameworks for the regulation, coordination, and prioritization of health research aligned with resources for effective functioning of the governance systems is integral to achieving effective and sustainable NHRS that remains a goal across the African continent (20). Establishing and strengthening national health research authorities and other statutory bodies with mandates to coordinate and regulate health research across all research institutions and stakeholders is central to this goal. Moving forward it will be critically important to think proactively about the governance of HSR to improve research outputs and use.

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List of Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| AIDS | Acquired Immunodeficiency Syndrome |
| COHRED | Council on Health Research for Development |
| CARTA | The consortium for advanced research training in Africa |
| GDP | Gross Domestic Product |
| ERB | Ethics Review Boards |
| IRB | Institutional Review Boards |
| HIV | Human immunodeficiency Virus |
| HRDC | Health Research and Development Committee |
| HSR | Health Sciences Research |
| KEMRI | Kenya Medical Research Institute |
| NACOSTI | National Commission for Science, Technology and Innovation. |
| NHRS | National Health Research System |
| NHREB | National Health Research Ethics Board |
| SERU | KEMRI Scientific Ethics Review Unit |
| STI | Science, Technology and Innovation |
| UNCST | Uganda National Council for Science and Technology |
| WHO | World Health Organization |

Declarations:
**Ethics approval and consent to participate**

We obtained approvals from the designated and recognized ethical review boards and institutions in the countries, as well as from the London School of Economics and Political Science Research Ethics Committee (REC Ref. 000757) in the UK. In Botswana, approvals were obtained from the University of Botswana and from the Ministry of Health (HPDME: 13/18/1). In Kenya, approvals were provided by the KEMRI Scientific and Ethics Review Unit (KEMRI/RES/7/3/1) and the National Commission for Science Technology and Innovation. In Uganda, approval was provided by the Makerere University School of Medicine Research Ethics committee (REC REF 2018-153). In Zambia, approval was provided by the ERES Converge IRB (Ref. No. 2018-Nov-014) and administrative approval by the National Health Research Authority. Participants provided written informed consent prior to taking part in the interviews. Identification codes were assigned to all individual audio-recordings and transcripts.

**Availability of data and materials**

Study materials and anonymized data are available by contacting Clare Wenham (C.Wenham@lse.ac.uk) in the Department of Health Policy at the London School of Economics and political Science.

**Competing interests**

The authors have no competing interests to declare.

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**Authors' contributions**

PAJ conceived, drafted, and finalized the manuscript by incorporating the inputs from the other authors. RM contributed to data collection, analysis, and review of the manuscript. CMJ analyzed data, drafted text, and revised the manuscript. NM, TM and GB supported the ethical approval and data collection in their respective countries. JP, CW, and JS reviewed and provided technical input to the manuscript. The manuscript was subsequently approved by all authors.

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