A Situation Analysis Report

The Mobilization of Resources for Health Research & Development in Africa.

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Acronyms

AAS African Academy of Sciences

ANDI African Network for Drugs and Diagnostic Innovation

ART Antiretroviral therapy

ARV Antiretroviral AU African Union

AUDA-NEPAD African Union Development Agency

CSIR Council for Scientific and Industrial Research
EACCR2 Eastern African Consortium for Clinical Research

EDCTP European & Developing Countries Clinical Trials Partnership

HIS Health Information Systems

HRISA` Health Research and Innovation Strategy for Africa

NCDNon-communicable diseasesNGONon-Government OrganisationNHRSNational Health Research SystemNIHNational Institutes(s) of Health

OECDOrganisation of Economic & Development**PMPA**Pharmaceutical Manufacturing Plan for Africa**PMTCT**Prevention of Mother-to-Child Transmission

PPP Public-Private Partnerships

PRNIDs Poverty-related and neglected infectious diseases

PrEPPre-Exposure ProphylaxisR&DResearch and DevelopmentTTTechnology Transfer

UN United Nations

WHO World Health Organisation

Executive Summary

The case for African Governments to take a stronger role in promoting health Research and Development (R&D), and in the mobilization of resources for such, is strong and multifaceted. In addition to reducing morbidity and mortality levels, health R&D can inform and contribute to economic and social development, job creation, skilling of the workforce, fruitful regional collaboration, leverage of other sources of funding and investment, reducing reliance on imports, decreasing African reliance on countries outside the continent and in finding African solutions for African health challenges. This report has found that there are a powerful range of arguments that civil society can voice, and approaches they can take, to make this case to government.

The need for research in disease prevention and improve health systems were identified as the two most critical areas requiring a much stronger focus. Effective prevention, improved programme implementation and delivery, are not only the prime keys to ensuring better health outcomes but also are also vehicles to reduce heavy burdens on public health systems and, ultimately, to ease pressure on public expenditure.

The report has found that there is great value in developing Regional Centres of Excellence for health R&D research. The findings also demonstrate that investment in domestic R&D by individual countries yields substantial benefits. This investigation has also concluded that it is reasonable for governments to allocate some of their own funds toward health R&D. This is an effective way to leverage substantial additional resources from potential investors and funders as it gives such stakeholders a strong indication that government is committed to health R&D. Investment of public funds provides the country with more leverage to ensure that R&D agenda is relevant to solving the country's specific and most pressing health challenges. It also helps to ensure the local capture of other benefits flowing from domestic (and regional) R&D.

Another core finding of this investigation is that there is great scope for government to create a more conducive environment to attract health R&D investment including from the private sector which plays only a fraction of its potential role. Through forming high-level partnerships to develop better financing and business models, reducing bureaucratic blockages but at the same time strengthening an enabling regulatory role, improving health infrastructure and developing solid proposals for public-private partnerships (which will necessitate the use of some public resources), government can do a great deal to lay the groundwork for increased R&D investment. Civil society can play a key role in helping government identify the institutional arrangements, the necessary partnerships to form and support to draw on to undertake these interventions effectively whilst remaining accountable.

The report concludes that African countries would have much more prepared to address the COVID-19 crisis had stronger health R&D collaborative structures been in place, especially those which inform health service delivery. The need for greater investment in health R&D to ensure that countries are prepared to deal with inevitable future pandemics needs to be clearly articulate to governments.

The report also concludes that civil society's advocacy efforts to government for greater health R&D resource mobilization would be strengthened by developing broader multidisciplinary and multisectoral partnerships with institutions and experts. This would help to build stronger cases demonstrating the range of societal benefits that expanded investment in health R&D can bring.

1. Introduction

This is a report commissioned by WACI Health in an effort to identify gaps, strengths and opportunities in health research funding. This is aims at informing strategy and advocacy for all stakeholders committed to expanding the resources for health research and development (R&D) in Africa drawing from the experience and lessons from existing health R&D investments.

Impact of HIV/AIDS Investments on Health Systems

Investments in HIV/AIDS have seen the direct impact of improved care and outcomes in HIV/AIDS. There have been related knock-on effects on care for potential comorbidities and health dimensions such as Tuberculosis, Bacterial, Viral and Fungal Meningitis and Pneumonia, Sexual and Reproductive Health, Nutrition, Maternal and Child Health *inter alia*. It has engendered in improvements in diagnostics, research, innovation, technology adoption and diffusion, program management and administration, and pandemic response all of which improve care beyond HIV/AIDS.

It has however been demonstrated that the heavy investments in HIV/AIDS by external sources disincentivized local ownership and funding hence threatening sustainability of interventions due to the resultant dependence. Further, the single disease focus in health investments has had the negative effect of weakening the broader health system at the expense of the focus intervention.

With the growing effort and focus on sustainability and transition to local ownership, there has been a significant investment in capacity development for local expertise in aspects of care, research, programme administration and management. This has also triggered a transition towards collaborations that foster dignity, equity, mutual benefit, and peer to peer engagements between the global north and south as well as south to south partnerships. This helps remedy the negative impact of the vertical implementation of HIV, TB and Malaria programmes.

Building the case for health R&D investments

The report, through utilizing the inputs of experts and a range of literature, builds a case for African governments to increase their commitment to health R&D. Recommendations from this report are targeted at providing a platform, argument ideas, and hopefully some inspiration for health R&D activists, scientists, practitioners, organizations and other stakeholders to put up a strong advocacy case to African governments.

A 2016 publication by WACI entitled *Research and Policy Report on Investments in HIV R&D in Africa* provides foundation for this report. While the previous report assessed the level of commitment to HIV research as a prime focus, the current report identifies the positive spin-offs of health R&D investment well beyond HIV & AIDS to other critical health issues.

A summary of the main findings as well as case studies of three African countries is included. It also provides some specific conclusion points and arguments when advocating for expanded health R&D and the mobilization of resources. It sets out the basis for alliances and collaborations to make this case and provides examples as to the negative consequences for the lack of investment and, more importantly the substantial payoffs when such investment is made.

2. Methodology

The investigation drew material from 20 expert comprehensive interviews and from a wide range of written sources. Interviewees (usually referred to in this study as "stakeholders") were identified purposively on the basis of their high level of expertise in the core areas probed by this study. Such stakeholders included:

- Scientists in Africa-focused research organizations;
- Medical practitioners with in-depth knowledge of R&D and field experience in Africa (including clinical trials);

- Funding and capacity-building organizations with a health R&D focus;
- Social scientists who have published material on health R&D issues in Africa;
- People in NGOs and other organizations which undertake health and R&D advocacy, including organizations that undertake health R&D monitoring and evaluation.

In some cases, the researcher undertook informal follow-up discussions and written communication with respondents to gather greater detail on important issues raised in the initial interview as well as relevant new information. The research tool consisted of an open-ended discussion schedule which posed 12 questions (or "items for discussion") in four categories namely: i) Appropriate roles for government in mobilization of resources for health R&D; ii) the role of civil society in advocacy and making the case to government for expanded R&D; iii) HIV-prevention R&D, and iv); health R&D in the context of the COVID-19 pandemic.

Limitations

This study was "time-sensitive" in that circumstances related to politics and advocacy with government, can change over relatively short periods of time. More to the point, however, contemporary scientific R&D data can also become outdated quickly, particularly data related to COVID 19. Recent literature on contemporary socio-political issues related to health R&D in Africa is rare and difficult to locate. From these perspectives it is difficult to provide a "snapshot" of the health R&D landscape in Africa with a high level of accuracy. Nevertheless, the researcher was able to identify a range of recent and relevant literature. This included academic and non-academic journal articles, media articles, official policies and discussion papers, strategies, frameworks, reports, educational and advocacy materials, and unpublished material for use within scientific and health advocacy organizations.

3. Findings and Analysis

3.1. Health R&D Landscape in Africa

The last two decades has seen slow but steady progress for the health research and development globally. The progress has also been reflected in Africa, albeit very slowly. Simpkin et al found that despite the ambitious country-set targets and frameworks, the health research funding and research capacity are insufficient to meet the Africa's health needs. (Simpkin *et al.*, 2019)). The Health Research and Innovation Strategy for Africa (HRISA) 2018-2030 (AUDA-NEPAD 2019) acknowledges that the Science, Technology and Innovation (STI) landscapes throughout Africa had improved over the decade prior to 2018. It attributes this to the growing recognition among policy makers of the importance of STI in social and economic development as well as increased emphasis to demonstrate impact at scale of STI investments (AUDA-NEPAD 2019:2).

The past and current advocates for health R&D have made some headway, albeit incremental, in communicating not only the importance of investment on health R&D, but also its critical link to socioeconomic development for countries and regions. However, policy makers in most African countries are still far away from making firm strategic and budgetary commitment required to create a viable and facilitative environment for expanded health R&D. There are less than 10 out of the 52 countries in Africa who invest at least more than 0.6% of their GDP in R&D. The R&D environment in Africa is marred with various diverse disparities. For instance, countries like South Africa, Nigeria and Egypt contribute to almost two-thirds of the total R&D investment spending. Also, there is clear Inter-regional and intraregional disparity on the number of researchers, publications, patent holdings, clinical trial networks and pharmaceutical manufacturing capacity.

The table below shows budgetary data gathered from some countries estimating the levels of expenditure on health R&D percentage of Gross Domestic Expenditure (GDP). (Simpkin *et al.*, 2019)

Levels of gross domestic expenditure in R&D (%) of GDP		
Expenditure		
on R&D (% of GDP)	Countries	
>0.6	Egypt, Kenya, Malawi, Mali, Morocco, South Africa, Tunisia	
0.4-0.6	Ethiopia, Gabon, Mozambique, Senegal, Tanzania, Uganda	
0.2-0.4	Botswana, Ghana, Nigeria, Seychelles, Sudan, Togo, Zambia	
0.1-0.2	Burkina Faso, Burundi, Gambia, Mauritius, Namibia	
0<0.1	Algeria, Cabo Verde, Democratic Republic of the Congo, Lesotho, Madagascar	
No Data	Angola, Benin, Cameroon, Central African Republic, Chad, Comoros, Congo,	
	Cote d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Guinea, Guinea-Bissau, Liberia,	
	Libya, Mauritania, Niger, Rwanda, Sao Tome and Principe, Sierra Leone,	
	Somalia, South Sudan, Swaziland, Zimbabwe	

(Simpkin et al., 2019)

3.2. Emerging Themes

Highlights.

- Lack of political goodwill to support health R&D in LMICs
- Health R&D research in Africa does not necessarily benefit Africans,
- The need for R&D to strengthen health system is paramount yet neglected.
- Low prioritization in budgetary allocation for health research.

Africa must find its own homegrown solutions for the health problems. One of the health advocate interviewee said that:

"This means that countries must work together – either through regional economic communities or any other economic blocs - to build the capacity of African scientists and centres of excellence that are strong enough to develop products and to build sufficient institutional capacity."

There are different arms of the required capacity. For instance, the development of a supportive environment in which health R&D can function and thrive. This should include a legal framework and incentives sufficient for research institutions to be innovative. Policies and laws are essential but there must be the political will, the expertise and sufficient budgets to implement them. One Kenya-based stakeholder noted that its government, and those of several others, do have various laws, official polices and frameworks which oblige them to utilize public funding for health-related R&D (sometimes with particular amounts or earmarked proportions). Yet, the stakeholder identified that:

"The biggest hurdle is how to make such commitments implementable. At country level there are so many completing priorities. But we are not allocating sufficient funds because policy makers still do not value biomedical R&D as an economic intervention of the state."

This underlines the importance of advocates emphasizing the range of economic benefits an increased health R&D will bring countries and entire regions. Collaboration at the regional level, including the allocation of funds for centres of excellence from which all participating countries would benefit, need not require "reinventing the wheel." Such centres could be developed and integrated through existing economic

communities and blocs. This would provide some basic structure, promote economy-of-scale and demonstrate that that health R&D contributes substantially to economic development.

However, while this study determined that there is an extremely well-informed, multi-faceted case for the development of regionally-based centres of excellence, the goal of developing such facilities should not distract from the great value of individual countries developing their own capacity for health research, development and innovations and initiatives. From district-based R&D to address specific critical health concerns of local communities to country-wide R&D and strategies to develop a national pharmaceutical manufacturing industry, the study found numerous instances of the significant payoff for health R&D investment within a single country.¹

This study found several references in the literature and the interviews as to the low rate of publication of the work African scientists in professional medical and related journals, compared to scientists from other continents. Most underlined the importance of measures to increase the rate of publication but not all stakeholders viewed this as a priority in and of itself. While making a strong case for investment to build technical capacity and the capacity of African health scientists, one advocate argued that:

"... but they (the scientists) must move well-beyond simply doing research for peer-reviewed publications. A lot of researchers are doing their work in order to get published rather than developing products or strengthening health systems."

A vital point to inform health R&D advocacy is that that relevant, practical outcomes need to be attributed to the research that has been done. The above-cited stakeholder cited a study of R&D investment in Kenya, the preliminary data of which shows that even money put in by state – just for elementary studies – were purely for academic purposes and concluded: "We could find very little for biomedical research for innovation and improvement to health systems."

This underlines some core findings of this study: That health R&D research in Africa does not necessarily benefit Africans, that government funding for R&D can be misplaced and that the need for R&D to strengthen health system is paramount yet neglected.

3.3. What Health R&D Issues are The Most Critical for Africa?

Highlights

- LMICs need community driven processes that systematically identify and prioritize health R&D needs.
- The scope of Health R&D in LMICs should be broad to encompass social determinants of health. This would help improve understanding of the links between poverty and disease.
- Research should focus on the entire continuum of short term, medium term and long-term impact.
- Investment in implementation research is essential as it is critical in demonstrating short term impact alongside scalability of interventions.
- African countries must invest in health information systems (HIS) as an enabler of health R&D.
- Health R&D needs to focus on improving the understanding of the psychosocial and psychocultural factors underlining treatment and health seeking behaviour.
- There is need for more research on chronic and non-communicable diseases in Africa.

3.3.1 Identifying R&D needs and ensuring participation.

A former official at the World Health Organisation (WHO), maintained that there are no simple answers to the question of what the health R&D priorities for Africa should be. Rather, there needs to be ongoing processes in place which systematically provides information to identify where R&D is most needed. He explained that (as of mid-2020) the WHO was in the process of developing guidelines to identify R&D priorities through undertaking systematic reviews to determine knowledge gaps.

Other stakeholders expressed the sense that communities and health programme staff on-the-ground need to be consulted on research priorities. One asserted that:

"The programme staff and many community members are aware where the challenges are and there is a distinct set of challenges which may not be directly-related to biomedical research. Many such issues can be addressed."

Ensuring that programme staff and community members have meaningful input into the process of developing a country's health R&D agenda is not only democratic and empowering in itself, but makes policy sense in that such stakeholders engage with the most critical health challenges for poorer communities on a daily basis. It can thus add to the transparency and relevance of the R&D agenda. Furthermore, these programme staff and community members may have important insights and ideas in terms of improving delivery.

Noting that undertaking this form of consultation to inform R&D is something that government can do with relative ease, one stakeholder invoked an apt African proverb:

"Those who sit under the mpundu tree know where the fruit falls."

In the same vein, another stakeholder underlined the importance of medical research in Africa being undertaken in tandem with communities. He noted that there is an "unhappy history" of research being undertaken in developing countries in a developed world context, often in a way that is exclusionary to local populations and not relevant to their needs. He asserts that:

"We should have local scientists and anthropologists working side by side with communities. And we should have multi-disciplinary local teams conceptualising research more effectively."

3.3.2. Disease Prevention

The need for health R&D to focus on disease prevention emerged as a leading priority was widely cited by interviewees and in the literature. A senior executive of a national science council asserted that:

"The lowest hanging fruit that costs government the least is prevention, the lack of which is still a major burden."

Others expressed the sense that further research is needed to make prevention measures work in the African context, with one asking (in the context of HIV):

"If there's been so much intervention why has there been so much transmission? Because so many messages do not hit the target – they lack credibility and purpose. We need to work locally to determine how prevention may best be achieved rather than rely on foreign-led interventions."

This underlines the need for both African-led, and locally focused prevention R&D.

One medical scientist and programme director made the case for R&D resources to develop chronic disease models to help African health practitioners and policy makers and the need for health R&D in Africa to have a significantly broader focus than just biomedical research, but also socioeconomic, environmental, basic infrastructure and other factors affecting public health. Indeed, the need to better understand the links between poverty and disease was cited by several stakeholders.

3.3.3. Implementation Research and Strengthening Health Delivery Systems

There was widespread agreement among stakeholders that, biomedical research notwithstanding, much more research is required around the effective implementation of health initiatives. The overall sense of this was summed up by an interviewee from a UN agency who asserted:

"Governments must focus research efforts to bridge the gap between biomedical research and the health systems."

Some stakeholders expressed the sense that most politicians want short-term immediate results from public investment such as schools, roads and other infrastructure, rather than wait for the long-term benefits that health R&D will bring. This underlines challenge for advocates of greater public investment in health R&D in changing a mind-set which sees such government expenditure as a competing interest rather than a core complementary investment alongside other priorities. At the same time, however, advocates also need to communicate the short and medium-term benefits of R&D.

Addressing the issue from a strategic and advocacy perspective, one stakeholder maintained that policy makers will ask when the returns of the potential research investment will be realised and they will want to see short-term results. However, basic biomedical research will usually only produce a "payoff" until the long-term. Initiatives such as clinical trials, drug research, diagnostic tests, etc. will generally produce tangible results in the medium-term. However, it is implementation research which is likely to have positive, tangible shorter-term effects.

An academic from the WHO maintained that implementation research occupies a critical niche between product R&D (i.e. generation of new drugs, diagnostics and vaccines) and the health programmes that deliver them.

There is a disconnect between great achievements in biomedical research and health delivery systems is starkly demonstrated by the situation with tuberculosis treatment in South Africa. A South African researcher interviewee lamented that despite having had some of the most comprehensive and successful tuberculosis (TB) trials in the world, South Africa's TB cure rate was lower than in Zimbabwe. This was reflected by a UN respondent who asserted that:

"South Africa has been a world leader on research on TB for decades and yet that country has one of the worst TB epidemics in the world and the research has not generally contributed substantially an improved programme response. South Africa knows all there is to know about TB but there is utter disconnect with health programme and treatment delivery."

While the stakeholder acknowledged that the situation with TB treatment is being addressed, he asserted that there is still a widespread situation in South Africa (and other countries) of very high-quality medical research not translating to a healthier population. On a similar noted a respondent from an international development agency maintained that:

"What we need is research into health systems strengthening – not just medical research. It's very hard to take these things and look at in separation."

The director of an organisation that runs 63 HIV & AIDS services sites in Eastern and Southern Africa asserted that:

"We need more operational research. We need to learn how to have operational know how. How to we take something to scale – how would a standard operation procedure work here? We need to develop things that can be implemented."

Some stakeholders argued that there must be a stronger nexus between biomedical research and the integration of its outputs into health service delivery.

Several stakeholders underlined the vital necessity for greatly expanded health information systems (HIS) to inform health interventions and accurately target them. To be effective, health R&D on implementation relies on comprehensive and well-functioning health information systems. Such systems fall short in most African countries and require urgent attention.

3.3.4. Uptake and adherence

A practitioner and former programme director underlined the importance of implementation research in Africa in relation to increasing the uptake rates of medications, both prevention and treatment. Noting that the take-up rates of medications for HIV, TB and other diseases are still far too low in many countries and that long-term adherence is an even challenge, the stakeholder asks:

"How do we integrate a new product into an existing health service and make people want to line up for it"? What are people balancing when they make a choice? What would make young women use an adherence app² for HIV meds? What are they sharing and how might it apply to treatment adherence? We don't know enough about this in Africa."

In framing these questions, the stakeholder underlines the need for focused research, including behavioural economics, to find ways to dramatically improve both medication take-up and adherence, the still-too-low rates of which result in needlessly high rates of morbidity and mortality.

At least three stakeholders emphasised the importance of research to better-understand the psychosocial and psychocultural factors underlining treatment, as distinct from purely medical research.

While acknowledging that PrEP is working in high income countries, one stakeholder added "but we need to make it work here." Another noted that in many areas in which her organisation operates, there is widespread resistance to commencing PrEP treatment and remaining adherent. She notes that, in Africa, the political and sociocultural context which affects take-up and adherence are fundamentally different to that of the Industrialised North and that strategies that may work well in the latter environment may fall flat in the former. This example underlines the need for implementation research specifically focused on this issue in the African context.

A representative from a vaccine research organisation strongly concurred and asserted that:

² A cell phone application which provides reminders and information to help people adhere to their medication regimen.

"We can't do HIV prevention on its own: It needs to be part of a broader package. Prevention alone is not so palatable. There are social and cultural barriers and issues around education affecting delivery to the most vulnerable."

The need for research to better-understand the sociocultural and other dynamics inhibiting medication take-up and adherence is clearly vital to the goal of reducing morbidity and mortality among young people in particular.

A practitioner and programme director reflected on the need for research to better understand the delivery of health products in the African context. Local communities, including structures, leaders and networks can play a key role in health service delivery much more than in most countries of the Industrialised North. This has often not been fully understood in programme delivery.

"It's not enough in Africa to have the right treatment alone. There needs to be overlap: The right treatment, for the right people, delivered in in the right way – a Rubik's cube.

3.3.5. Non-Communicable Diseases

The need for more research on chronic and non-communicable diseases in Africa is reflected in the literature and was identified by several respondents.

An article published by the African Academy of Sciences (AAS) (2019) asserts that there is insufficient research on non-communicable disease (NCD) prevalence and mortality. Using South Africa as an example, the AAS notes that this country has experienced a quadruple burden of disease which (in addition to of infectious diseases, accidents & injury and disabilities) includes increasing prevalence of NCDs such cardiovascular diseases, obesity and hypertension. This perspective also underlines the need to understand the underlying socioeconomic factors linked to non-communicable disease.

In terms of the need for research The AAS (2019:1) asserts that:

"While research has, until now, focused on the biomedical causes, little research has examined the demographic and socioeconomic determinants and causes in the country (South Africa). This could have potentially devastating consequences on the country's economic and social growth."

3.4. Research Centres

Highlights.

- Incorporate more stakeholders in R&D.
- Increase national and institutional research capacity across the region.
- Increase the number of accredited research centres and laboratories regionally.
- There is a lack of sustainability and scaling up of launched innovations.
- There is a general lack of political goodwill and backing by local governments.
- Ensure sustainable financing through local and existing institutions.

The need to capacitate and incorporate more stakeholders and research institutions in health R&D was strongly reflected in the interviews and the literature. AUDA-NEPAD (2019) cites a 2016 evaluation of

over 3000 health research projects across the world undertaken by around 900 research organisations. Among its findings, the evaluation showed that in Uganda, Tanzania and Kenya, most of the research was being undertaken in a statistical average of less than three institutions in each country. Based on these findings, AUDA-NEPAD (2019), strongly underlined the need for increased national and institutional research capacity across the region. A medical researcher and programme director claimed the need to increase the number of accredited research centres and laboratories has intensified over the last 15 years. Furthermore, he views that with a good network of high-functioning labs, collaborating with other institutions and in vaccines and drugs research will be more targeted and meaningful. This will enable adequate leveraging on existing resources.

On the other hand, it is vital that there should be proper strategic planning to ensure that high-quality research centres are not only established but are sustainable. The case of the African Network for Drugs and Diagnostics Innovation (ANDI) highlights an example of the need for sustainability. Launched in 2008, ANDI's core goal was to promote and sustain African-led product R&D innovation through the discovery, development and delivery of affordable new tools. In addition, to support R&D capacity development as well as infrastructural and economic development. ANDI's prime focus was to address Africa's unmet health needs by harnessing the untapped power of collaboration among African researchers as well as equitable North-South and South-South partnerships, with the vision of creating a sustainable platform for health innovation in Africa. ANDI has contributed significantly to the innovation space in Africa by setting up a network of 32 centres of excellence across Africa involved in drug discovery, pre-clinical and clinical work. (Simpkin *et al.*, 2019)

Unfortunately, over the years, the study found anecdotal evidence that operational and other support for ANDI has not been sufficiently sustained. ANDI's website, once a rich source of contemporary health R&D and innovation information, networking and linkages and more, has clearly not (as of September 2020) been updated for some years. Informal enquires revealed that ANDI's programmes and operations have been greatly scaled down in recent years with its scope, influence and outputs substantially reduced. One scientist and instructional executive noted that communication from ANDI has faded away and that the organisation does not appear to be present at key forums and collaborations. He expressed the shock and disappointment that such a promising initiative anchored to the AU can 'die a natural death'. His main displeasure was the fact that there will be a delay over the next 15 to 20 years in developing a vaccine or drug targeted for specific Africa health problems.

Far too often in Africa great innovations have been launched but have not been sustained. Yet, to advance R&D and innovation that its outputs have a substantial impact—on the health of the population, research institutions must be able to thrive over the long-term. According to the above-cited stakeholder, ANDI was set it up with excellent strategic plans, including the plan for long-term financing support through an Africa Development Bank and individual governments. While it is unclear what transpired, ANDI has not scaled up and propelled as expected due to an inadequate sustainability support from required parties.

3.5. Impact of Covid-19

Highlights

- The COVID-19 pandemic underscores the value of health R&D investment.
- Caution must be taken to ensure health system resilience during disasters with adequate investment in continuity of services.
- COVID-19 has fostered greater understanding and collaboration between the scientists and politicians in managing the pandemic.
- COVID-19 Research and Development is synergistic to the progress in HIV/AIDS R&D.

A strong theme emerged in the stakeholder discussions that while the impact of the COVID-19 pandemic has, on one hand, understandably diverted attention and resources away from broader health R&D, it has also underlined how much more prepared African countries would have been to address the crisis had stronger health R&D collaborative structures been in place, especially those which informed health service delivery.

Indeed, the Africa Health Strategy 2016–2030 (AU 2016:21) underlines the need for country-led health research and information management systems to inform disease surveillance, preparedness and response in the event of an epidemic emergency. The Policy identifies the need for "a paradigm shift" to establish effective disaster preparedness and response management systems at continental, regional and country levels. In this sense the impact of the COVID 19 crisis itself provides a powerful demonstration of the need for greater health R&D investment.

A director of a multi-region HIV programme referred to the "accumulative effect of urgency presented by COVID" and asked "How do we build back stronger? We need to understand why some systems cope and some didn't." The stakeholder expressed grave concern around the effect of HIV and TB services being disrupted due to the COVID-19 crisis. The stakeholder asserted:

"We cannot let prevention measures slide. The minute we think we've run the course we find something else. Prevention strategies have to be continual, consistent, integrated and repetitive, and always evolving."

While in no way understating the severity of the COVID-19 pandemic, some participants expressed concern around the diversion of health R&D funds away from other deadly diseases including, but not limited to, HIV and AIDS. A central fear here is that the shift of focus and resources away from HIV and AIDS, malaria and TB may see a resurgence of these diseases as both prevention and treatment initiatives are deemphasised. Cautioning that the AIDS crisis is far from over in Africa, one scientist asserted that:

"In all this excitement around COVID, we must not forget the ongoing HIV & AIDS crisis which we still have not sorted out. Even if infection levels were to dwindle – even if 90-90-90³ was achieved – we will still have, foreseeable future, large numbers of people with HIV requiring treatment."

Noting, however, that there have been many swift and effective responses to COIVD-19 in several African countries, an expert in HIV policy and programmes underlined how HIV & AIDS R&D have helped inform such helpful responses. He asserts that:

³ A global target by which 90% of all people living with HIV will know their HIV status, 90% of those testing HIV-positive infection receive sustained antiretroviral therapy (ART) and 90% of those receiving ART achieve viral suppression.

"The COVID-19 crisis could have hit us much worse than today. Even in the responses from a medical scientific perspective, we have relied a lot on the experiences gained from the fight against HIV."

Some of the leading scientists who have been providing the basis for national responses to COVID-19 in Africa have backgrounds as leading HIV researchers. The firm grounding of many African scientists in not only HIV & AIDS, but other diseases such as TB and Ebola, has meant that they did not have to "start from scratch." Some have applied important lessons learned these other epidemics / pandemics into their COVID-related research and responses.

One scientist asserted that the onset of the COVID-19 crisis provides a strong basis on which to undertake advocacy with governments:

"We need to tell them that if we don't invest, Africa will not be able to draw on its own knowledge and products to address such things as pandemics (when we become isolated). We must prepare to be able to solve our own problems in health crises."

One participant (not a scientist themselves) portrayed the COVID-19 crisis as a stark indicator that the role of scientists is more relevant and more critical than ever. Noting that the use of scientists to speak alongside senior leaders had added vital credence to the need for behavioural change and precautions, this stakeholder asserted that "There is no better demonstration of the relevance of health science research as a result of this crisis." It is also noteworthy that new COVID-focused committees of scientists has brought skilled medical researchers closer to government officials and politicians and promoted greater understanding and collaboration.

Staff members at a global HIV & AIDS organisation argued that some of the of the biomedical developments that have occurred in relation to COVID-19 are synergistic for HIV. They noted that, in the few months between the onset of the pandemic and July 2020, there had already been substantial progress in terms of research for a vaccine.

There is a strong case for African governments to facilitate and leverage funds for large clinical trials for a potential HIV-vaccine trials in their countries utilising this COVID-19 platform. However, stakeholders also noted that there would have to be sufficient infrastructure to support this form of trials. Unlike others, DNA vaccines⁴ need to be deep-frozen. Yet, most African countries would not have the delivery systems necessary to deep freeze the vaccine at the number of sites necessary for national clinal trials. This situation demonstrates how vital it is for African governments to invest in the cutting-edge equipment needed to facilitate the increasingly important and emerging research around DNA-vaccines.

Governments need to understand that, in all likelihood, other potentially devastating epidemics and pandemics will affect Africa in the future. In this event, the continent will need to have its own knowledge and capacity to draw on, rather than rely on foreign assistance which may not come in time and may not be sufficient to meet the challenge.

Envisaging the post-COVID period, at least two stakeholders emphasised the importance of moving forward and not losing the many gains in health R&D that have been achieved.

⁴ DNA vaccines are "third generation vaccines". They contain DNA that codes for specific proteins (antigens) from a pathogen. The DNA is injected into the body and taken up by cells, whose normal metabolic processes synthesize proteins based on the genetic code in the plasmid that they have taken up. Alarcon JB, Waine GW, McManus DP (1999). "DNA Vaccines: Technology and Application as Anti-parasite and Anti-microbial Agents". Advances in Parasitology Volume 42. Advances in Parasitology.

At a 2017 conference examining what East African experts learned from fighting the Ebola epidemic in West Africa⁵, Dr Michael Katende⁶ sounded a warning which, three years later, came to manifest in the COVID crisis. Dr Katende stated that the experience of the delegates in combatting Ebola presented a "unique treasure of knowledge for preventing, combating and mitigating future outbreaks of infectious diseases of public health concern in the region and beyond."

Two years after the conference Dr. Ndekya Oriyo reasserted the central theme of the importance of African countries having the biomedical research capacity to understand and provide the medical basis to swiftly and comprehensively address disease outbreaks when they inevitably occur:

"Public health threats are increasing daily. It is becoming necessary to strengthen the research community in African countries to provide evidence and inform on disease outbreak and prevention not only within our boundaries, but also beyond because diseases affecting people in our communities do not have boundaries as is seen in outbreaks such as Ebola in Congo."

Several interviews for this report expressed concern that the poor resourcing for health R&D in Africa leaves countries vulnerable to epidemics and hampers decisive responses to them. Some also expressed the view that there must be broader R&D involvement of, and education for, non-scientist practitioners and role players. Both points were clearly reflected in the 2017 conference (East African Community 2018:30) in which participants expressed that:

"...research on preparedness, response and resilience lagged behind in the wake of the fast-moving epidemic due to limited human and financial resources, and this in turn led to further delays in research outcomes. Case managers were not involved in research and few national personnel had any training on research methodologies."

If the lessons learned from the Ebola epidemic, per the successes and weaknesses identified by the 2017 conference (East African Community 2018), had been used to better-inform health R&D policy and practice, the continent may have been in a stronger position to respond more decisively to the COVID crisis. In this sense, Dr Oriyo's (2019) call to urgently strengthen health research in African countries is also particularly noteworthy.

⁵ Lessons for the Future: What East African experts learned from fighting the Ebola epidemic in West Africa A regional conference with international participation held in Nairobi, Kenya from 6th to 8th November 2017

⁶ Then Principal HIV and AIDS Officer and Coordinator for the East African Community's Integrated Health Programme.

3.6. Advocacy Messaging

Highlights.

- There is a disconnect between priorities of the scientists and those of the policy makers.
- Identify opportunities to build government interest in R&D resource mobilisation and partner with government.
- Clinical trials do not necessarily benefit the people who are vulnerable to the very disease for which a treatment is being researched.
- Trials should be structured in a way that ensures the effective delivery of the final to the people in the host country who need them.
- Clinical trials are of limited benefit to vulnerable people when the host country's health system lacks the capacity to deliver the final product or treatment.
- Health R&D advocates must ensure that their proposals are cost-effective and align to government goals.
- Lack of public investment works against the ability of government and their partners to control the R&D agenda which would otherwise be well placed to focus on the country's particular health challenges (see Malawi and Eswatini case studies).
- Positive approach through a collaborative tone and solution-oriented proposals to government, potential funders and investors.
- Multidisciplinary approach in advocacy efforts for health R&D to strengthen their case.

3.6.1 Ensuring African Beneficiation

African stakeholders should not only become more actively involved but also take stronger leadership in advocacy for health R&D. A global health policy expert asserted that, while countries like South Africa and, Kenya have shown efforts in advocacy, the bulk of advocacy work is not undertaken by a majority of African countries.

Participating and collaborating during clinical trials should be the aim of Africa countries and its institutions. This will give them legitimacy to exert influence over key aspects of the clinical trials. Eventually the individual country will benefit by having their health research needs and concerns addressed.

The current covid19 pandemic is a low hanging fruit to be potentially exploited. Representatives from a global health organization stated that there is a great potential for COVID vaccine trials potentially occurring in Africa and could pave way to early access to a COVID vaccine in Africa. They recommended an advocacy strategy that reflects legitimate concerns around previous foreign clinical trials. One emphasized that: "You need to mitigate against the tendency to exclude real benefits for Africa in clinical trials, build trust among people and pave the way for early treatment for Africans."

In terms of clinical trials, the findings of this study strongly suggest that:

- Clinical trials do not necessarily benefit the people who are vulnerable to the very disease for which a treatment is being researched.
- It is a fundamental imperative that trials are structured in such a way so as to ensure the effective delivery of the products resulting from them to the people in the host country who need them.
- Clinical trials are of limited benefit to vulnerable people when the host country's health delivery system lacks the capacity to deliver the final product or treatment.

Opportunities for a country to benefit from technical transfer of knowledge, even beyond the health industry occur when adequate investment in R&D is made. This is the message a stakeholder from a pharmaceutical research organization underlined as important in helping policy makers and other stakeholders understand. Technology transfer (TT) is a process by which the knowledge and outputs of scientific and technical research are transferred into and utilized by the marketplace and in the broader society (European Commission 2020). Newly developed skills and procedures are prime examples of such transfer, ones which can have substantial direct and secondary benefits for a country.

Another stakeholder added that health R&D can facilitate linkages between economic centres, boost allied industries, and expand the manufacturing base (e.g. packaging) and the retail sector. However, the government must invest along the whole value chain in order to realize the fruits of the resulting health care products and the stimulation of other sectors. Such investment could have a substantial economic impact in addition to improved health outcomes for the population.

Finally, strong political will and leadership is the catapult required to drum up support for R&D. Co-financing for projects and programs has occurred previously in various aspects of health like HIV research. This is a prime opportunity and governments should be encouraged to take a much stronger role to help facilitate the expansion of health-allied industries, strengthen the links and work collaborate with health R&D to improve the value chain.

3.6.2. Empower Scientists and Policy Makers

The disconnect of communication between technical scientists and policy makers has led to politicians who do not have the full grasp of the of the tremendous value of R&D and its potential to foster improved public health, expanded higher education, new industries and other socioeconomic benefits. In fact, one medical researcher mentioned that there is continuing mistrust between government and scientists in many African countries. He paraphrased what he sees as a widespread and counter-productive attitude where some scientists say, in effect: "I work here and if they (government) don't come that's their problem. If they had their people at heart, they would come." If such attitudes are indeed widespread, it is important to educate the scientists themselves that they must be more proactive and initiate engagement rather than wait for politicians who never come.

New generation of scientists should undertake much more evidenced-based advocacy to government. This can be achieved if students in top academic institutions are taught the skills through inclusion of elements of the political economy of health R&D in the coursework.

Doctors and scientists should play a critical role bridging the gap between potential R&D funders and politicians. They should be more involved in political processes at all levels and using all opportunities to promote the idea of increased investment in health R&D. Previously, many opportunities have been missed. One doctor and institutional executive maintained that:

"When funders come, we must be in a position to facilitate their access to ministers. We often find ourselves in a situation where ministers say: "you've never come to my office."

He also identified the need have facilitators that keep the negotiations going between potential funders and government and to reinforce the notion to policy makers that they can use science as an investment tool.

Scientists should be more politically savvy and engage more actively in both formal and informal policy making and budgetary processes. While some anecdotal indicators in the recent literature, and in the interviews undertaken for this report, show an improvement since 2016, it is not enough. A medical scientist who is also an executive of a major funder organization, asserted that many scientists still lack

the skills to engage with government and also underlined how the two parties can have very different motivations and perspectives:

"Generally, scientists don't like to check boxes because they are fascinated by science alone– while politicians are interested in impact which they can showcase to win another election. We should ask 'what appeals to policy makers when they hear about my work"? This will open a door for them to participate in funding R&D."

The stakeholder claimed that many scientists are "obsessed with publishing in high impact journals" and sometimes criticize the same politicians they need to bring to their side, ending up being seen as opponents of the state.

"When I go to a ministry, I am sometimes asked why we (our organization) is funding a particular institution or scientist that is critical of the government. It is vital to relate well to politicians in private. We should say 'we will do this on your behalf, 'we will help you solve these problems."

This suggests that, in Africa, spinning a public narrative that a government experiences as sharply critical or shaming, may be counterproductive. Rather, advocates need to position themselves as assets, potential partners and allies who will help government meet the country's most pressing health challenges through expanded R&D.

3.6.3. Address Government Concerns and Priorities.

It is also important to understand the challenges that many African governments face, even when key officials are supportive of health R&D, especially in terms of competing priorities for expenditure from a limited public fiscus. From this perspective, it is helpful to make the case to government in the context of monetary and budgetary issues. For example, with the input of supporters with the right expertise (including economists), R&D advocates could develop a solid case that funding a particular intervention would save government money. The cost of not investing could be, for instance, higher rates of morbidity and fatality, great pressure on the public health system and a slowing economy could also be demonstrated to government. One stakeholder, who had undertaken health R&D advocacy with several governments, emphasized that:

"We need to show that our proposal is a cost-effective measure. It is the job of a minister to make decisions based on finances. Civil society must learn this. We don't do this enough in Africa."

Some stakeholders expressed the sense advocacy campaigns for greater mobilization of domestic resources for health R&D must go well beyond simply engaging with politicians and the formal policy making process. Building support for health R&D needs to involve a broader community movement, including young people. One stakeholder argued that:

"We need to get the youth involved and build their capacity for advocacy. In South Africa there is a dearth of leadership from the old guard and us a need new generation of health activists."

This stakeholder argued that younger activists would be more adept at using social media and blogging to educate others of the need for greater health R&D, in addition to print and electronic media journalists and commentators. She also emphasized the need to communicate hope, achievements, and positive

messages and to create a vision when undertaking advocacy to government. Using the example of HIV prevention R&D she maintained that:

"We need to demonstrate in numbers how many lives have been saved through the outputs of R&D, and how many more could be saved through greater investment. Politicians like to hear this this, especially in terms of mothers, children, pregnant women, girls, etc. If there is information on these demographics, we need to calculate how much we will be saving from pockets of citizens and the state."

Health R&D has multiple interdependencies with related disciples and can both gain from and contribute to them. A research and development official from an international health NGO underlined the importance of engaging with government on multiple levels and with multiple departments to ensure maximum outcome. He notes that the Ministry of Finance may have vast influence in terms of budgetary priorities but that Ministries of Education, Health, Science & Technology and others may also play an important role in facilitating greater resource mobilization for health R&D. The stakeholder explains:

"We have other research institutions in the country including Wellcome Trust and many others. We need to bring them together even if their prime foci are is different. Health research is a specialized discipline but a number of researchers affect health. It could be Agriculture that is looking at genetically modified food – This not health research but it is a research for health."

The need to demonstrate the economic value of health R&D to policy makers is a strong theme that emerged from this investigation. To do so effectively, advocates need to better-understand the wide range of primary and secondary socioeconomic and other benefits that greater investment in health R&D will bring to a country. When engaging, advocates should use language and contexts that policy makers understand and which are most relevant to them. Advocacy efforts would be strengthened in this sense by such things as building a broader movement to support health R&D, collaborating with institutions and persons with expertise in such disciplines as economics, public finance, international development, industries allied to health and broader civil society organizations.

At least two stakeholders suggest another angle of engagement with government of comparing the achievements through health R&D in different countries, along with all of the benefits a more involved country can achieve. One interviewee explained:

"if we can identify our bottom line it will be easier to compare how we are doing compared with other African countries and looking at those country's return on investment – e.g., number of jobs created, lives saved, health economic indicators, quality of life, adjusted life 3 years, etc. Just by inventing 2 or 3 products this is what we see."

It is important to create a sense of potential economic development opportunities arising from public investment in R&D. Whenever possible this should include calculations of how much such investment could add to revenue and or / ultimately save money for the saving the national fiscus.

Many funders want politicians to attend scientific meetings and other fora, yet few scientists support meetings which they see as political. Yet, advocacy efforts could be more fruitful if more scientists learned to, and were willing to, articulate the benefits of health R&D in a way that would appeal to politicians. There should be a balance between academic output and political engagement and advocacy for sustained research and development.

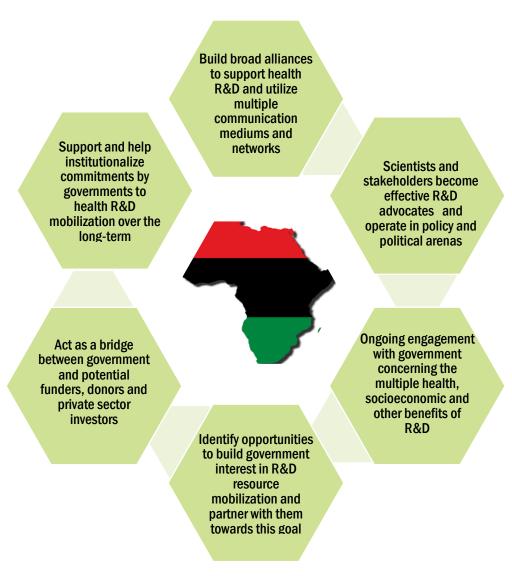


Figure 1: Building government and multi-stakeholder support for R&D mobilization.

3.7. African Control of the Health R&D Agenda

Highlights

- 1. Health R&D in Africa must be context relevant and must prioritize value to the continent.
- 2. The Africa Union needs to coordinate financing mechanisms for health R&D in the region.
- 3. Health research resource mobilization must be coupled to robust accountability structures.

3.7.1. Capturing the Benefits of R&D

A consistent theme that emerged from the interviews was the sense that much of the health R&D undertaken in Africa does not necessarily benefit African people. A number of stakeholders spoke to the need to further "Africanise" the health R&D agenda so that it becomes more relevant to priority health concerns on the continent.

A health policy expert felt that that much of the health R&D that takes place in Africa is too "northern-centric" and does not sufficiently recognise the vast socioeconomic and sociocultural differences between the Industrial North and Africa. The result of this can sometimes be the alienation of African people and the output of products and programmes that do not necessarily work well for them. In the context of HIV-prevention, a scientist asserted that important aspects affecting the research are often neglected. One

such aspect is a poor understanding of sex, intimacy and health, which are therefore not woven into prevention R&D. One expert, a genetic scientist, contended that:

"A lot of research is done in Africa that does not benefit Africa. For COVID and other diseases, when people say 'let's try that outside of Africa', we need to ask at what point do we get products that respond to our gene pool"?

Speaking to the sense of alienation, a health R&D advocate, who works in several countries across the continent, lamented what he saw as a high level of resignation and even apathy among Africans in terms of participation in clinical trials and even mediation adherence.

"This is the case even with people whose relatives have died. They may well ask 'Why should we keep on participating if our people are going to die anyway"?

3.7.2 Financial Models

The development of clear and context-relevant financing models, strategies and mechanisms are necessary in order to generate more public, private and international investment in R&D throughout the region (Simpkin and Namubiru-Mwaura et al: 2019:1). While identifying elements for financial models to facilitate expanded health R&D is beyond the scope of this report, there are some important indicators from the literature and interviews which could inform the development of such models.

One stakeholder, an advocate for health R&D, argued that financing needs to be addressed, not just by individual countries, but by much broader regional alliances. On the issue of finance, he strongly underlines the need for coordination within the African community and asks:

"How can we build an R&D financing mechanism for Africa? To do so within scope of Africa Agenda 2063. The African Union Development Agency (AUDA-NEPAD) must be at central coordinating point to bring in all of these players."

The stakeholder also identified that a prime purpose of Agenda 2063 is about building an R&D ecosystem and that this must include developing a financing mechanism for Africa.

Accountability International (AI) (2019) notes that Africa has played host to a great many clinical trials testing interventions to understand and ameliorate conditions or co-morbidities of HIV and, in more recent years, prevention of HIV infection. Yet, Al also asserts that the range of resources brought by African countries can be considerable and often go largely unrecognised.

"While African clinical trial participants provide an immeasurable benefit to these trials by volunteering their time and bodies, African countries also contribute through uncompensated costs borne by African communities when research occurs in their institutions, hospitals, and clinics" (Accountability International 2019:11).

Noting that African countries, through trial volunteers and the provision of staff, support and infrastructure, have contributed to vast global advances in HIV R&D in particular, Accountability International (2019:11) argues that such contributions should be more acknowledged and supported.

"This investment (by African countries) should also be supplemented through donor assistance in technical and financial support to build up clinical trial capacity in Africa. This is a matter of equity and good trial practice."

3.7.3. Tracking and Monitoring

The lack of effective tracking mechanisms works against the push for greater mobilisation for resources for health R&D. Several sources suggested that many governments simply do not know exactly how much they are investing. One R&D advocate explained that:

"When we ask for investment by the state, government responds by asking asked 'why do you need the money', what will it do? why is it not enough as now"? However, in many instances, the state does not know what is putting in terms of health R&D. They lack the institution arrangements to track it.

Just as there needs to be sufficient political will and a firm commitment by government in order to mobilise R&D resources (and use resources productively and efficiently), Accountability International (AI) (2019) identify that there must be the commitment and the mechanism to track the progress of research, in this case HIV.

"There is no purpose in developing a response to increase HIV financing in a country if we identify at the research stage that there is already an existing lack of political will to track the epidemic and respond to it until now."

A significant theme arising from this investigation was that African countries would have been much better prepared for the COVID-19 pandemic if bio-medical R&D had been well-funded and undertaken in a collaborative manner across regions. As an example of a missed opportunity, one medical scientist noted that the herb a*rtemisia* (often used in traditional African medicine) grows widely in Southern Africa including Madagascar. Madagascar had commenced research into the medicinal properties of artemisia, research that should have continued and been expanded in Africa. Yet, it was scientists in the United States who studied the main components of the herb, cultivated it and developed a purified form which, as of August 2020, was being trialled as a treatment for COVID. By then German scientists had begun testing the plant's potential against COVID (DW 2019).

3.7.4. Insurance

The limited or complete lack of coverage offered the African insurance companies may be another inhibiting factor for clinical trials being undertaken on the continent. One medical researcher lamented that "we have struggled to convince local companies to cover trials." The researcher noted that, in some cases, companies have provided insurance in South Africa while their subsidiary or branch in another African country refuses to do so. He concluded:

"I have a feeling that the risk of trial insurance is misunderstood by most African underwriters and because death and disability can occur in trials they decided not to participate."

3.8. Creating an Enabling Environment for R&D Investment and Private Sector Involvement

Highlights.

- Promote more public-private partnerships in health R&D
- Leverage on existing financial and non-financial resources
- On boarding and capacity building of local staff to ensure ownership and acceptance of clinical trials.
- Encourage utilisation of local existing human resources and institutions.
- Government should streamline the official processes for companies to undertake trials and reduce the current burdensome bureaucracy.
- Government must negotiate to ensure that trials are structured and conducted in a manner that will confer benefits of the host country and communities.

3.8.1. Clinical Trials

The African Union's Specialized Technical Committee on Education, Science and Technology (AU 2020) underlined that, since 2014, there has been substantial effort and achievement by member states, and the AU itself, in establishing vital institutions which can help develop an enabling environment for Science, Technology and Innovation (STI). Such institutions cited by the AU (2020) include the African Centre for Disease Control and Prevention (Africa CDC).

While potentially of great value to Africa, clinical trials controlled by non-African entities are not necessarily benefiting the people who are vulnerable to the very disease for which a treatment is being tested. In many cases, the outputs of such trials provide a vast net gain for countries of the Industrialised North and comparatively little for African countries. Yet, there is great potential to attract substantial investment from, and collaborate with, pharmaceutical companies to expand trials on African terms (with greater local influence and control) in order to benefit from the health and local socioeconomic outcomes.

Governments must further ensure that there is a conducive environment to attract companies to undertake and invest in the trials. Carrying out drug studies can be extremely expensive. A medical scientist and programme director advised that;

"We need to find intelligent ways to leverage funds for these trials and to also leverage non-financial resources."

Governments should offer incentives and valued partnerships beyond the clinical trials. In the past, companies may have been reluctant to invest in drug trials because some have had the experience of inheriting responsibility for the ongoing care of the participants beyond the trial period. Complications and expenses related to mass recruitment of participants for trials may be another factor contributing to the reluctance of some companies to undertake them. Government and its partners could work closely with the companies helping to structure and drive the recruitment. This may also lend greater legitimacy to the trial in the eyes of potential participants. One scientist and programme director argued that government must be open to other incentives and that simplifying administrative processes, the complexity of which, and length of time it can take, could serve as a disincentive.

"Government partnering to cut through red tape is a prime example of how an attractive environment can be created. In many instances, researchers have found it near impossible to navigate the bureaucracy."

Sometimes health care staff feeling alienated from the research, not seeing the benefit in it and feeling that the presence of the R&D operations can be hindrance to their own work. Delegates to a 2017 conference reflecting on lessons learned from the Ebola (East African Community 2018:30) identified a major deficiency in that local "case managers were not involved in research and that few national personnel had any training on research methodologies." There were also incidences of resistance from, and even sabotage by, local health workers. One stakeholder identifies an important role of government in bridging this gap.

"It's also about counselling local managers in clinics and hospitals on the importance of the role of the researchers to the health agenda of the country. Local officials and practitioners need to come to see the researchers as partners who need assistance."

The companies and the researchers themselves also have some responsibility here and, if government facilitates the process, they too must work collaboratively to promote understanding of the importance of the research among local health providers. Some short-term tangible benefits for clinics and hospitals, even if relatively minor, may help this process.

3.8.2. Private Sector Participation

The need for synergy and pooled resources calls for enhanced public-private partnerships. Several national statements, and international agreements to which African governments are party, underline the need to leverage more private sector investment in health R&D (WACI Health 2016). Increased public investment, if well-targeted, should serve to leverage more private funds and develop productive public-private R&D partnerships. Caveat is that the government ensures that research processes and agreed-upon outputs are aligned with the country's health R&D needs. There are many opportunities for win-win situations in public/private funding for health R&D, one stakeholder concludes that:

"Civil society has an important role to play in first convincing government, bringing parties together and in ensuring there is sufficient public benefit from such partnerships."

In the year 2020 private sector plays only a fraction of its potential role. There are very few private hospitals and private which feature in high performance R&D networks. Lack of solid business models attached to R&D leaves limited donor and public funding to make up at much of the investment vehicle gap. There have been many lost opportunities here. One stakeholder cited evidence that in many countries in the Industrialised North, the initial investment in developing candidate molecules for potential vaccines, drugs or diagnostics is made by private businesses. One medical scientist noted that while Nigerian businessman Aliko Dangote has begun to invest in some aspects of health R&D, the levels of private sector investment at both the country and regional levels remain very low. It is imperative to better-understand why so many private sector entities are excluded or exclude themselves from health R&D.

An executive of a research institution underlined the importance of assisting governments to develop good business models that attract investment from partners for expanded R&D. He asserts:

"In as much that governments can put in their own funds – we must help them develop good business models that will attract partners... Partners require strong, well-functioning institutions. But many countries are not able to attract big companies because we don't have the infrastructure with strong governance."

This stakeholder argued that the critical need for strong business models to attract private investment needs to be demonstrated to government. He maintained that the current set up is a *consumption model* that is entirely unsuitable to attracting investment.

"If we have institutions that have good business models and are able to produce good products that can generate money, even local banks may come on board. It would fit into the ethos of solid investment."

In most countries of the OECD⁷, the private sector is the largest source of R&D funding. In Africa, however, significant proportions of financing in many countries comes from international sources (in addition to limited public sector sources). It was also found that some of the challenges that limit private sector investment in R&D in Africa include perceptions of unstable political environments, poor governance and corruption. (Simpkin *et al.*, 2019)

One academic specialising in psychological and socioeconomic aspects of disease and public health, underlined the importance of a well-functioning public sector in supporting health R&D and pointed to significant successes in economically stronger countries in Africa. However, the role of the private sector is not as clear:

"The question arises as to what is the contribution of the private sector to R&D. This is a weak link and there has not been much appreciation, and they have not quite been playing ball."

The stakeholder stated that the private sector contributes its own resources and skills to R&D along with some support to community health services. He further agrees that there is much more space for the private sector to participate, leading to greater benefits for public health and even for the companies.

The Health Research and Innovation Strategy for Africa (HRISA) (AUDA-NEPAD 2019:9) identifies limited participation of the African private sector in most of the research projects as a significant gap. HRISA places this issue in the broader context of the low levels of funding from both public and private sectors making health research dependent on external funders. The Strategy also asserts that:

"Even more disturbing is that for most countries, health research and innovation is mainly funded by external partners outside Africa, which is inadequate, unsustainable and often not targeted at national health research priorities."

Promoting more public-private partnerships in health R&D is also underlined by HRISA (AUDA-NEPAD 2019). In its 2019 *African HIV Financing Scorecard* Accountability International (AI) found that, Public Private Partnerships (PPPs) were not just effective investments for HIV financing but also the quality and acceptability was high.

The scorecard also cautioned on the danger conflicts of interest can play in corrupting the PPP sector. Setting up transparent accountability frameworks with all parties in PPP's agreeing to work towards agreed objective is one way to mitigate this.

⁷ The Organisation for Economic Co-operation and Development is an intergovernmental economic organisation with 37 member countries, founded in 1961 to stimulate economic progress and world trade.

3.9. Collaboration within Africa

Highlights

- It is critical that African countries collaborate in R&D to solve shared problems.
- Pooling resources for health R&D among LMICs bears great potential for multiplier effects.
- A common market approach is essential in spurring collaboration, including in health R&D and regulation, in Africa.
- Political goodwill and partnership with Government are enablers to impactful health R&D.
- Understanding contextual differences and their impact on collaborative R&D efforts is key.

The need for African countries, at least in regional settings, to collaborate closely was emphasised by many stakeholders and in the literature. HRISA (AUDA-NEPAD 2019) identifies that there is a low-level of research collaboration among African researchers. This is demonstrated by the estimate that South-South collaboration in the period of 2010 to 2014 was at less than 5%, whereas collaboration between African researchers with Europe and America was more than 40%. The strategy emphasizes the need to "strengthen collaboration in research in Africa in order to collectively solve shared health problems" (AUDA-NEPAD 2019:12).

One of HRISA's identified priority interventions is:

"Strengthening health research & innovation and training capacity through South-South, North-South collaboration and fostering linkages between researchers, research institutes, industry, and governments as well as regional and global stakeholders" (AUDA-NEPAD 2019:18).

Connell et al (2018) argue that while there is considerable support for more South/South connection around health R&D, there are few economic resources for it. This is precisely where even relatively small contributions by African governments working to create such collaborations could be pooled to create a multiplier effect. Developing a basic pool would provide a sound basis to leverage further funds. Such collaborative efforts may be attractive to donors and investors given the likely economy-of-scale and other positive features.

A number of interviewees underlined the importance of cross-border and regional collaboration while utilising and building on the already existing substantial body of health R&D initiatives in various countries. This sense captured by Simpkins and Namubiru-Mwaura et al (2019:1) who assert that:

"Disparities in R&D capacity within Africa suggest the likely value of support for collaborative science, technology and innovation networks between African nations, with any new partnerships harnessing the substantial momentum of R&D initiatives that already exist."

A regional accelerated pooled funding model for health R&D may be a suitable one for Africa to consolidate skills, and provide a strong and cost-effective platform to address health challenges for entire region. One stakeholder suggested that pooled funding in Africa for COVID-19 responses would have been of immense benefit.

The future prospect of maximizing value and building capacity in conducting clinical trials in Sub-Saharan Africa lies in countries working together in existing programs such as demonstrated in the Eastern African Consortium for Clinical Research (EACCR2).

Noting that developing a strong R&D ecosystem for low- and lower-middle income countries is a costly affair, one stakeholder explained that his organisation (an enabling and funding body) has, in recent years, made efforts to bring in more countries. Emphasising the need for close collaboration and resource-sharing around health R&D between countries with differing assets, he argued that:

"All lower and middle-income countries should come together through economic regional communities and share capacities. Kenya (for example) may not have the land but it has the expertise. In lower-income countries they may have the land and other resources to bring to build capacity. Everyone has something to offer. We need to think about this innovatively. Once Africa is together, we could move as unit."

The goal of developing a broader, internationally collaborative R&D ecosystem not only lends itself to greater inclusion of smaller and lower-income countries but also to more efficient use of scare resources. Noting that not all countries can afford the infrastructure required for expanded health R&D, a senior executive for a national science council asserted that the region must approach this as a common market and with the same set of regulations. She added that manufacturers should be incentivised to produce for a regional market rather than a country-by-country strategy.

This approach makes for good *economy-of-scale* and is facilitative in terms of putting larger regional facilities in place. A stakeholder from an Africa-focused NGO concurred. Arguing that regulatory bodies are neither modernised nor functioning to ensure that research proposals get underway in a timely manner, she advocated for a system of regional regulation covering numerous countries with an expert, well-functioning authority.

However, as noted in Section 3.2, this study has also found that there can be great benefits in facilitating small- to medium-scale health R&D programmes in individual countries8 and in developing local capacity for such. There is substantial evidence of this in larger, relatively well-resourced countries. But most notably, the three case studies included in this report illustrate that even in small, low- to lower-middle income countries, when there is strong political will and close collaboration with government, the outputs of health R&D efforts can have significant impacts in terms of addressing the most critical health needs specific to the country, influence the development and implementation of health and health industry policies, and spur local social and economic development. It is in no way an "either-or" scenario between developing regional R&D centres of excellence, a common market with the same set of regulations, etc. and developing health R&D sectors in single countries. All of these can be achieved if there is sufficient and sustained political will and an active, long-term commitment to mobilising the necessary resources.

While strongly supporting the notion of greater regional collaboration on R&D, an executive with an international NGO sounded a note of caution. She emphasized that it is vital to understand the range of regional contextual differences that will affect most aspects of collaborative efforts. She asserts that there are vast cultural differences across the region, including, but not limited to language. What might be understood from the perspective of government and scientists in a Portuguese language setting, for example, might be understood very differently in an Arabic Muslin context. It is therefore vital to consider what this means for collaborative R&D.

⁸ See all three case studies.

3.10. Pharmaceutical R&D and Manufacturing

Highlights.

- Few African countries are active in pharmaceutical manufacturing.
- Potential to attract South-South private sector investment as well as for spurring job creation and local economic development.
- Governments can facilitate the growth of a pharmaceutical manufacturing through investing in this branch of R&D, developing a regulatory framework and working with potential investors.
- The case to be made to governments to invest in R&D towards the goal of local production of active pharmaceutical ingredients and intermediates is extremely strong.
- An expanded manufacturing industry would help ensure that pharmaceutical R&D into the country's most critical disease treatment concerns can inform the development of products much more quickly and at reduced costs.
- Stepwise approach in building a network of laboratories to work together regionally.

The Pharmaceutical Manufacturing Plan for Africa -PMPA (African Union 2012) emphasises the importance of R&D biological production as a prime focus area for Africa and of developing expertise in this field. R&D in biotechnology has great potential in developing pharmaceuticals for uniquely African diseases and providing opportunities for optimizing traditional medicines. It notes that African countries had very limited capacity for the production of biological products and emphasises the need to develop different models for the development of this segment of the industry given the unique manufacturing, distribution and market considerations that apply.

Over 8 years since the establishment of the Pharmaceutical Manufacturing Plan for Africa (PMPA), the number of African countries producing medications has barely changed and almost all countries are net importers of medicines and various pharmaceutical products and technologies. While there have been significant developments in pharmaceutical manufacture in some African countries in recent years, much of the vision and many of the objectives of 2012 Pharmaceutical Manufacturing Plan for Africa (PMPA) remain unrealised. While pharmaceutical manufacture is increasing in several countries, a core inhibiting factor is that almost all pharmaceutical ingredients and intermediates are imported.

Regulatory authorities in many countries lack the basic capacity to oversee the supply of products. Countries with medium level of manufacturing output like South Africa, Tunisia and Algeria have stronger public institutions which have provided both support and regulatory oversight. The PMPA also noted the high level of pharmaceutical manufacture in other developing countries such as China and India, have benefited from a number of policy measures. These include; protection through tariff regimes, procurement preferences, interest subsidies, export credits, cheap utilities, working capital credits and tax holidays. On the other hand, the PMPA notes that, rather than developing an enabling environment for manufacture in these ways, some African governments have actually provided subsidies for pharmaceutical imports and slashed (or eliminated) tariffs. It was also found that there are limited domestic capabilities to undertake the experimental development or translational research phase. Thus the need for expert government oversight and the creation of a conducive environment for investment, (Simpkin *et al.*, 2019)

Unexpected crises can lead to severe inequality. A medical scientist and funder-organisation executive warned that "If (African) countries have no R&D and support the manufacture of their own products; this leaves them very vulnerable to crises. According to him, the COVID crisis has demonstrated how vital it is to invest in the expansion of pharmaceutical manufacture in Africa. Together with his colleagues, they pointed out that as a result of the COVID crisis and lockdown, governments and UN bodies like WHO,

UNICEF and other such entities providing treatment rely on a pharmaceutical supply chain which, had unfortunately slowed down. They expressed their grave concern to governments that the shutdown of these supply chains could result in medication shortages and could even impede the availability of a COVID vaccine.

It is important to note that many such impeded supply chains originate not from high-income countries but from other middle or lower-middle income countries where there is significant capacity for vaccine manufacture. An executive member of a large research entity quoted figures from the South African National Department of Trade and Industry (DT) which showed that approximately five percent (5%) of that country's trade imbalance is related to pharmaceutical imports, the fifth largest item contributing to this deficit. This situation spurred the South African Government to support plans to expand pharmaceutical production in that country, a decision that was most likely arrived at through strong advocacy by, and close collaboration with, a range of key stakeholders. Encouragingly, as of mid-2020, the South African Council for Scientific and Industrial Research (CSIR) was undertaking research to produce drug prototypes that can be taken into further clinical development.

The production and manufacturing phases of the value chain remains weak even as African countries have built capacity for the third phase of clinical trials. A mix of regulatory and financial barriers to commercialisation, weak intellectual property rights and a lack of basic infrastructure are factors inhibiting pharmaceutical R&D and production in Africa. (Simpkin *et al.*, 2019)

Globally, pharmaceutical companies are among the top investors in R&D in the health science sector, however, this is not the case in Africa. Few African pharmaceutical companies have R&D units or R&D directors to oversee product development and technology transfer (Simpkin *et al.*, 2019). The need to build such expertise in Africa is critical if the pharmaceutical manufacturing industry is going to flourish.

Investing in in R&D towards local production of active pharmaceutical ingredients and intermediates by governments is needed. If implemented successfully, then creation of local job opportunities, reduced dependency on imports, as well as improved affordability of essential drugs are outcomes expected.

To implement this, a step-wise approach is the preferred option. A researcher and director who engages frequently with government, advises that prior to scaling up manufacturing centres, stepwise capacity building should be carried out regionally. He further explains that:

"If we have networks of labs which can conduct high-quality trials, then we can build on this. We need a network where scientists work together as a team – possibly a federation – or Pan African consortium. This may mean developing a solid Pan-African platform in which good centres at same level of accreditation can work together."

The stakeholder uses the hypothetical situation of a COVID vaccine being developed. In that instance, there should be enough centres to do trials in shortest possible time. But very few centres in Africa would be ready to take a COVID or an HIV vaccine to licensure. They lack fundamental capacities in genomic techniques and bio-banking, or connections with centres that have them.

3.11. Resource Mobilization in Low-Income Countries

Highlights.

- Disease burden justifies earmarking resources for health R&D in LMICs.
- Governments should go beyond non-financial support to health R&D and actually fund R&D. This not only signals commitment but is also key in incentivizing additional investment by partners.
- Transparency in the utilization of health R&D funding essential for continued investment.
- Health R&D funding proposals must demonstrate mutual value to governments and partners.
- Tertiary institutions are plausible targets for investments in health R&D.

An important question addressed by some stakeholders was that of whether it is reasonable to ask governments of low- and lower-middle income countries to earmark some of their own fiscal resources for Health R&D. A scientist and funder (who is close to several Ministries of Health) responded that:

"It is reasonable. The case is not being made by us - It is being made by diseases. It is the poorer countries who suffer the burden (of the lack of R&D). It is in their interest to do so and would bring them much more to the forefront."

At least three stakeholders maintained that even relatively small budgetary commitments by governments - in addition to forms of non-financial support — can send a powerful message to potential investors and donors that such a government is committed to expanding health R&D. One scientist noted that there are several African countries with heavy disease burdens which are contributing nothing in terms of cash even if they are willing to provide in-kind support. A programme director, however, asserted that, while very welcome, non-financial support provided by government:

"...cannot solve all problems and is therefore not translatable in terms of equipment, skills development. Some poor countries' GDP has increased in recent years to over \$1000 per capita. If only two percent of that \$1000 goes towards the health of a citizen, and a portion of that to R&D, it is still a very small amount, but it would make a great difference."

Simpkins and Namubiru-Mwaura (2019) maintain that incentivizing investment is crucial to foster current and future research output and research capacity. A number of respondents expressed the sense that African governments need to make a stronger financial commitment to health R&D in order to a leverage matching funds. A scientist and programme director asserted that:

"Lots of countries would be willing to match funding but not be the sole provider. They want to see that the country is buying in. There are huge opportunities here. From the government side, it only needs to be limited amounts of money but enough to say, "we are serious about this."

This stakeholder noted that that South Africa has had significant success in attracting investment through matching funds in various proportions. He argued that countries should make calls for proposals in which they say, "we bring some domestic money, and you can track (or together we can track) the use of these funds." This underlines the importance ensuring that there is a proper process and full transparency in the allocation of such domestic resources.

Proposals need to be balanced in such a way as to attract funders whilst ensuring that the country benefits from the outputs of the R&D. Buy-in may have great benefits for the donors and this is an important

negotiating platform to help ensure that the health R&D addresses concerns relevant to the country and yields tangible benefits for all parties.

Staff at a global health organization maintained that, where possible, funders should support R&D that spans low-, middle-, and high-income country. Governments of lower-income countries in particular need a strong presence in the relevant forums to advocate and build support for such opportunities. These stakeholders also reinforced the contention that it should not be necessary for governments of lower-income developing countries to commit a substantial amount of public funds. One interviewee asserted that:

"If there was a matching program – just in terms of start-up capital - there would be possibilities created. But in the absence of such a commitment, such opportunities are lost."

The stakeholders maintained that investing in universities in countries where governments show an interest is often a good option. This can build on existing infrastructure and lend itself to "right sizing", i.e., designing the research facility or project at a size in which it can be appropriately supported. Some universities in lower-income countries already have sufficient infrastructure on which to base the building capacity for clinical trials. In Africa, some countries may have language barriers which might complicate building capacity for trials and other health research. However, two stakeholders pointed out that Mozambique, has built up an equivalent of a National Institutes of Health (NIH).

4. Recommendations and Conclusions

4.1. Most Critical Health R&D Priorities

4.1.1. Prevention R&D

Governments should prioritize investments in disease prevention R&D.

- The "lowest hanging" fruit that costs government the least is prevention. But the most effective prevention measures and approaches can only be identified through rigorous and contextualized R&D.
- Disease prevention R&D, and the timeous application of its findings in public health policy, programmes and services, will help relieve burdens on the health system and budgets while concurrently helping to reduce morbidity and mortality rates.

4.1.2. Implementation Research

Governments and researchers in LMICs should prioritize investments in implementation research in health as well as building local capacity in the same.

- While basic biomedical research will usually only produce a payoff in the medium to long-term, implementation research can provide for shorter-term effects in terms of tangible results and in making an impact.
- Investing in R&D efforts to improve health delivery systems provides for "quick wins", enables the timely application of results and outputs biomedical R&D, provides for better targeting of health resources, in addition to ultimately reducing costs for government.
- There is a need to better understand the links between poverty and disease. In Africa, health R&D must have broader focus than biomedical research and needs to address the connections between disease and socioeconomic, environmental, infrastructural and other factors.
- Governments need to understand that when they invest in, and help mobilize resources for health R&D, it
 is not just improved health outcomes that will result. Health R&D with interconnected foci can provide vital
 information to inform government policy and efforts to address poverty, act on environmental concerns
 and improve infrastructure.
- Investment in biomedical research must be complemented with investment in health system improvement. Biomedical research may produce exceptional products and outputs, but the value of these are only realized when health systems are structured and functioning in such a way so as to effectively implement or deliver them.
- Effective implementation R&D and the operation of effective health services delivery relies heavily on access to comprehensive, well-functioning health information systems (HIS). Such systems require substantial improvement in most African countries.

4.2. Advocacy and Core Arguments

Health R&D advocates must learn to demonstrate that their proposals are cost-effective measures for government. Consequently, the advocates must build their capacity in effective targeted communication as well as in economic analysis of proposed interventions.

- Such fiscal / budgetary knowledge must be built in addition to being able to effectively articulate the range of
 other health and socioeconomic benefits that expanded health R&D investment will bring, benefits that will
 enable government realize some of its broader objectives.
- It may be a powerful argument in some cases to outline the consequences of *not* investing. In addition to increasing rates of morbidity and mortality, and great pressure on the public health system, such consequences could include contributing to a slowing economy, a worsening trade imbalance, reluctance of potential business and funder entities to invest, a "brain drain" of science and medical professionals and the loss of the R&D benefits to other countries.

- Lack of public investment works against the ability of government and their partners to control the R&D agenda which would otherwise be well placed to focus on the country's particular health challenges.
- Avoiding a conformational approach, civil society health advocates and scientists should work to ensure that
 government views them as potential assets, partners and problem solvers with whom relationships can be
 formed towards the realization of health objectives and the mobilization of resources. Civil society and
 scientists should also seek to play a facilitative role between government and potential funders and
 investors.

4.3. Forming Alliances for Advocacy

Advocacy efforts for health R&D would be strengthened by partnering with experts in such disciplines as economics, public finance, business and international development, industries allied to health and others.

• Such collaborations could be used to help form and advocate for, well-founded and broader arguments to take to government concerning the secondary benefits of health R&D.

4.4. State Resources

Governments must invest in strengthening monitoring and evaluation systems to ensure real-time and accurate tracking of investments in health R&D as well as transparency and accountability.

- Many governments are not even aware of much of the health R&D being undertaken in their countries, let alone how such are supported through public mechanisms. A greater understanding (e.g., a national audit or evaluation) of how a government provides direct, indirect, financial and non-financial support in a country could generate indicators that government may wish to showcase.
- In terms of securing greater state investment, advocates could argue along the lines of: "Look what we already bring to health R&D. Imagine how much we could achieve towards national health goals with some public financial investment to leverage more funds, (and how much more the government would be recognized for the R&D products and outcomes)."
- Beyond a strong political will to mobilize health R&D resources, there must be the commitment and mechanisms to track and monitor the progress of the R&D, its outputs and outcomes. This will not only provide vital information to help improve R&D and identify its impacts but may also produce positive material that governments may wish to showcase.
- Such proposals, however, would need to outline measures to ensure good governance, transparency and the containment of costs.

4.5. R&D at Regional and National Levels

Governments in LMICs must prioritize and ensure budgetary allocations to health R&D beyond the non-financial investments as this has the potential to attract additional investments by partners and demonstrates local commitment.

- Even relatively small budgetary commitments by governments of low-to middle-income countries in addition to forms of non-financial support can send a powerful message to potential investors and donors that the government is committed to expanding health R&D. There is great potential for the leveraging of matching funds that amount to considerably more than the government contribution.
- While there is considerable regional support for more South-South collaborations around health R&D, there are few economic resources for it. Even small contributions by African governments working to create such collaborations could be pooled to a produce a strong multiplier effect.
- Collaboration at the regional level to develop or expand health R&D Centres of Excellence need not require the development of new facilitative, regulatory or implementation bodies. Such centres could be developed and integrated through existing AU structures and / or economic communities and blocs.
- Governments should understand that such centres provide for great economy-of-scale in terms of costs, a
 highly suitable platform to address regional-wide health problems, to leverage substantial funding and

- private investment, widespread capacity building and the best collaborative environment to develop vaccines and drugs for Africa.
- However, as illustrated by the unfortunate demise of the African Network for Drugs and Diagnostics Innovation (ANDI), a major risk in the development of Health R&D Regional Centres of Excellence in Africa is that they will not be sustained over the long-term. Efforts to establish or revive such institutions must include rock-solid commitments from a wide range of stakeholders, including some financial support from governments, a long-term plan to grow and expand funding sources and the backing of financial institutions such as an African Development Bank.

4.6. Attracting Investment

Governments in LMICs must take lead in creating an enabling environment for collaborations in health R&D through effective regulation (laws, policies, regulations) and responsive governance.

- A key indicator of an attractive environment attractive for potential funders and partners is where the
 government takes a catalytic, facilitative and oversight role in close collaboration with stakeholders, and
 drives the effort to mobilize resources.
- However, in as much as governments work towards creating such an environment (including earmarking their own funds), inadequate financing and business models, and poor infrastructure, continue to deter potential investors. But many countries are not able to attract big companies because they do not develop quality business models or even the necessary infrastructure with strong governance.
- Working closely with government, Health R&D stakeholders should assist in developing good business models
 in order make investment in health R&D more attractive.⁹ To do so may require collaboration with experts
 in such fields as businesses management, public administration, business economics, legal and others.
 Once finalized, governments must make firm commitments to the implementation of the business
 model.

4.7. Clinical trials

Government must negotiate to ensure that trials are structured in such a way as to promote delivery of the products resulting from them to the people in the host country who need them.

- An experience of non-cooperation and even resistance from staff at local health authorities and facilities
 when trials are underway, has inhibited the appetite of some drug companies to invest in new trials.
 Government must make every effort to educate such staff as to the vital nature of the trials and act as facilitator
 to address any legitimate concerns they may have.
- But the companies themselves must also address this challenge. A condition of the approval trials should be that the country's domestic pharmaceutical R&D personnel and health institutions are incorporated in the trials to the extent feasible and that there is a legacy plan to further build and capacitate the domestic pharmaceutical R&D sector.
- Companies may be reluctant in invest in drug trials because some have had the experience of inheriting
 responsibility for the ongoing care for the participating patients once the trials have been completed.
 Government could change this by guaranteeing that the state will accept a transfer of the care for such patients
 once the trials are competed.
- Government should streamline the official processes for companies to undertake trials and reduce the current burdensome bureaucracy (while maintaining full transparency) which, in many countries, works against potential investment in trials.

⁹ A Health R&D business model may, for example, outline the core objectives and agreed upon strategy for R&D projects. It would set out the expectations and role for each stakeholder. From the government perspective the strategy would set out exactly how the machinery of government will be used to support and regulate the initiative, how public instrumentalities will be involved, what infrastructure and services will be utilised, financial arrangements, leadership and processes. It may outline the outputs and outcomes expected and who and how will benefit from these. Responsibilities of all parties are outlined and the "how to" is logically explained and must be realistic.

4.8. Pharmaceutical R&D and Manufacture

The governments in LMICs must prioritize investments in R&D towards the goal of local production of active pharmaceutical ingredients and intermediates so as to maximize value to the local economy and reduce dependence on external sources.

- Among other positives, this may help boost the mining and allied industries, and reducing reliance on imports. There is even potential to develop an export industry (as has been the case in other developing countries such as India and Thailand).
- There is great potential to attract South-South private sector investment as well as for spurring job creation and local economic development.
- An expanded manufacturing industry would help ensure that pharmaceutical R&D into the country's most critical disease burden can inform the development of products much more quickly and at reduced costs.
- There is plenty that governments can do to facilitate the growth of a pharmaceutical manufacturing from investing in this branch of R&D, to developing a regulatory framework, to working with potential investors.

4.9. COVID-19

African Countries must invest in strengthening health R&D collaborative structures towards improving health service delivery, preparedness and resilience during pandemics and epidemics.

• When future epidemics and pandemics inevitably hit, Africa will vastly be better positioned to draw on its own knowledge and products to address the crises, rather than become isolated and dependent, if there has been substantial preparation informed by well financed R&D.

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Appendix 1: List of Respondents

Ms. Susan Atuhura: Director: Spectrum Uganda Initiatives.

Dr Rachel Chikwamba: Group Executive: Chemicals, Agriculture, Food and Health: Council for Scientific

and Industrial Research (CSIR). Former Group Executive: Strategic Alliances and

Communication (CSIR).

Ms. Azeza Fredericks: Former Director: Parliamentary Liaison Office: Council for Scientific and Industrial

Research (CSIR).

Dr Anthony Harries: Senior Advisor: International Union Against TB and Lung Disease. Honorary

professor of tropical medicine and infectious diseases, London School of Hygiene

and Tropical Medicine.

Ms. Luanne Hatane: Senior Programme Manager: Paediatric-Adolescent Treatment Africa (PATA).

Former Director: Networking AIDS Community of South Africa. Former

Programme Manager: National AIDS Council of South Africa (NACOSA).

Dr Sue Kinn: Head: Health Research & Evidence Division: United Kingdom Foreign,

Commonwealth & Development Office (formerly DFID).

Dr Dermot Maher: Coordinator for Research Capacity Strengthening & Knowledge Management:

TDR Programme for Research and Training in Tropical Disease: World Health

Organisation (WHO).

Dr Rob Morrell: Director: Next Generation Professoriate: University of Cape Town.

Dr Thomas Nyirenda: Strategic Partnerships and Capacity Development Manager: European and

Developing Countries Clinical Trials Partnership (EDCTP): South African Medical

Research Council.

Mr Jeanpaul Omollo: R&D Advocacy Program Officer: PATH (Program for Appropriate Technology in

Health) (Kenya Office).

Ms. Josephine Osikena: Director: Government Affairs and Global Public Health External Affairs and

Communications: ViiV Healthcare.

Dr Anna Ray:Board Chair: Lubombo Health Research Unit. Lubombo Region, Eswatini.

Dr Kevin Rebe: Sub-specialist in infectious diseases physician (currently on frontline of COVID-

19 treatment). Former researcher and programme director at Anova Health

Institute.

Ms. Fatima Riaz: Program Coordinator: Policy, Data & Analytics: AIDS Vaccine Advocacy Coalition

(AVAC).

Ms. Jessica Rodrigues: Director: Product Introduction & Access: AIDS Vaccine Advocacy Coalition

(AVAC).

Dr Leikness Simbayi: Executive Head: Centre for Science, Technology & Innovation Indicators (CeSTII):

Human Sciences Research Council (HSRC).

Ms. Phillipa Tucker: Research Director: Accountability International.

Prof Francois Venter: Deputy Executive Director: Reproductive Health and HIV Institute, University of

the Witwatersrand. Former Head of Infectious Diseases: Charlotte Maxeke

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Prof Alan Whiteside: Chair in Global Health Policy: School of International Policy and Governance:

Wilfrid Laurier University and Balsillie School of International Affairs.

Ms. Rachel Wilson: Principal: Catalysts for Change. Former Senior Director: Policy and Advocacy at

PATH. Former Director: Policy & Communications at Global Health Council.

Appendix 2: Interview Questions

Role Of Government In Mobilization Of Resources

- 1. In your view, what specifically should your and other African governments do in the next few years to facilitate and support expanded health R&D and HIV-prevention research?
- 2. What do you see as the main factors in your country / region that are working against a greater government commitment to health R&D, particularly in terms of use of domestic resources?
- 3. What do you think your governments (and those in the region) could realistically do to demonstrate a commitment to health-related R&D?
- 4. What potential resources, including technical, fiscal, professional etc., could government possibly utilize to leverage greater support for health R&D? What of partnership and collaboration (including a greater role by the private sector)?

Role Of Civil Society

- 5. What approaches could civil society including scientists, health activists, NGOs, service provides, communities, etc., take to convince government to increase its commitment to health R&D? What key messages and actions should inform this approach?
- 6. How could civil society, major funders and other stakeholders assist government to mobilize greater resources for health R&D?
- 7. In the last few years have there been any successes, nationally and regionally, in mobilizing public resources for health and HIV R&D? If so, what are these?
- 8. If yes to the above, what were the key elements that led to that success? What role did civil society play in achieving such successes?

HIV-Prevention R&D

- 9. What would you say are the emerging research imperatives in terms of reducing HIV-transmission in your country / region? (e.g. treatment research, PrEP, TasP, pre-natal, microbial etc.)?
- 10. What do you see as the gaps in knowledge and the implementation challenges related to HIV prevention treatment in your country and the region at this time?

COVID-19 Crisis

- 11. What are the lessons of the COVID crisis in terms of health service delivery systems and infrastructure in African countries?
- 12. Connected to the above does the effect of the COVID crisis provide any lessons or indicators to shape health R&D in African countries?