



AIDSAccountability
I n t e r n a t i o n a l



Research and Policy Report on Investments in HIV R&D in Africa

A Map and Guide for Civil Society to Hold Governments Accountable



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Feedback

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Every attempt has been made to ensure the accuracy of this report but any errors or omissions are our own. The author and AAI and WACI Health welcome any feedback, comments, and/or corrections on the content. Contact Rosemary Mburu at WACI Health with any questions, comments or feedback



Table of Contents

Copyright Notice/Creative Commons	2
Feedback.....	2
Table of Contents	3
EXECUTIVE SUMMARY	5
1. Introduction.....	6
2. HIV R&D funding trends.....	8
2.1 Global picture	8
2.2 Specific funding allocation trends in preventative HIV-related R&D.....	9
3. Tracking Health and HIV-related R&D in Africa	12
3.1 What can we ascertain?.....	12
3.2 Fulfilment of regional obligations.....	13
3.3 Kenyan Initiatives.....	14
3.4 Accountability.....	14
3.5 Foreign Investment in health R&D.....	15
4. Commitments to HIV R&D through binding agreements and protocols.....	16
4.1 Catalytic Framework.....	16
4.2 Africa's Common Position to the UN General Assembly (2016).....	19
4.3 Commitments through the African Union.....	20
4.3.1 Declaration of the Special Summit of the African Union on HIV/AIDS, TB and Malaria (2013).....	21
4.3.2 Luanda Declaration (2014)	23
4.3.3 Science, Technology and Innovation Strategy for Africa (STISA) 2024.....	24
4.3.4 Agenda 2063: The Africa We Want (First Ten-Year Implementation Plan: 2013-2023	25
4.3.5 Africa Health Strategy (AHS) 2016-2030.....	25
4. Making the case for greater R&D.....	27
5.1 STISA / strategic disadvantage.....	27
5.2 Broader economic benefits of health / HIV R&D.....	27
5.3 Fiscal returns and savings resulting from health / HIV R&D investment.....	28
5.4 Key lessons for Africa in health R&D.....	29
5.5 Building on strengths / Regional Centres of Excellence	30
5.6 Acknowledgment of the role of civil society.....	30
5.7 Role of African R&D in promoting a pro-poor and human rights agenda.....	32
5. Advocacy Direction for Civil Society	33



6.1 Identification of possible sources of funding for R&D	33
6.2 Clarity and specificity in R&D proposals	33
6.3 Promoting implementation of regional agreements	34
The use of the AAI Accountability Framework in this circumstance is a useful tool.	34
6.4 Forming strategic partnerships	35
6.5 Effective use of the media	35
6.6 Role of civil society as envisaged by the Kenya HIV and AIDS Research Agenda	36
6.7 The need for greater collaboration with government.....	36
6.8 Understanding policy making and the budget cycle.....	37
6.9 Other key advocacy considerations	37
6.10 Concluding comment on advocacy.....	38
7. Promoting African control of the health and HIV R&D agenda	39
8. SUMMARY OF FINDINGS	41
9. RECOMMENDATIONS	43
References	46



EXECUTIVE SUMMARY

In probing the current HIV Research and Development (R&D) investment landscape in Africa and the socioeconomic and political affecting this landscape, this report has concluded that there is both significant danger and great opportunity. The potential danger is that critical HIV prevention R&D will not be sufficiently funded and that this could lead to a decimation of prevention efforts and a deepening of the HIV / AIDS crisis in Africa. The great opportunity, one that civil society must fully embrace, is that there has never been a clearer case for and demonstrable need for African governments to greatly increase public investment in HIV R&D. This opportunity is underlined by indications that more African leaders are recognising this case and need, and that this is already manifesting in at least some increased expenditure on health and HIV R&D.

This danger is underlined by a continuing identified decline in global expenditure on some key components of HIV R&D, by a projected decline in HIV and health R&D in Africa from international funders and by African governments continuing to fall short of their regional commitments to invest in health and HIV R&D. Yet, as of mid-2016, important developments are underway which, if implemented, will create an enabling political environment for substantially expanded R&D to take place. This report will demonstrate that the 2016 promulgation of the *Catalytic Framework to end AIDS, TB and eliminate Malaria in Africa by 2030* and the concomitant *Common Position* (of African health ministers) provide a stronger basis than ever to push African governments to fulfil their commitments in terms of public investment in HIV R&D. A landmark HIV research agenda is being proposed in Kenya (along with a ground-breaking parliamentary bill) which would earmark substantially greater funding for HIV R&D and define a critical role for civil society in the agenda's implantation.

However, civil society must be sufficiently capacitated to rise to the tasks offered by these opportunities. This includes the ability of both holding government accountable and to take on new responsibilities in the implementation and the monitoring of greatly expanded HIV R&D activities. Among other challenges identified in this report, civil society must be able to understand and articulate the broader socioeconomic benefits to society of greater funding for HIV R&D, to fully understand and utilise national public policy-making and budgetary processes and to identify and utilise appropriate public fora to influence policy and budgets.

Health / HIV civil society must build its capacity so that it can work more collaboratively with government, assist government in identifying potential new funding sources for HIV R&D, and to help develop vital cross-sector and public private partnerships. Civil society needs to make better use of the media and engage more effectively with grass roots communities. Above all, civil society must further professionalise its approach so that it can clearly identify and articulate to government the specific gaps in HIV R&D that needs to be addressed, provide costed proposals as to precisely what level of funding is required and to articulate the mechanisms which will facilitate the funds being utilised for their intended purpose.

Central to civil society's mission, and the prime motivation thereof, must be to hold governments across the region fully accountable to the full range of commitments and to do so in a way that is effective, efficient and fully transparent. A key component of this is the implementation of a comprehensive, African-led and African-controlled HIV R&D agenda utilising domestic funding. The time is right for civil society to capacitate itself and fulfil this challenge.



1. Introduction

The intention of this report is to provide key and updated information to support African HIV-focused civil society organisations, professionals and activists, in Kenya as well as in counties across the entire Eastern and Southern regions, in realising their goal of securing greater budgetary commitments (i.e. investment) by African governments to HIV Research and Development (R&D).

Sub Saharan Africa has the most serious HIV and AIDS epidemic in the world, accounting for nearly 70% of the global total. In 2012, there were 1.8 million new HIV infections on the continent (UNAIDS Global Report 2013). Over the past 3 decades, there has been a slowed but not reversed tide of new HIV infections. The need for new tools to bolster existing strategies for prevention and ultimately end the pandemic is of paramount importance. Treatment as Prevention (TasP), Pre-exposure Prophylaxis (PrEP) and Adult Voluntary Medical Male Circumcision (VMMC) have now been added to the arsenal of prevention options. These breakthroughs would not have been possible without investments in HIV prevention R&D. This report demonstrates, however, that recent trends indicate a decline in key aspects of biomedical new HIV prevention funding.

Changing funding dynamics and priorities in donor countries have shaped these trends and will continue to do so in years to come. Currently, neither national budgets nor regional commitments to health demonstrate adequate investment in new HIV prevention R&D.

There is, therefore, a need to renew advocacy efforts to increase pressure on African and world leaders in order to raise political will towards increased investments in HIV prevention R&D. This will serve, among other positive outcomes, to accelerate research and rollout of New Prevention Technologies (NPTs). It is also imperative to raise the level of awareness on new HIV prevention R&D and the funding landscape among civil society leaders to scale up momentum for advocacy in Africa.

Currently, neither national budgets nor regional commitments to health demonstrate adequate investment in new HIV prevention R&D

To address the needs outlined above, WACI Health has partnered with AIDS Accountability International, and funded by the International AIDS Vaccine Initiative (IAVI) to produce a policy report on HIV R&D investments for use as an accountability tool which can also be utilised by civil society

to inform advocacy efforts around HIV R&D. AIDS Awareness International (AAI) has been brought on-board to research and write the report. AAI, an international NGO with a strong focus on Africa, is an independent research and policy think tank which aims to hold country leaders accountable for the commitments they have made to address health needs and HIV & AIDS-related needs in particular.

In developing the report AAI has drawn extensively from a wide range of policy statements, conference / summit reports, presentations, strategies, protocols, other research reports, articles, and has also undertaken informal interviews and discussions with key stakeholders, including HIV researchers and activists. Material informing this report was also drawn from presentations, panel and group discussions of a two-day meeting held in Nairobi in May 2016 entitled *Strengthening CSO Leadership in HIV Prevention Research & Development*



(R&D) in Eastern and Southern Africa (ESA) Region. WACI and IVAI co-hosted the meeting with three key HIV & AIDS umbrella organisations¹.

While Kenya is the prime focus of the report, it should also be useful for health and HIV civil society members from countries across Eastern and Southern Africa. The range of commitments examined, the advocacy tactics discussed and the recommendations presented are relevant for activists across the region.

This main body of the report begins (section 2) with a summary of identified trends in HIV R&D investment globally and particular attention is then given to expenditure patterns for specific preventative interventions. In section 3 the report examines the tracking of health and HIV R&D in Africa. Funding models proposed in Kenya are briefly examined in this context. The issue of accountability in connection with the monitoring of health and HIV R&D allocation and expenditure is also addressed. In section 4 the report identifies and examines key binding agreements and protocols entered into by African Heads of State (or their ministers) which create, directly or indirectly, commitments to support health and HIV R&D. It is vital that civil society is fully aware of such commitments.

The content of some key arguments civil society can utilise in making the case to policy makers for increased budgetary commitment to health and HIV R&D are outlined in section 5. This is followed in section 6 by an examination of the current landscape of, and possible directions for, health / HIV R&D advocacy in Africa and also touches on strategy and tactics. In this context, the possible broader economic benefits of investing in health / HIV R&D are briefly examined and, in section 7, the issue promoting African control of the health / HIV R&D agenda is briefly addressed.

The report concludes with a brief summary of findings and a set of recommendations for civil society to consider when planning advocacy, strategies and tactics going forward.

¹ These 3 were: i) KANCO- Kenya AIDS NGO's Consortium-A national umbrella network of AIDS Service Organizations in Kenya; ii) EANNASO- East African National Networks of AIDS Service Organizations; and iii) MANASO-Malawi National Network of AIDS Service Organizations, which is coordinating a steering committee working towards strengthening Southern Africa National AIDS Service Organizations (SANASO).



2. HIV R&D funding trends

2.1 Global picture

A comprehensive study by AVAC (2015) provides a detailed global picture on HIV prevention research & development (R&D) funding trends between 2000 and 2014. While the study tracks worldwide trends, there are some important implications for Africa.

The broader picture is a static one. AVAC concludes that overall funding remained at nearly the same level from approximately 2004 to 2014. However, a more nuanced examination is more revealing. In 2014, the reported funding for HIV prevention had R&D decreased by US\$10 million from the previous year to a total of US\$1.25 billion (AVAC, 2015). However, investments in research for AIDS vaccines, PrEP, female condoms and prevention of vertical transmission did show increases (certainly up to 2014), while investment for research in microbicides, treatment-as-prevention and medical male circumcision showed a decrease.

Of considerable concern was the finding that investment by public-sector agencies in the US and Europe declined considerably between 2013 and 2014, representing a drop of US\$13 million in one year alone. Trends of significantly declining overall levels of HIV R&D investment were also noted in Australia, Canada and South Africa, with smaller declines in India, Japan and Thailand. Worryingly, AVAC (2015) could identify that South Africa had significantly decreased investments in microbicides.

In notable contrast to the public sector, the AVAC study identified a trend in recent years in philanthropic support for HIV prevention, reversing a trend of steady decline observed in the early to mid- 2000s. Most significantly, philanthropic for HIV-related R&D increased by US\$9 million, up to US\$200 million in 2014.

Global trends in R&D:
R&D investment is expanding beyond research to rollout
The majority of investment comes from several large funders
There is a decrease in number of philanthropic funders engaged

From around 2005 philanthropic support gradually increased reaching its highest level in 2012 at US\$203 million (AVAC, 2015). Disaggregating for sub-categories of HIV R&D, overall philanthropic

investment in preventive vaccines and PrEP increased, while investments in microbicides, treatment-as-prevention and medical male circumcision declined. AVAC (2015) was also able to determine that commercial sector funding saw a substantial increase, due, in large part, to an increase in reported funding for preventive vaccines and female condom R&D.

In brief sum, some of the most important trends and findings of the AVAC study included the following:

R&D investment is expanding beyond research to rollout

Noting that “most failures happen at delivery” AVAC (2015) identify a critical direction for HIV R&D to inform the best possible delivery of HIV prevention products and ensure that those products meet the needs of, and reach, end-users. The report underlines the critical importance of investing in products beyond bench science and clinical trials such as roll out / scale-up of options such as voluntary medical male circumcision, female condoms and PrEP.



The majority of investment comes from several large funders

While some funders had increased their HIV R&D contributions up to 2014 at least, the overall picture is one of fewer individual funders supported the HIV prevention research field than in previous years. As one example, the investment from countries hosting clinical trials and other HIV prevention R&D, including African countries, remains small. AVAC (2015) underlines the importance of expanding and diversifying the investment base not only to sustain critical R&D work but to also facilitate a broader range of perspectives, human capacity and innovative concepts to the HIV prevention research agenda. This approach would make local R&D efforts in Africa so much more relevant to local populations. Noting that a very small number of donors have a disproportionate impact on the whole field, AVAC strongly asserts that building a more diverse global cadre of supporters involved in and dedicated to advancing HIV prevention R&D, would better ensure sustained and consistent funding.

There has been a decrease in number of philanthropic funders engaged

While noting that the total amount of philanthropic funding had increased to 2014, AVAC (2015) also identified a concerning trend of the number of philanthropic funders engaged in HIV prevention research steadily declining from 2010. By 2014 only 16 identified philanthropic funders were investing in HIV prevention research, down from 30 in 2010. More positively, however, a few more countries had embarked on investing public-sector funds in HIV prevention research, from 17 in 2010 to 20 in 2014. While asserting that the importance of investments from private donors cannot be overstated, AVAC also notes with concern that substantial decreases in philanthropic support from just a few funders has had a large and negative impact on overall funding levels.

Development funding priorities are changing

The 2016 expiration of the UN Millennium Development Goals (MDGs) and the creation of the Sustainable Development Goals (SDGs) will inevitably change the landscape in relation to HIV R&D funding. The UN Millennium Declaration in 2001 had called for increased investment in research related to HIV/AIDS and, more specifically, for the development of sustainable and affordable prevention options, such as vaccines and microbicides. AVAC (2015) asserts that the importance of investment in R&D as crucial to health gains articulated and reflected in the global goals can lead to increased political support and thus, investment, in global health R&D as has happened in past years. However, after hitting an all-time high in 2013, AVAC concluded that overall development support in 2014 remained static. More concerning, however, was the finding that development agency support for HIV prevention research declined by six percent.

2.2 Specific funding allocation trends in preventative HIV-related R&D

Microbicide research and development

Global investment in microbicide R&D has declined significantly. By 2014 funding had dropped by US\$17 million, down to US\$193 million, reflecting decreases from both government and philanthropic sources. Disappointing results from clinical trials have contributed to decline in funding. However, some HIV activists have contended that the manner in which microbicide R&D has taken place (in many instances) may have contributed to these results. The claim has been made that in some instances the research has been divorced from necessary community consultation and participation and a lack of cognisance of critical sociocultural factors.



AVAC (2015) reports that the microbicide pipeline also comprises ongoing work on rectal microbicides and that results from the first phase-2 trial of a product intended for rectal use, are expected in 2016. These results should inform the way forward for the rectal microbicide R&D agenda.

Multipurpose prevention technology

The aim of this sub-field of research is to develop of technologies or strategies that combine protection against unintended pregnancy and sexually transmitted infections (STIs), including HIV. An important emerging product from this R&D pipeline is the intravaginal ring which combines various antiretroviral agents and hormonal contraception with topical gel designed to prevent HIV and other STIs. AVAC (2015) reports that in 2014 total investment in multipurpose prevention technologies (MPTs) stood at US\$32 million. While US public sector accounts for the majority of investment there is considerable potential for biotechnology companies and university based research institutions to become involved in various MPT components. Again, there are sound very good sociocultural reasons why MPT research should be undertaken in Africa by African scientists, to ensure its applicability and efficacy.

Pre-exposure prophylaxis (PrEP)

Global investment in PrEP increased to US\$48 million in 2014 (AVAC 2015) and this included public, philanthropic and commercial sector contributions. This represented an increase of US\$12 million over 2013 Investment. AVAC reports that two clinical studies (from Canada and France) have shown PrEP to be highly protective against HIV for men who have sex with men (MSM) at high risk of infection, and this was reinforced by a subsequent trial. This example could also underline the importance of African-based, socio-culturally contextualised research on PrEP for MSM. In France and Canada, where the study took place, gay / MSM populations are relatively easy to access and most members of this community would be quite willing to be identified and come forward for treatment. This is simply not the case in most African countries and PrEP research, when considering use by MSM, must be relevant to the local context.

Treatment as prevention

In 2014 the value of research investment into AIDS treatment drugs as a prevention strategy reached US\$92 million in 2014. AVAC (2015) particularly notes results which indicate the benefits of earlier initiation of treatment. Importantly, trials have shown that people who start ART with CD4 cell counts between 350 and 500 were significantly less likely to transmit HIV to their sexual partners, compared with people who treatment at much low CD4 cell counts. Once again, African-based and controlled research is critical here as most national guidelines in the regional would not facilitate people commencing ART with counts as high as 500. Such research on treatment as prevention in Africa must have strong links with, and mandated implications for, government health policy.

Voluntary medical male circumcision

AVAC (2015) calculates that global in R&D and operations research related to voluntary medical male circumcision (VMMC) amounted to US\$26 million in 2014, representing a decrease of US\$6 million from 2013. The report cites numerous trials in Africa (including in Kenya, South Africa, Tanzania and Zimbabwe) which generally showed mixed results. The challenges of the rapid development of sites with all the necessary equipment, supplies and protocols for effective VMMC delivery were also noted. In many parts of Africa, VMMC as an intervention can only be successful with considerable community support and input and an acknowledgement of, and links with, the cultural and traditional practices around circumcision. R&D around VMMC, therefore, needs to be undertaken in this context and should be African-led and funded.



Vertical transmission prevention

AVAC (2015) calculates that funding for research related to prevention of vertical transmission of HIV from mother to child at birth and during breastfeeding increased between 2013 and 2014, from approximately US\$44 million to US\$49 million.

R&D around vertical transmission prevention in Africa needs to be linked with the broader goal (identified in the Luanda Declaration and numerous national health policies) of ending preventable maternal and child death. African-based and funded R&D on this issue can also better consider and build on the considerable successes on vertical transmission prevention in the region.



3. Tracking Health and HIV-related R&D in Africa

3.1 What can we ascertain?

Tracking health R&D, and particularly HIV R&D statistics and indicators for African countries, presents civil society with a significant challenge. As noted in a comprehensive policy brief entitled *Accelerating Health Research for Africa's Development* (Ouma-Mugabe, 2013), estimates are difficult to make as few countries publish such information in its entirety. There is a strong sense among some civil society organisations and

There is little tracking and documentation of R&D in Africa, and even less that is publicly available, accurate or disaggregated in useful ways.

health advocates that much of the data that is available on health and HIV R&D expenditure is not necessarily reliable, that much of it is dated and that it is often not disaggregated into subcategories. In South Africa, the Human Science Research Council (HSRC) (a parastatal of the National Department of Science and

Technology) does track and publish annual figures on several categories of public health R&D expenditure (see chart at the end of this section). Even there, however, information on HIV-R&D investment is not disaggregated from TB and Malaria R&D.

This limitation is located in the broader context of poor monitoring of science-related expenditure and achievements overall, and general poor accountability in terms of the use of public funds. With specific reference to Africa, the UNESCO Science Report (2016:507) concludes that:

“The lack of targets and a robust monitoring and evaluation strategy to track progress in implementation has led to minimal demonstration of the Africa's Science and Technology Consolidated Plan of Action's (CPA's) achievements. There should have been a strong, operational accountability framework for implementing partners.”

Drawing from World Bank R&D expenditure data (2016) and other sources, however, Ngongo et al (2016) ascertained that expenditure on health R&D appears to have increased in Sub-Saharan Africa and attributed this to renewed commitments by African leaders to transform African countries into knowledge-economies by increasing R&D spending to 2% of Gross Domestic Products (GDP). As a prime example, Ngongo et al (2016) cite that that Kenya has increased its R&D spending from extremely low levels to 0.79% of GDP in 2010. They identify similar trends in several countries including Ethiopia which reached 0.61% GDP in 2013, Gabon 0.58% of GDP in 2009 and Uganda 0.48% in 2010. In 2012, almost meeting the 2% target, Mauritius devoted 0.18% of GDP to GERD² and about 85% of public R&D expenditure was invested in S&T-related fields (UNESCO, 2016).

Ngongo et al (2016) also cite data showing that South Africa increased its R&D spending from 0.73% in 2013 to 0.76% in 2014. However, this needs to be seen in the longer-term context and it is instructive to note that South Africa's ratio of R&D expenditure has come down from 0.89% of GDP in 2008. UNESCO (2016) clarifies that the drop in South Africa's GERD/GDP ratio from 2008 was mostly due to a sharp drop in private sector R&D, despite rising public spending on R&D. This is concerning because one role of public expenditure on R&D is to help leverage private sector funds. South Africa's research output, however, still comprises

² Gross Domestic Expenditure on Research and Development



about 85% of Southern Africa's total output and it is encouraging to note that R&D expenditure as a percentage of GDP in that country is again on the rise.

3.2 Fulfilment of regional obligations

In terms of health R&D however, as noted by Ouma-Mugabe (2013), few African governments have met their obligations made in the Bamako Communique and Algiers Declaration which commit them to invest at least 2% of their national health budgets in health R&D. Ouma-Mugabe (2013) also notes that countries have fallen fall short of the 2007 African Union Summit pledge of spending at least 1% of GDP on overall R&D. While acknowledging significant improvement in recent years, Ngongo et al (2016) also note that most Sub-Saharan African countries still lag significantly behind India, China and Brazil in terms of percentage of GDP spending on R&D. They note that India invested 0.82% of its GDP in R&D in 2012 while Brazil invested 1.15%. In 2012 China invested 1.93 % of its GDP in R&D increasing such investment to 2.01% in 2013.

Underling the lack of domestic funding in African R&D generally, the UNESCO Science Report (2016:507) asserts that:

“With hardly any (African) governments having raised GERD to the target level of 1% of GDP, more than 90% of funding mobilized for implementation of Africa's Science and Technology Consolidated Plan of Action (CPA) came from bilateral and multilateral donors.”

UNCESO (2016) also notes that disparities in research and development (R&D) are evident the across the Southern African region in particular. This phenomenon is illustrated by the Gross Domestic Expenditures on the R&D GERD/GDP ratio, which ranges from a low of 0.01% in Lesotho to a high of 1.06% in Malawi.

HIV, TB and Malaria R&D expenditure in South Africa

Financial Year	Millions of Rands (R 000)
2005/06	733 338
2006/07	934 760
2007/08	1 120 028
2008/09	1 616 410
2009/10	1 816 901
2010/11	2 052 521
2011/12	2 006 625
2012/13	2 478 422
2013/14	2 867 954

Source: Statistical Report 2013/14: South African National Survey of Research and Experimental Development.

While underlining that the overall budgetary commitment to R&D across Africa is generally too low, the UNCESO Science Report (2016) acknowledges that there have been important innovations in recent years. These include the establishment of four networks of centres of excellence within the African Biosciences Initiative as well as two complementary networks, Bio-Innovate and the African Biosafety Network of



Expertise, the African Science, Technology and Innovation Indicators Initiative and the launch of the African Medicines Regulatory Harmonization.

Even as South Africa's overall GERD/GDP ratio has moved down (due largely, as noted above, to a sharp drop in private sector R&D) annual tracking by the Human Sciences Research Council (HSRC, 2016) at least demonstrates significant growth in overall actual Rand expenditure on HIV, TB and Malaria R&D since FY 2005/06. This is illustrated in the following table.

3.3 Kenyan Initiatives

A January 2016 Kenyan Government Policy Brief notes that 90-95% of HIV and AIDS research funding in Kenya is provided by donors. However, the government projects that this commitment will be reduced by approximately 20% per year and notes that this threatens the scientific gains made and the goal of ending AIDS. It is estimated that that \$43 million USD will be required annually by 2019 to fill the financial gap and fully resource and implement the proposed *HIV research agenda* (Kenyan Ministry of Health, 2016 A). A mixture of public, private and philanthropic domestic funding options has been considered and are believed to be feasible and economic viable.

Public sources will include:

- Five percent of the health budget under the National Research Fund (NRF) will be allocated to HIV/AIDS research;
- Health-related levies raised on tobacco alcohol products;
- Other innovative sources of funding for HIV R&D have been suggested including debt swap, an AIDS lottery, interest from dormant public funds, and contributions from individuals and the informal sector.

Proposed possible private sources include philanthropic contributions through local major foundations and the Kenya Commercial Bank. University contributions will also be made through allocation of \$10 USD to health research per year for every student undertaking a science course and 50% of the amount would be earmarked for HIV research (Kenyan Ministry of Health, 2016 B). Most notably, the Kenyan Health Ministry's policy brief (2016 A) asserts that 10% of the 2015/2016 government's HIV and AIDS response budget of USD 24 Million should go into HIV research as per the *Kenya AIDS Strategic Framework* (KASF) commitment.

Another initiative underway in Kenya is a Parliamentary Bill (before the Kenyan Senate as of mid-2016) which would mandate that 30% of the national health budget be earmarked for health R&D. Both this Bill and the proposed funding model for the HIV research agenda are landmark developments the progress of which should be monitored by health authorities and civil society across the region with a mind to possibly adapting them in other countries.

3.4 Accountability

The poor tracking of health / HIV R&D expenditure in most African countries as outlined in this and other reports reflects poorly on transparency in terms of the use of public funds and is a major public accountability issue that civil society must further address. This issue was identified in the IAVI Policy Briefing of 2013 (authored by Ouma-Mugabe), which, inter alia, recommended that:



- Appropriate institutions, including but not limited to the AU and NEPAD, need to collaborate to develop an African framework and set of indicators for monitoring health R&D expenditure;
- Each country should have a specific budget line for health R&D integrated into annual national budget framework. (Such a line-item should be further disaggregated for specific types of health R&D);
- Each country should be required to prepare a biannual report on health R&D status and financing.

These recommendations are just as relevant in 2016 (perhaps more so) and should be embraced by civil society.

An HIV activist interviewed for this report reflected that the difficulty in tracking health R&D investment is not necessarily specific to individual countries but is truly a region-wide problem. The lack of solid, reliable and timely evidence on R&D expenditure hampers civil society's interactions and advocacy and limits its ability to hold government to account.

Another issue undermining accountability in health R&D is that many different institutions are funded by a range of entities (often with very different R&D agendas). Tracing the allocation, utilisation and outputs of such funding becomes complex for civil society, if not impossible. There is a growing call in civil society for a single AU-wide umbrella body whereby health R&D money is channelled to address agreed-upon set of

objectives with built in mechanism to evaluate, audit and track R&D funds.

There is a call for a proper statutory umbrella body for the distribution of health R&D fund, one that is fully accountable.

A HIV researcher interviewed for this report reflected a belief among her colleagues of the need for a proper

statutory umbrella body for the distribution of health R&D fund, one that is fully accountable. She stated that attempts to create an umbrella body in Kenya were not successful as each institution was required to pay too high a sum for annual registration, funds which would take away from their research. An umbrella body could operate at different levels with a member of staff at each research site or district entity sending a delegate to a national branch, which could in turn nominate delegates to the regional body. The researcher asserted that:

"We currently have no research agenda to guide what we are prioritizing (i.e. A, B and C). We have not no tracking mechanisms – no monitoring to determine how funds were allocated or utilised, and no one is held accountable."

Ensuing transparency and accountability in the use of health R&D funds would be a leading function of a regional umbrella body.

3.5 Foreign Investment in health R&D

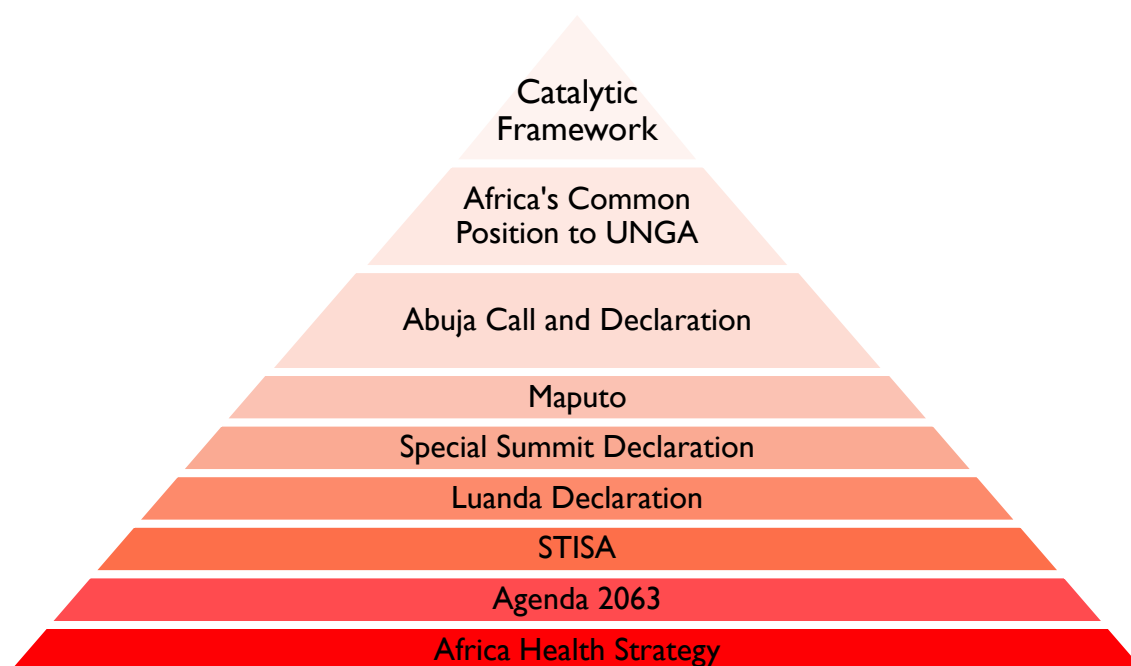
While insufficient government funding is a critical issue to address, Ngongo et al (2016) also conclude that Sub-Saharan Africa is also lagging behind in attracting Foreign Direct Investment (FDI) in health R&D. The researchers note that, on average, between 2003 and 2014, India and China attracted 28.7% of knowledge-based health R&D FDI, Latin America 4.3% while Sub-Saharan Africa attracted a statistical 0%. Health civil society's objectives, therefore, need to include not only increased domestic budgets for health R&D but also to help ensure that regional governments and the AU develop strategies to attract a great share of Foreign Direct Investment (FDI) for this purpose.



4. Commitments to HIV R&D through binding agreements and protocols

A highly significant development in mid-2016 in terms of agreements which oblige African Governments to invest in health R&D, and more specifically, HIV-related R&D, was the release of the *Catalytic Framework to end AIDS, TB and eliminate Malaria in Africa by 2030*, and the concomitant *Africa's Common Position to The UN General Assembly Special Session High-Level Meeting on AIDS* (June 2016). As it is an overarching, landmark document which itself refers to, and builds on, several other key commitments, the *Catalytic Framework* is examined up-front in this section. This is followed by a review of the *Common Position*, a set of joint policy positions by African health ministers to bring to the UN which reflect key elements of the catalytic framework. Important commitments (Declarations, Strategies, etc.) made by African leaders through the auspices of the African Union (AU) which preceded the catalytic framework and common position are then examined in chronological order. Agreements made outside the context of the AU are also briefly noted.

The following pyramid chart demonstrates the various key commitments entered into by African leaders in recent years which undergird the catalytic framework and provide important background and context for it.



4.1 Catalytic Framework

In June, 2015 the AU Assembly directed the AU Commission (AUC) to work with the New Partnership for Africa's Development (NEPAD) Agency and in consultation with Member States and partners to develop a *Catalytic Framework* which would outline the milestones towards ending AIDS, TB and malaria in line with the Abuja +12 targets (AU, 2016 A). The Assembly's Decision also requested the AUC to work in consultation



with Member States and partners to develop an accountability framework with clear targets and indicators to monitor and measure progress.

Critically, the catalytic framework (AU, 2016 A), released in May 2016, identifies the need to strengthen and expand HIV research efforts and to *increase financial investment* to ensure that this occurs. The framework asserts that:

“Health research provides the tools and evidence for effective policy and decision making at all levels. African countries should intensify research aimed at strengthening preventive and curative measures to curb the spread of the three diseases in line with the Abuja +12 commitments” (AU 2016 A:11).

And even more significantly:

“African countries should increase investments in research and innovations to address the health needs of the continent. Governments should strengthen collaboration with universities and research institutions to enhance innovation and evidence informed policies and programmes” (AU 2016 A: 11).

While the otherwise highly significant *Luanda Declaration* of 2014 (see below) fell short in clearly identifying the R&D investments needed to bring about its vision and implement its commitments, the catalytic framework not only identifies that expanded HIV R&D is critical to achieving its goals but also urges governments to increase investments accordingly.

More broadly, the catalytic framework notes that there have been a range of commitments made by African governments (including the Abuja Declarations) which have recognised the need to invest in health for sustainable development. However, the Catalytic Framework goes a step further and asserts that to achieve the Agenda 2063 (see below) and the Sustainable Development Goals³ (SDGs) health outcomes, AU Member States must fully implement their costed National Strategic Plans for HIV, TB and Malaria to ensure the efficient utilisation of the allocated resources. The framework adds that:

“African countries should continue to champion true transformation and paradigm shift towards optimal domestic financing for health and diversifying sources of financing” (AU 2016 A: 11).

As part of its *Force Field Analysis* the catalytic framework identifies as a driving force (i.e. a positive aspect) that biomedical responses and technological advancements to respond to HIV/AIDS, TB and Malaria have advanced significantly since 2000. Significantly, however, the framework also identifies as an inhibiting factor that funding for research innovation in this field has not been prioritised.

As part of its *Contextual Analysis*, the framework addresses the technological environment within which the framework itself is developed. In doing so, it identifies that technological advancement in clinical and diagnostic innovation have contributed to a higher standard of health care. The framework notes that most African countries have access to high quality, rapid-turnaround laboratory services for key diagnostics and that

³ At the United Nations in September 2015, countries adopted a set of goals to end poverty, protect the planet, and ensure prosperity for all as part of a new sustainable development agenda. Each goal has specific targets to be achieved by 2030. Goal 3 (of 17 goals) is to *Ensure healthy lives and promote well-being for all at all ages*. Preventing the spread of HIV/AIDS is a key component of goal 3.



pharmaceutical manufacturing capacity is gradually increasing due to technology transfer through north-to-south and south-to-south collaboration. The framework asserts that the effect of this is that:

“(African) Countries increasingly recognise the long-term goal of sustaining access to health through advancing Africa’s local production. Innovation, research and development has created new opportunities for strengthening health service delivery” (AU 2016 A: 7).

This conclusion, however, is not necessarily reflected in the experience of civil society or the health scientific community which asserts that the financial commitment by African Governments to health innovation, research and development continues to fall well short of the level required to seriously address the health goals of those same governments and the AU as a whole. There will be a key role for civil society to play in holding government to their commitments under the catalytic framework (and other agreements) in constantly stressing that the fulfilment of many of the key commitments are contingent on increased and strategic targeted domestic investment in HIV R&D.

Most significantly, the framework emphasises a paradigm shift towards African-led initiatives for funding disease responses. Logically, this must include funding for R&D. In terms of domestic funding. The framework asserts that:

“Emphasis will be placed on increasing domestic financing for health including innovative mechanisms in line with African Union and global commitment;” and “Results-based financing at the local level should be used to leverage more resources thus contributing to health systems strengthening” (AU 2016 A: 14).

The framework also asserts that the development of private-public partnerships is critical in terms of unlocking further resources but also refers to potential sources of public revenue (for increased financing at the country level) including tobacco and alcohol tax, airport levies, bonds and trust funds.

However, the framework in no way de-emphasises the ongoing importance of international financing. It asserts that international community is expected to honour commitments to strengthen health systems and finance R&D for HIV, TB and malaria in Africa and specifically references the need to enhance grant mechanisms to African countries from the Global Fund, Global Financing Facility (GFF), and other multilateral and bilateral donors. Importantly, the framework asserts that it is the responsibility of recipient countries to strengthen accountability processes, governance and absorptive capacities. Again, civil society must play a role in this overall process and it also ensure that provision for HIV-related R&D is made, and honoured, in any international agreements, and that proposals to strengthen accountability processes are fully implemented.

There are important HIV-related R&D (and financing) implications, needs and opportunities arising from the Catalytic Framework’s Implementation Plan as set out in considerable detail in the document. While the Plan should be read as a whole, some key aspects are summarised as follows.

The portion of the catalytic framework Implementation Plan for dealing with AIDS has as its goal to *End AIDS as a public health threat by 2030*. Its ambitious milestones and targets for between 2020 and 2030 include:



- ✚ Reducing AIDS-related deaths to less than 150,000 per year with a treatment coverage of 95-95-95⁴;
- ✚ Reducing New HIV infections to less than 150,000 per year;
- ✚ Ending discrimination.

Some of the identified strategies to reach these goals strongly suggest the need for significantly increased HIV-specific R&D, including the strategy to *Eliminate new HIV infection in children and keeping mothers alive*. However, the implementation plan more explicitly addresses the need for expanded research and for funding under its strategic directions and approaches section of the AIDS section, in which it identified the need for:

- ✚ Enhancing research and innovation to end AIDS; and
- ✚ Increasing domestic and international financing for AIDS.

4.2 Africa's Common Position to the UN General Assembly (2016)

In May, 2016 African Health Ministers met to develop a common position on AIDS to the UN General Assembly Special Session High Level Meeting on AIDS scheduled for June, 2016. In doing so the ministers drew heavily from the *Working Group of the Specialised Technical Committee on Health, Population and Drug Control Experts* who had met in Addis Ababa earlier in 2016.

Among the recommendations and commitments made by the ministers under the common position which would necessarily require a significantly greater domestic investment in HIV, TB and malaria-related R&D by their own governments include:

- ✚ Innovating in the use and scale-up of testing initiatives such as home testing and rapid point-of-care diagnostics, and use social media and mobile technologies to reach populations left behind; work with partners to scale up and accelerate the development and testing of vaccines, female-controlled methods with male involvement, microbicides and other prevention tools such as post exposure prophylaxis;
- ✚ Taking urgent steps to improve the quality, coverage and availability of disaggregated data and use new innovative tools such as location risk analysis to identify underserved and overburdened populations, gaps in community and health systems and areas needing service saturation, to ensure that no one is left behind;
- ✚ Continue processes for the establishment of the Africa Centre for Disease Control, and monitor progress towards ending AIDS as one of the core achievements;
- ✚ Proactively advocate for accelerated implementation of the Business Plan for the Pharmaceutical Manufacturing Plan for Africa to advance local production of medicines and other commodities, bulk purchasing, transfer of technologies and development of traditional medicine;
- ✚ Continue advocating for more affordable, quality assured, more resilient, less toxic, longer-acting and easier-to-use drug regimens, including timely development and availability of the most efficacious and ARV formulations suitable for children as well as more effective treatment for common coinfections such as TB, STIs and Hepatitis;
- ✚ Actively support and strengthen the capacity of national institutions and community systems to mount multi-sectoral, evidence-informed and rights based responses.

⁴ 95% of people living with HIV knowing their HIV status; 95% of people who know their status on treatment; and 95% of people on treatment with suppressed viral loads.



Most significantly in terms of the uses of domestic financial resources, the common position (AU 2016B:6) commits itself to:

“Drawing on principles of Shared Responsibility and Global Solidarity, significantly increase domestic resources for the AIDS response including but not limited to meeting the Abuja Declaration target of allocating at least 15% of national budget for health, and exploring and implementing innovative financing mechanisms in partnership with the private sector and other stakeholders.”

The common position recognises that many national responses to the AIDS epidemic in African countries remain highly dependent on foreign support and that such support is very tenuous given the competition for resources from other global emergencies. Implicit in this recognition, in addition to the ambitious set of recommendations made by ministers, is the absolute necessity for sustainably African-led and African-funded HIV R&D.

4.3 Commitments through the African Union

Between 2000 and 2010 several key important commitments were through AU bodies concerning HIV and AIDS, which directly or indirectly underlined the need for more and targeted HIV R&D. These commitments included the following.

- In 2001 the *Abuja Declaration* affirmed the AIDS epidemic as a state of emergency on the continent and committed governments to allocating 15% of the national budgets to health by 2015.
- In 2003 the *Maputo Declaration on Malaria, HIV/AIDS, TB and Other Related Infectious Diseases* reaffirmed Abuja Commitments and recognised that important progress had made in many countries in terms of mobilising resources to respond to the three diseases.
- In 2006 action by AU Member States against the three diseases was reinforced by the *Abuja Call for Accelerated Action towards Universal Access to HIV/AIDS, Tuberculosis and Malaria Services in Africa*. The Abuja Call was intended to translate political declarations into concrete action.

While not made under the auspices of the African Union, many African countries⁵ are signatories to the Bamako Communique of the Global Ministerial Forum on Research for Health Agreement of 2008, officially termed the *Bamako Call to Action on Research for Health*. The commitments made by countries under this agreement include obligations to:

- Give priority to the development of policies for research and innovation for health;
- Allocate at least 2% of budgets of ministries of health to research;
- Establish mechanisms to monitor financial flows to research;
- Develop national research and innovation strategies that include research for health; and
- Integrate health R&D into their National Poverty Reduction Strategies (WHO, 2008).

⁵ Including Algeria, Angola, Benin, Burkina Faso, Cameroon, Cape Verde, Chad, Congo, Guinea Bissau, Libya, Malawi, Mali, Mauritania, Namibia, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, South Africa, Sudan, Tanzania, Uganda and Zimbabwe.



Earlier, in 2000, signatories to the *Bangkok Declaration on Health Research for Development* declared that health research is a key component for sound social and economic development and that R&D is critical for the attainment of health as a fundamental human right (Ouma-Mugabe, 2013).

Since 2010, the African Union's commitment to the struggle against HIV and AIDS has solidified in and this has manifested in a range of formal decisions and declarations. Prime among these commitments are the following.

- In January, 2012 the AU Assembly affirmed⁶ the revitalisation of *AIDS Watch* as the highest Africa-wide advocacy, resource mobilisation and accountability platform for AIDS, TB and Malaria. *AIDS Watch Africa (AWA)* was established at the Abuja Special Summit in 2001 and is an Africa-led instrument to urge leaders into action and mobilise the resources needed to address AIDS, TB and Malaria in a manner that is sustainable, effective, transparent and accountable manner.
- Also in 2012 the AU Assembly endorsed the African Union Roadmap for Shared Responsibility and Global Solidarity for AIDS, Tuberculosis (TB) and Malaria Response (2012-2015). This was later extended to 2020.
- In 2013 the Special Summit of the African Union on HIV/AIDS, Tuberculosis and Malaria made an important declaration was entitled *Abuja Actions Toward the Elimination of HIV and AIDS, Tuberculosis and Malaria in Africa by 2030* (see sub-section below).
- In January, 2014 the AU Assembly adopted⁷ the Common African Position (CAP) on the Post-2015 Development Agenda (Jan 2014) which includes 'Ending the epidemics of AIDS, TB and Malaria' by 2030 under the Pillar III on People-Centred Development. (The latest version of the Common Position of May, 2016 is detailed earlier in this report);
- In 2015 the AU adopted the first ten-year implementation plan for Agenda 2063 (detailed below);
- The Decision on the *Report of the AIDS Watch Africa (AWA) of Heads of State and Government* that requested the Commission working with NEPAD Agency in consultation with Member States and development partners to develop a *Catalytic Framework* detailing milestones towards ending the epidemics of AIDS, TB and malaria in line with the Abuja +12, 2030 target. The framework (detailed earlier in this report) was delivered in May 2016.

Some of the key binding agreements made since 2013 which have clear implications for the funding of health / HIV R&D are summarised below.

4.3.1 Declaration of the Special Summit of the African Union on HIV/AIDS, TB and Malaria (2013)

The 2013 "Abuja Declaration" emanating from the above-referenced special AU summit, affords top priority to the health field in the AU Agenda 2063 and the Post-2015 Development Agenda. Most notably, the Declaration sets the ambitious targets of ending AIDS, TB and Malaria in Africa by 2030. As part of this goal the Declaration also:

- Underlines the importance of fully implementing the AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa.

⁶ Decision Assembly/AU/Dec.395(XVIII)

⁷ Assembly/AU/Dec.503(XXII)



- Supports the reinforcement of the policy environment and regulatory systems, including active cooperation among Member States to boost investment in the local production of quality essential medicines (AU 2016 C).

The framework directs the AU Commission, the UN system and other development partners to cooperate with Member States for implementation of these commitments.

The 2013 Abuja Special Summit highlighted the need for African countries to utilise and build on their own research capacities in order to produce new and effective medicines, diagnostic tools, vector control tools and vaccines (AUC, 2014). Also, strongly emphasised was the need to promote research, invention and innovation in strengthening local health ecosystems, considering the socio-cultural and environmental dimensions of situation of African, a critical aspect which is not always well addressed when the R&D funding and agenda are driven largely by external donors.

This Declaration resulting from the Abuja Summit also addressed the critical issue of accountability in R&D. The AU and Member States must implement improved coordination among health stakeholders (and other related sectors) contributing to the development of science and technology to build governance structures to promote ethics and research integrity. One of the objectives here is to increase public trust in research.

Many if not most of the 30 specific commitments made under the Abuja Declaration would necessitate, in terms of their full implementation, significantly increased local investment and initiative in R&D. However, some commitments more explicitly require such investment. These include the following:

- xii. Invest in the integration of HIV/AIDS and TB programmes and accelerate the scale-up of technology for early diagnosis and treatment of the three (3) diseases such as same diagnosis of TB infection and point of use CD4 counts for early initiation of HIV treatment, to maximize potential for effective access to medicines; and
- xxii. Create an enabling environment to support and leverage technological innovation as well as manufacturing capacity around medicines, vaccines, diagnostics and laboratory reagents, thus contributing to the strengthening of the capacity of the health system;

and, most explicitly:

- xxix. Intensify research aimed at strengthening preventive measures to curb the spread of the three (3) diseases.

Commitment xxvii of the Abuja Declaration also binds the AU to align itself to the *Report of the Global Thematic Consultations on Health on the Post-2015 Development Agenda*, which in turn, underlines the need for greater health-related R&D investment and in parts, more specifically, for HIV-related R&D.

Under this Commitment the African Heads of State solemnly resolved to “take serious action toward the elimination of the pandemics.” These actions included:

- Scaling up the implementation of the earlier “Abuja Commitments”;
- Increasing access to prevention programmes targeting the youth, especially young women, to ensure an AIDS-free generation;
- Eliminating mother-to-child transmission of HIV while keeping mothers alive;



- Mobilising domestic resources to strengthen health systems while ensuring that strategies are in place for diversified, balanced and sustainable financing for health, in particular AIDS, TB and malaria through development of strategic health investment plans and strategies for innovative financing, including partnerships with the private sector.

The leaders emphasised the importance of South-South Cooperation and collaboration with the BRICS partners to scale up investment in African pharmaceutical manufacturing capacity, especially for generic essential medicines and other essential commodities.

4.3.2 Luanda Declaration (2014)

African Health Ministers met in Luanda, Angola in April, 2014 for a summit sponsored by the AU and WHO. The *Luanda Declaration* was issued at the end of the historic meeting in which six specific commitments were made. In addition to universal health coverage and addressing non-communicable diseases, these commitments included:

- Establishing an African Centre for Disease Control and Prevention;
- Establishing an African Medicines Agency (AMA); and
- Ending Preventable Maternal and Child Deaths.

Surprisingly, there was little mention of R&D in the official post meeting summaries. Clearly, for continent-wide Centre for Disease Control and Prevention and a Medicines Agency to be truly effective, innovative and scientifically sound, such institutions would need substantial resources to conduct core research

activities. Should these agencies lack this critical capability they would simply become white elephants and bureaucratic entities.

The ability of any African Centre for Disease Control to perform its critical functions will be hampered unless there is a substantial and ongoing commitment to funding well defined and highly focused research and development activities.

WHO (2014) asserts that a prime motivation of the Minister's to call at Luanda for the establishment of the African Centre for Disease Control and Prevention on was to strengthen the continent's ability to timeously detect epidemic prone

diseases. The ability of any such centre to perform this and other critical functions will be hampered unless there is a substantial and ongoing commitment to funding well defined and highly focused research and development activities.

Similarly, the ministers' identification of the urgent need to establish the African Medicines Agency (AMA) needs to be accompanied by a commitment to provide for the research capacity such an agency would require as a core function. As envisaged by the ministers, the AMA would (inter alia) have a prime role in supporting the continent's pharmaceutical industry, improving access to quality medicines and medical products, and helping prevent the circulation and consumption of inferior-quality medicines (WHO, 2014). Such a role could only be undertaken if the AWA has a cutting-edge, world class R&D capacity.



The commitment to end preventable maternal and child deaths would also clearly require a substantial increase in regionally-focused research and development, certainly in HIV-related matters but also more broadly. A WHO report on the Luanda Declaration (2014:1) asserted that:

“The Continent’s health leaders agreed that despite the commendable efforts of African countries to improve maternal and child health, many of them continue to die during pregnancy, childbirth and the post-delivery period. They committed themselves to address this scourge by putting in place an integrated package of essential actions and services and advocate for adequate resources to address the social, economic and environmental determinants of health.”

Again, the efficacy of such a monumental and far-reaching “integrated package” as envisaged by the ministers will be limited unless informed by rigorous research and development on localised conditions and factors.

Finally, the Luanda Declaration underscored the critical need to establish monitoring and accountability mechanisms assess the implementation of the commitments made by the health ministers. This would require the well-functioning monitoring and evaluation research skills and infrastructure as well as substantial input from civil society.

4.3.3 Science, Technology and Innovation Strategy for Africa (STISA) 2024

A 10-year Science, Technology and Innovation Strategy for Africa (STISA-2024) was adopted by the AU Heads of State and Government Summit in June 2014. The strategy complements the longer-term *AU Agenda 2063* which is underpinned by science, technology and innovation as multi-function tools and enablers for achieving continental development goals (AUC, 2014).

Priority Two of STISA-2024 is: *Prevention and control of diseases (and ensure well-being)*. Specific priority research and innovation areas for Priority two include:

- Better understanding of endemic diseases - HIV/AIDS, Malaria (among others); and
- Maternal and Child Health.

Clearly, the realisation of priority two will require governments to increase their funding commitment for the priority research and innovation areas.

While noting that there are conventional mechanisms for funding Research and Development (R&D) and Innovation, STISA-2024 (AUC 2014: 10) strongly asserts that it is “essential to establish efficient, effective and coordinated financing mechanisms to implement the strategy.” It is vital for civil society to note that STISA-2024 commits the African Union Commission (AUC) and the NEPAD Agency to mobilising and coordinating resources for technical support in developing and implementing national and regional plans and priority programmes. Even more significantly for civil society, STISA-2024 directs that both individual AU Member States and Regional Economic Communities (RECs) will take a lead role in mobilising public, private and donor resources for the coordinated implementation of national and regional programmes.

The critical need for governments to invest in infrastructure to support research and development is also explicitly addressed in STISA-2024 (AUC 2014: 31):

“The development of Science, Technology and Innovation in Africa requires the upgrading of science laboratories and the establishment of world class infrastructure. This includes research and



innovation facilities such as laboratories (for teaching and clinical trials), teaching hospitals, Innovation Spaces, Living Labs and National Research and Education Networks (NRENs)."

STISA-2024 also notes that governments will need to make the necessary steps to ensure this enabling environment exists towards facilitating research innovations.

Specifically, in relation to health, STISA-2024 (AUC 2014:22) asserts that

"(The) AU and its Member States must prioritise establishing greater coordination both among health stakeholders as well as with other related sectors contributing to the development of science and technology and building governance structures to promote ethics and research integrity, thus increasing public trust in research."

An overarching goal of STISA-2024 is to move the African continent towards an Innovation-led knowledge based economy (AUC, 2014). However, the strategy itself identifies that the success of STISA-2024 will depend on (among other factors) on increased R&D budgets at national, regional and continental levels.

4.3.4 Agenda 2063: The Africa We Want (First Ten-Year Implementation Plan: 2013-2023)

Agenda 2063 was adopted, in January 2015 in Addis Ababa by the 24th AU Assembly of Heads of State and Government, following 18 months of extensive consultations with all formations of African society.

Among its wide range of objectives, the first Ten Year Plan of Agenda 2063 envisages that by 2023 there will be universal access to Anti-Retroviral medication (ARVs) for persons with HIV/AIDs and that the proportion of deaths attributable to HIV/AIDS and malaria will be reduced by 50%. It also envisages that the African Centre for Disease Control will be functional and will be providing the leadership in coordinating continental efforts in preventing and managing communicable diseases

There are many commitments in the Ten-Year Plan which will necessitate an increased policy and financial commitment to health-related R&D. Some of these commitments include

- Developing / implementing programmes for health research and surveillance through the African Centre for Disease Control and Surveillance;
- Putting in place policies to nurture research and innovation culture;
- Increasing financial support to R&D programmes in educational institutions;
- Promoting collaborative policies between the public and private sectors for the finding of research.

These commitments need to be seen in the context of Goal 20 of the Ten-Year Plan which is that: *Africa takes full responsibility for financing her development.*

4.3.5 Africa Health Strategy (AHS) 2016-2030

A key component of the new *Africa Health Strategy (AHS) 2016-2030*, is that that it integrates the research and innovation for health. The strategy underlines the need to strengthen health research, innovation, ICTs for health, technological capabilities and developing sustainable evidence informed solutions for Africa's health challenges.



The new AHS demonstrates the need to institutionalise mechanisms for defining, producing and utilizing African research in ways that can transform the health sector as well as develop the African economy. The AHS (2016: 20) asserts that:

“Achieving health goals and targets requires matched investment in research and innovation in order to improve access to medical technologies and products. Furthermore, data from health research and innovation must be collected and analysed to inform policy and decision-making at all levels of the healthcare system.”

This not only provides a very strong impetus for greater public investment in health R&D but also underlines the importance of R&D findings being utilised to inform health policy-making at multiple junctures and levels.

The AHS 2016-2030 asserts that AU Member States must encourage locally driven and financed research through the empowerment of local research institutions and the setting up of innovation hubs. Most importantly, the AHS reasserts the responsibility of Member States to allocate 2% of their national budget for research and innovation, noting that this is also envisioned in the Science, Technology and Innovation Strategy for Africa 2014 - 2024.

The AHS also asserts that building regional expertise in research should be supported where it offers more returns through strengthening regional research centres, building research networks and sharing results across countries.



4. Making the case for greater R&D

There is a range of powerful arguments from different perspectives that civil society can utilise (in various fora) to make the case to policy makers of the need to substantially increase public investment in HIV R&D. In doing so, civil society can draw from key empirical sources including those endorsed or connected with African governments themselves. Some key sources and arguments are summarised below.

5.1 STISA / strategic disadvantage

Drawing from a range of sources, including statistics from UNESCO and ASTII, the Science, Technology and Innovation Strategy for Africa 2024 (STISA) (AUC 2014) firmly concludes that the current level of investment in R&D by Africa as a continent (of which more than half is externally funded) puts Africa at a strategic disadvantage.

The Strategy (2014) argues that many, if not most Science, Technology and Innovation (STI) activities in Africa are not sustainable in part because they are over-reliant on short-term project funding often linked to events such as time-bound clinical trials, short-term demonstration projects, workshops and consultancies. It notes that important aspects of STI policy development, such as establishing comparable baseline data and Monitoring and Evaluation (M&E), are not budgeted for (and thus not resourced) in most Member States. Most pertinently, the STISA (AUC, 204) concludes that this situation reflects the gap in achieving the 1% of GDP target agreed by AU Member States as desired minimum expenditure on R&D.

The consequence of the lack of public investment in R&D which places African countries, and the continent as a whole, at a strategic disadvantage (in which so many developmental and economic opportunities are lost) should be consistently and emphatically conveyed to policy makers. Civil society should contribute to a vision of how much more effectively African countries could compete on the global level through much greater investment in STI and R&D.

5.2 Broader economic benefits of health / HIV R&D

In making the case for substantially expanded African production of medicines and other essential health commodities, Sidibé et al (2014) assert that African countries can learn a great deal from BRICS' successful experience in leveraging the AIDS response as an engine for innovation and for research and development. The researchers note that:

“In addition to political support and financing, this endeavour requires a far-sighted vision, the optimal combination of mutually supportive national policies, good governance and rule of law, the establishment of robust national regulatory authorities and other relevant institutions, the availability of diverse technical expertise and access to viable markets.” (Sidibé et al 2014:1).

The broader economic benefits of which can be realized, in part, through increased investment in health R&D is also underlined in the IAVI policy briefing (Ouma-Mugabe 2013). Like the BRICS example provided by Sidibé et al (2014) the briefing argues that Latin America and Asia offer examples of how the implementation of relevant policies for public health and health research and development (R&D) can help to sustain long-term economic growth. Ouma-Mugabe (2013:2) asserts that:

“The recent economic history of countries such as Brazil, China and India shows that improvements in public health and investments in health R&D for innovation helped to stimulate



economic growth and industrialization. Indeed, these countries are rapidly industrializing and integrating their economies into the global economy, in part, because of the investments that they are making in health R&D for innovation.”

Asserting that health R&D is an economic investment when products are commercialised, the IAVI Policy Briefing laments that Africa, compared to other regions, Africa has not effectively invested in, nor reaped the benefits of, health R&D. Concluding that Africa's long-term economic growth and sustainability are threatened by high burden of disease, the briefing (Ouma-Mugabe 2013) strongly asserts that sustaining and spurring growth will require more investment in public health, including health (R&D).

Ouma-Mugabe (2013) also highlights the experience of Brazil in demonstrating the importance of investment in health research not only for the industrial production of medicines, vaccines, and diagnostics but also for the consequential secondary benefits for the national economy. The briefing notes that between 2000 and 2003 Brazil country devoted 3.3% of public national expenditure to health R&D. Brazil is also a good example of a middle-income developing country setting and financing its own health R&D agenda as International or external funding accounted for only 3.5% of the budget for national health R&D).

5.3 Fiscal returns and savings resulting from health / HIV R&D investment

The Kenyan Ministry of Health (2016 B) estimates that the return on investment from implementation and funding of the Kenya AIDS Research Agenda could result in a five to eight-fold cash return, representing a saving of up to \$30 million USD over a period of five years. Short-term term returns are expected through investment in behavioural and implementation and longer-term returns are expected through investment in biomedical research.

The Science, Technology and Innovation Strategy for Africa 2024 (STISA) also strongly supports the notion that increased fiscal commitment to, and coordination of, Research and Development in line with national and regional priorities will bring substantial economic benefits for the continent, and asserts that (AUC 2014:31):

“Such commitment to national and cross-border coordination of research and innovation actors will strengthen the socio-economic situation of the continent through local ownership and wider utilization of research outputs and technology acquisition. Taking a systematic approach to technology transfer and knowledge sharing, co-creation and adaptation of new products, services, processes, business models and policies and commercialization of research and innovation outputs will stimulate local, national and regional Innovation ecosystems.”

The STISA asserts that this will result in improved public services (including entrepreneurial innovation), the creation of new economic sectors, wider employment opportunities in the formal economy and commercialisation of technologies with regional relevance and global potential.

The issue of research around the AIDS vaccine can illustrate, as one of many examples, how greater public investment in HIV R&D will almost certainly result in longer-term public savings. In Kenya, one rough estimate puts the cost of getting to the next level of research necessary for the development of the vaccine at 100 million shillings. Civil society needs to communicate to policy makers that the fiscal cost alone to Kenyan society will be much greater than this if the vaccine is not developed. For a start, a vaccine would obviate the need for life-long treatment for many thousands of people over the long term. It would obviate the costs associated with treating the side-effects of ARV treatment and decrease costly overheads and



operational costs at public clinics and hospitals (among numerous other direct and indirect savings). As of mid-2016 a paper was in the pipeline analysing the long terms savings resulting from increased public investment in vaccine research.

5.4 Key lessons for Africa in health R&D

Asserting that examples in Brazil, India and China demonstrate policy and funding success stories, Ouma-Mugabe (2013) identified three key lessons for Africa. In brief sum, these lessons are:

- Placing stronger emphasis on R&D (both in terms of policy and funding) for innovation serves to modernise national health systems. Health R&D policies and activities need to drive, and be central to, national innovation systems rather than be standalone instruments.
- There is a critical need to build and endow centres of excellence in health R&D for innovation. Brazil, India and China have all invested significantly in establishing world class research institutes and have come to rely less and less on external international donors for their country's health R&D budget.
- In all three countries, there has been considerable executive and political leadership for R&D.

This needs to be considered in the context in which Africa's long-term economic growth and sustainability are threatened by high burden of disease. Drawing stark links between the AIDS crisis and the harmful effects on the African economy, Ouma-Mugabe (2013:1) estimates that between 1990 and 2013:

“HIV/AIDS has reduced economic welfare by 1.7% per year in Africa; countries with particularly high HIV burdens offer a good illustration of the economic cost of poor public health.”

Ouma-Mugabe (2013) also asserts that spurring regional economic growth, and sustaining such growth, will require more investment in public health, including health research and development. In this sense, the low level of health related (and more specifically HIV-related) R&D in Africa not only results in missing the sorts of economic growth and innovation experienced by other developing countries, but serves to reduce economic welfare overall.

This view is strongly reflected in the *Science, Technology and Innovation Strategy for Africa 2024*. STISA (AUC, 2014) which underlines the importance of realising the full potential of science, technology and innovation in order to support sustainable socio-economic growth and development, and improving African competitiveness in global research and innovation. To achieve this, the STISA asserts that AU Member States must significantly increase R&D and innovation output at national and regional levels.

The resulting secondary economic and socioeconomic benefits of greater investments in health / HIV- R&D must be fully understood and articulated by health civil society. It is important that policy makers understand the links between increasing budgetary allocations to R&D and the broader benefits this will bring for the public fiscus and the national economy. There are solid examples and case studies which from many countries including Brazil, China and India showing exactly this. Civil society must be able to demonstrate to policy makers how increased public investment in health / HIV R&D for innovation can help stimulate economic growth, spur industrialisation, create jobs, reduce dependency on imports and even boost the potential for export. The case must be convincingly made that increased public investment in health R&D is one tool, if one of many, to help small African economies integrate into the global economy.



It should be noted that certain sectors have, in some African countries at least, successfully made the argument to government that increased public R&D investment in their field will have important secondary multiple economic benefits for the country. The Agricultural and Information Technology and Communications (ICT) sector, for example, have been able to do this in some countries. Health advocates

Examining evidence from a multi-country survey the UNESCO Science Report (2016) identified limited public and financing support for R&D as factors serving as deterrents to FDI in R&D.

have not generally been as pro-active in making such arguments for the funding of health R&D.

Some other industries have also been more successful than health in securing Foreign Direct Investment (FDI) for R&D. The UNESCO Science Report (2016) notes that ICT has attracted more FDI than in any

other sector at 7.2% followed by Education at 5.9% of global share. The low performance in attracting FDI for Health R&D is notable. Again, this is an issue that must be rigorously addressed by civil society, government and the private sector. There are also indications that low public investment in R&D serves to discourage FDI. Examining evidence from a multi-country survey the UNESCO Science Report (2016) identified limited public and financing support for R&D as factors serving as deterrents to FDI in R&D. (Other inhibiting factors included lack of clarity and enforcement of intellectual property rights).

5.5 Building on strengths / Regional Centres of Excellence

While maintaining that the level of public investment in R&D by African government continues to fall well-short of level that would be required to truly realise full socioeconomic benefits, the STISA (AUC, 2014) acknowledges that some AU Member States have demonstrated leadership in establishing National Funds for Research, Innovation and as, in some cases, entrepreneurship. Some African government instrumentalities have also established bi-lateral STI calls for research proposals to promote research collaboration.

However, the STISA strongly emphasises the need for AU Member States going further and prioritising increased investment in STI research and innovation. At the national level, STISA urges African governments to streamline funding for STI, and entrepreneurship in their national development strategies and to adapt existing STI policies to support implementation of STISA-2024. At the regional level, STISA encourages RECs⁸ to establish regional funds to support existing or new regional centres for excellence that respond to STISA -2024 priority areas as well as cross-border research and innovation collaboration to address common challenges.

Health civil society organisations need to help ensure that such regional centres of excellence as envisaged in the STISA are established or expanded to address STISA Priority Two: *Preventing and Controlling Diseases* and, more specifically the implementation of that priority's identified research areas including *Better understanding of endemic diseases such as HIV/AIDS and Malaria* and *Maternal and Child Health*.

5.6 Acknowledgment of the role of civil society

The STISA itself fully acknowledges that civil society has an important role to play in the key aspects of the strategy. The strategy defines a role for civil society in helping create an enabling environment, as a

⁸ Regional Economic Councils



development partner in collaboration for implementation, and as a key stakeholder group whose support is required. However, the strategy also contains what could be interpreted as a warning for African civil society organisations. The STISA (AUC, 2013:19) asserts that:

“Civil society organisations and Think-Tanks are championing the use of African indigenous knowledge to support sustained economic growth, and inform public attitudes and understanding of the relevance and importance of STI. While they contribute to STI policy debate (in various areas) most contributions are not supported by evidence.”

A perception reflected here is that while civil society advocates are well-intentioned and represent genuine needs, the policy positions for which they argue are not generally seen to be back-up by empirical evidence. Whether this view is unfair it is a perception civil society must work hard to change in the coming years in part by ensuring that the positions argued for are backed-up by solid empirical data. Civil society health advocates pushing for a greater public financial commitment to health R&D, and in particular for HIV-related R&D, need to ensure their empirically-based arguments are solid and convincing. It is also important for civil society to utilise the most appropriate policy-making forums and to communicate their arguments in a manner that resounds with the intended audience.

While recognising civil society’s continuing role of supporting implementation and advocacy, the Catalytic Framework (AU, 2016A:13) identifies an expanded role for civil society in building capacity, providing strategic information and the mobilisation of resources and asserts that:

“Non-Governmental Organisations, Civil Society Organisations and Faith Based Organisations non-state actors play an important role in supporting the implementation of policies and advocating for accountability and community mobilisation. Besides these traditional roles non-state actors should play an increasing role in strategic information, capacity development and resource mobilisation to address the three diseases.”

This is a significant position and differs from the stance the STISA of 2013 published only 3 years before the catalytic framework which suggested that civil society’s advocacy was not “evidenced-based”. The catalytic framework (AU, 2016 A) provides a sound basis for health activists making a strategic case for increased investment in HIV-related R&D and to be part of discourse around the mobilisation of resources to fund such efforts.

The Africa Health Strategy 2016-2030 (AU 2016 B) also defines important roles for civil society in the strategy’s implementation. One role is to assist the African Union Commission (AUC), RECs and Member States to promote, disseminate and advocate for the AHS itself while another is to assist in monitoring, reporting at the national and REC levels. A third role for civil society is identified as contributing to innovation, implementation resources, technologies and financial resources in support of the African Health Strategy. It is in this third role that civil society can utilise policy spaces and make the case for a greater public commitment to health R&D.



5.7 Role of African R&D in promoting a pro-poor and human rights agenda

A strong pro-poor and human rights-based case for HIV-related R&D being supported financially by developing world governments can be drawn from a ground-breaking 2012 report by the *Global Commission on HIV and the Law*. The report asserts that research and development departments of large pharmaceutical companies have neglected tropical diseases that affect and kill millions because the potential consumers are poor. A 2006 WHO Commission on Intellectual Property Innovation and Public Health is cited as concluding that diseases affecting millions of poor people in developing countries, patents are not a relevant factor or

The 2012 report by the *Global Commission on HIV and the Law* asserts that research and development departments of large pharmaceutical companies have neglected tropical diseases that affect and kill millions because the potential consumers are poor.

effective in stimulating R&D and bringing new products to the market (Cited in *Global Commission on HIV and the Law*, 2012). The report strongly asserts that drug donations do not offer sustainable solutions but rather leave underlying problems unresolved.

Among its many findings, the *Global Commission on HIV and the Law* report asserts that Trade-Related Aspects of

Intellectual Property Rights (TRIPS) have not encouraged and rewarded the kind of innovation that makes more effective pharmaceutical products available to the poor in developing countries, especially for neglected diseases. The Global Commission concludes that governments of developing countries themselves must develop, agree and invest in new systems that genuinely serve this purpose.

The Global Commission report also notes and supports the call of the WHO Consultative Expert Working Group which has called for countries to start negotiations on a binding international treaty on health R&D.



5. Advocacy Direction for Civil Society

The landscape for health and HIV advocacy is changing. To bring about the desired policies and budget commitments for R&D, civil society must not only lobby government but must capacitate itself and position itself to be part of the enabling functions that help bring these changes about. Some key advocacy concerns for civil society to focus on and to build capacity to implement are summarised below.

6.1 Identification of possible sources of funding for R&D

It is no longer sufficient for health advocates to simply make the case to government for greater public investment in health and HIV R&D pointing to the binding contractual commitments they have made (although this is an important part of the process). Ministers, parliamentarians and other public officials may respond along the lines that they are fully aware of the government's regional and international obligations but that they are faced with the stark reality of a severely limited public fiscus and a vast array of other national priorities competing for scarce public funds.

Among a range of roles, health civil society needs to be positioned itself as a partner to help government identify possible public funding sources which could be leveraged and utilised for expanded R&D. In the *Catalytic Framework to end AIDS, TB and eliminate Malaria in Africa by 2030* (AU 2016A) the

There is a need for civil society hold leaders accountable on research and development, by skilling up on budget monitoring, medical treatment information and public funding sources.

working group of experts have considered the importance of identifying sources of funding for R&D in relation to the three diseases. Potential sources mooted for the country level, as presented to the health ministers, included tobacco and alcohol tax, airport levies, bonds and trust funds. As noted earlier in this report a range of additional potential public sources of funds are also being considered to support Kenya's HIV research agenda.

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Civil society must be part of this discourse. This may be difficult or even uncomfortable for some health advocates who may not feel they have sufficient knowledge of public finance, fiscal and monetary policy. The challenge is then to become sufficiently informed on these matters and to partner with allies with a strong grounding in economics and public finance. It will be particularly important to work with health economists to build a theoretically and practically sound case.

6.2 Clarity and specificity in R&D proposals

Also critical is for civil society to be very specific and detailed as to precisely what is being requested in terms of the R&D budgetary allocation. This includes developing and submitting:

- A description as to exactly what types of research / innovations will be funded, the outputs of the research and how this links to identified national priorities;
- A proposed actual amount of money being requested in the budget, fully costed and linked with the R&D activities;
- The mechanisms /structures/networks through which the funds should be allocated.



The second point ties in with the recommendation of the IAVI Policy Briefing (Ouma-Mugabe 2013) that each country should have a specific and permanent budget line for health R&D integrated into its annual national budget framework. Furthermore, civil society should advocate that this budget line item be further sub-specified for specific types of health R&D, including HIV. One Kenyan researcher asserts that there has been too much concentration of scarce health R&D resources on TB and Malaria and that HIV has been consequently placed on the backburner. There needs to be very specific health R&D targets and these needs to be connected to specific R&D activities, for example, an HIV R&D budgetary sub-line item might allocate X amount of funding for X number of sites undertaking clinical trials.

This final point (above) on mechanisms and structures requires clarity as it pertains to the institutional arrangements for the R&D to take place. Will, for example, the allocation take be made through the auspices of the Department of Health, the Department of Education, a national statutory science council or entity, or through university-affiliated research bodies?

6.3 Promoting implementation of regional agreements

An approach of taking a stronger and more well-defined role in assisting government in no way suggests that civil society should be reluctant to constantly remind government of, and hold government to, their regional and international commitments (as outlined earlier in this report) to expand health and HIV R&D investment. On the contrary. The fact that governments have signed onto many commitments but have largely failed to honour them shows, among other shortcomings, a lack of public accountability and civil society cannot be silent about this. But the challenging question remains for civil society as to how it can effectively push government to honour these commitments. As noted by prominent Kenyan parliamentarian: “Signing is one event. Follow up is another event. Implementation is key.”

A helpful perspective on this difficult strategic question was offered by the same parliamentarian who asserted that “if country governments are well managed we can easily achieve our regional obligations in a stroke.”

This suggests that effective and transparent national governance is synonymous with the fulfilment of regional and international obligations and provides a basis for health civil society to support and participate in the broader push for better improved standards of overall governance and the implementation of better government accountability mechanisms. In terms of the process of adoption of regional commitments relevant to health R&D, the public figure who is, first and foremost, responsible to implement

Ensuring accountability does not have to be conflictual, often barriers to implementation are based on a lack of capacity. AAI's Accountability Framework is useful in creating Transparency on the challenges, Dialogue around solutions and Action for a pragmatic, implementable way forward.

them is the national minister of health. It is primarily the responsibility of that minister to ensure that national health budgets are in line with regional health commitments.

The use of the AAI Accountability Framework in this circumstance is a useful tool.

The tool is a 3 step Accountability Framework as a lens on all of our work. The framework suggests a way to ensure that the principle of accountability is translated from rhetoric into action, and is a highly effective way of holding leaders accountable on commitments.



AAI believes that strong and accountable leadership is necessary to ensure effective responses to health needs. We do this by increasing transparency, promoting dialogue and supporting action to improve the response.

- Transparency: Data, full, relevant, correct, accurate and unbiased data that is methodologically sound, periodically collected and collectively reported, discussed and reported as well as transparent about its failings and limitations is a vital starting point for any discussion on developing a response to health problems.
- Dialogue should mean all relevant stakeholders can meaningfully and freely participate, without fear, in the discussions and debates on the delivery and performance of health by public servants, especially in relation to the commitments that they as governments and leaders have made.
- Action is necessary for public servants to improve their delivery of health, share their successes and learn from their failures making for quality, improved, sustainable and human rights based health access for all a reality. All leaders, not just governments, need to act to ensure transparency and dialogue are part of the health development process.

6.4 Forming strategic partnerships

The need to form broader partnerships and alliances to promote increased health/HIV R&D investment by government is also critical. This may include key figures in other sectors and networks who may also have a stake in expanded R&D, the private sector, among others. It is equally important for civil society to develop and nurture well-placed champions to help forward the R&D agenda. These may include, for example, key figures in parliament, the health ministry and treasury, ministerial advisors and others. A strategy such as this may require patient and consistent engagement over the long-term aimed at not only building the capacity and knowledge-base of the potential champions but earning their loyalty, developing their sense of solidarity and giving them a shared sense of “ownership” over the objectives and outcomes.

6.5 Effective use of the media

Civil society also needs to become more media savvy in terms of promoting the case for greater health / HIV R&D. Many journalists and media outlets may not regard R&D as particularly “appealing” to their readers, viewers or listeners. However, when health R&D is undertaken the media is very often not aware of it even when the outputs of such R&D are of national importance. A greater effort needs to be made to inform and engage with the media but in a manner that is appropriate for that sector. Simple language should be used and scientific and medical terms generally avoided. Important messages around critical R&D issues are sometimes lost because ideas have not been communicated in ways that are specific and understandable.

Members of the media will want to understand exactly how the R&D under discussion will help ordinary people and the nation as a whole. The production of succinct, strategically timed information packages for consumption by the media is a good idea but the producers of such materials should be highly mindful of the target audience. The media will also usually want a human-interest aspect to the story – to “put a face to the data.” On issues pertaining to HIV R&D they may wish to speak directly to PLWHIV⁹ and let them speak for themselves.

⁹ People living with HIV and AIDS



6.6 Role of civil society as envisaged by the Kenya HIV and AIDS Research

Agenda

The policy directions identified in support of the *Kenya HIV and AIDS Research Agenda* (Kenyan Ministry of Health, 2016 A and B) provide a model and a means for civil society to help ensure that the public financing targets are met and that the returns on the investment are realised. Key elements of the agenda include:

- A recognition that health R&D advocates, researchers and research stakeholders must be a part of a coordinated advocacy agenda for domestic financing for HIV R&D that targets the full range of decision makers.
- The National AIDS Control Council (NACC) is tasked with helping ensure that commitment to allocate of 2% of GDP to the National Research Fund (NRF) and 10% of total HIV spending to HIV research are manifested, and that a clear roadmap for progressive implementation and accountability are developed.
- The NACC is also tasked with facilitating improved coordination of HIV research funding to increase productivity, impact and alignment with national priorities.

The Kenyan Health Ministry (2016 A) recognises that the government's commitments to HIV R&D need to be integrated into the national and county budget cycles and discussions. This, in turn, will provide further opportunities for ongoing meaningful input by civil society into the budgetary process. The development of coordinated mechanisms for data sharing, transparency and co-funding with the Government of Kenya is also proposed and this would also provide significant opportunities for civil society input.

The model outlined by in support of the *Kenya HIV and AIDS Research Agenda* is a good one and may provide a template for other counties to emulate. While providing critical opportunities for civil society, however, the model also creates a tremendous responsibility for health and HIV-activists. Civil society must reflect as to whether it currently has the capacity and knowledge base to undertake such tasks as monitoring public expenditure, monitoring the performance of public officials and holding them accountable, and effectively coordinating HIV research funding. A reflective analysis such as this might evince the need for greater capacity building within civils society.

6.7 The need for greater collaboration with government

In addition to working to secure increased funding for health / HIV R&D, civil society should also strongly underline the need for greater collaboration with government. The *Kenya HIV and AIDS Research Agenda* model outlined above may, at least in part, provide a suitable template for this). Such collaboration should, among other objectives, aim to broaden the scope to work with other parties while also maintaining control of the R&D agenda.

As noted by one researcher and activist: "We need to be more recognised as a government initiative." In the situation of undertaking clinical trials, for example, government entities could use their authority and communication mechanisms with affected communities to assure them that such initiatives are fully supported by government and educate people as to the benefits such R&D initiatives will bring. The message to communities needs to be that this is something (e.g. clinical trials) supported by the government. This will help build trust in the target communities and, in turn, provide a more conducive environment for R&D efforts.



In fact, the need to appropriately engage communities to ensure the quality, soundness and applicability of health R&D is in itself a strong argument as to why more R&D needs to be African controlled and funded. Some HIV activists have even suggested that new laws are required to ensure that transparent research committees (with community representation) approve R&D proposals and ensure that communities are appropriately engaged.

6.8 Understanding policy making and the budget cycle

It is vital that health civil society comes to understand how to influence the public policy making process, and processes to influence the budget, in their country. In this sense health activists must become political scientists as well as campaigners. The critical points of interaction to influence public policy and budget development need to be identified and utilised. This will vary significantly from country to country. In Kenya for example, important governance changes have shifted some power away from the executive to parliament. Therefore, in that country civil society should primarily focus on reaching parliamentarians and members of the health and finance committees. (But it would be also important to develop relationships in the health and finance ministries). In other countries, there may be greater power invested in the executive arm of government and in these cases, while targeting parliament and relevant committees remain important, a greater priority may be to target the health and finance ministries, key ministerial advisors, etc.

In any country, it is important for civil society to understand and utilise the range of influential spaces, platforms and processes to influence public policy and budgetary processes. These tend to change over time as structures / processes to facilitate participation develop and wane. One opportunity that only occurs after a national election is the education of members of a new incoming parliament. Many new parliamentarians will be eager for information, capacity development and support now and health civil society should utilise this opportunity to build new key partnerships.

In many countries, the national budget cycle will have several opportunities for public input and civil society must understand these well. In fact, in many instances, public participation in the budget process is mandated by law. Before engaging with the process there needs to be an understanding of where the gaps are and clarity on what exactly budgetary measures are being proposed. This needs to occur before parliament receives the estimates from the national treasury.

In some countries, South Africa and Kenya included, parliament has the power to adjust allocations to specific budget line-items and can thus shift funds in the governments proposed budget. For this to occur the support of budget committee member may be critical, and, in some countries, the support of the chair of budget committee would be key. As overarching objectives, it is important to build key allies in the budgetary process, to work with policy makers as partners and to invest the necessary time resources into education and capacity building.

6.9 Other key advocacy considerations

It is important that civil society to think not only in terms of advocacy at the national government level but also at the regional level. As one of many examples underlining this principle, it may take a concerted collaborative cross-border effort by civil society to hold the African Union Commission (AUC) accountable in terms of its commitment to establish the African Centre for Disease Control.



Another issue for civil society, and indeed for governments, to ensure that the role of health R&D in helping address and solve national health challenges and priorities is properly assessed and publicly recognised.

A significant shortcoming concerning R&D in Africa identified by the UNESCO Science Report (2016) was that there is limited focus on assessing how research efforts are contributing to solving needs in a range of areas, including health.

Civil society also has the challenge of working more closely with communities and networks on the ground to educate them as to the critical need for greater health R&D investment by government for people such as themselves and the country. In this sense the call for greater investment in health R&D will come not only from professionals and established organisations, but also from the grass roots. The desired situation would be would be politicians and officials being asked, by community leaders and at public gatherings, what the government is doing to ensure that there is more health and HIV research.

6.10 Concluding comment on advocacy

A central advocacy message to policy makers in terms of health / HIV R&D needs to be that recognition that “whomever has the cheque determines what we are going to do” and that it is critical for African countries to develop, finance and implement their own health R&D agenda. In one sense, however, this is simply recognising the inevitable. As noted by the Kenyan Ministry of Health (2016 A) donor funding for HIV-related R&D is projected to fall steadily in the next few years. African governments will less and less have the option of saying “donors will take care HIV R&D and we can rather invest in other R&D priorities.” But there is great opportunity presented in the context of donor withdrawal and these opportunities must be effectively communicated by civil society.



7. Promoting African control of the health and HIV R&D agenda

There is a growing recognition across the continent that African health challenges require African-developed solutions and that the status quo of health R&D being overwhelming funded by foreign donors does not serve this objective. The point has been made by African health advocates that treatments and products developed outside of the African context (and with scant regard for sociocultural, community and other factors), will not necessarily be suitable for the African population. Limitations and challenges arising from foreign-sponsored R&D on microbicides is one of several examples.

Most health-related R&D in Africa continues to be funded by foreign donors and companies from all over the world and there is no real overarching set of goals and a common agenda which would direct the R&D in such a way that it would ensure primary benefits for African health consumers and local economies.

The full spectrum of Africa development stakeholders need to own the African R&D agenda, budget and outcomes if the continent is going to see any long-term benefits.

Comparatively little current health R&D in Africa is government or community controlled and much of it is not necessarily linked with identified national development priorities.

Also, there is comparatively little local “capture” of such R&D research results and outcomes to utilise for the public good. In many cases local people may be utilised as research subjects but the results and knowledge gained are exported with minimal knock-on benefits for the host

country and its people. This is a paradigm which must fundamentally shift and civil society must passionately take on the task to ensure that it does so, armed with convincing arguments and a multi-layered advocacy strategy.

Governments should understand that increased investment in health / HIV- R&D will not only serve to assert more control over the research and innovation agenda, bring it closer in line with critical national priorities, better capture the benefits for local utilisation and facilitate positive secondary socioeconomic effects, but could also, if well planned and coordinated in collaboration with key stakeholders, serve as leverage for greater private sector investment.

Numerous policy statements attest to the need to stimulate more private sector investment in health / HIV R&D. Substantially increased public investment, if properly targeted in consultation with potential private sector investors, may serve to leverage more private funds and develop important public-private R&D partnerships, but with the critical caveats that government does not lose control of the agenda, that provision is made for local “capture” of outputs and that the R&D undertaken is in line with national policy priorities. There should be many opportunities for win-win situations in public/private funding for health R&D. Again, 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.

There is also significant potential to leverage more private African-based philanthropic funding for health /HIV R&D and this could become part of the mix of funds utilised in public-private partnerships. While civil society must certainly advocate to government to for much greater R&D investment it must also be remembered that there is a growing pool of wealthy Africans who spend heavily on philanthropy but not necessarily on



health. A growing number of African-based companies (such as Safari.com) have developed significant philanthropic/developmental functions but, in general, health concerns seems to be at the periphery. Health civil society must find ways to begin to engage with such companies around the possibility of support for health / HIV R&D and to bring government into the discussion. There is fertile ground for investment here particularly regarding the area of technology and health.

It is also important to note that shifts have, for the last few years, been underway in the international development landscape in both policy and strategy which may have profound effects on HIV prevention research funding, creating, in effect, a greater responsibility for developing world governments to fund their own health R&D. AVAC (2015) notes that there is an increasing trend by government donor agencies towards country-ownership models for the HIV/AIDS response. In other words, there is a growing expectation among donor countries that beneficiary countries will take greater “ownership” and responsibility for their HIV prevention research.



8. SUMMARY OF FINDINGS

A decrease in funding for R&D globally, does not conceal the fact that spending on R&D in Africa is difficult to ascertain and not transparent. African govts might be increasing expenditure, especially East and Southern Africa, but still spending less than committed. If Africa is going to reap the benefits of home grown benefits, counter the effects of withdrawing foreign donor countries, and live up to the 2016 Catalytic Framework and other commitments, all stakeholders need to treat the issue as urgent. Civil society especially needs to up-skill to hold leaders accountable and ensure the sustainable African investment in local R&D.

- While overall funding for HIV-related R&D at the global level has been static, a more nuanced examination reveals significant decreases in funding for some key HIV prevention R&D initiatives in recent years.
- The difficulty in ascertaining with certainty how much is currently being spent on HIV R&D in most African countries reflects poorly on transparency and is a major public accountability issue.
- The information that is available suggests that many African governments have increased spending on health R&D in recent years. However, almost all still fall short of their obligation to spend 1% of GDP on overall R&D and 2% of the national health budget on health R&D.
- There is an array of good reasons, including sociocultural reasons (as summarised in section 2.2.1 of this report) why African-funded and African-led R&D on HIV prevention measures is more effective than foreign led and funded R&D.
- Even within the context of low expenditure on health R&D in Eastern and Southern Africa there are notable variations in the region between countries.
- There are indications that donor funding for HIV-related R&D will fall steadily in the next few years, creating a widening gap which governments will need to address.
- There is also a trend by government donor agencies towards favouring the country-ownership models for the HIV/AIDS response.



- ✚ There is little local capture of health R&D research undertaken in Africa to utilise for the public good as results and knowledge gained are exported with minimal knock-on benefits.
- ✚ While budgetary commitment to R&D across Africa is too low there have been some important innovations in recent years.
- ✚ Compared to other regions, Africa has not effectively invested in, nor reaped the range of benefits of, health R&D.
- ✚ The promulgation of the 2016 Catalytic Framework and Common Position represent renewed regional mandates for governments to increase their HIV R&D expenditure.
- ✚ Civil society needs to better-understand and utilise the full range of spaces, platforms and processes to influence public policy and budgetary processes.
- ✚ Important budgetary and legislative proposals in Kenya to significantly increase HIV R&D funding should be monitored and closely examined by governments across the region.
- ✚ Recent policy developments define important roles and opportunities for civil society around health / HIV R&D and in ensuring accountability. Effective utilisation of such roles and opportunities may require significant capacity building within civil society.
- ✚ Civil society must be prepared to engage in the discourse around the issue of identifying innovative sources of public finance to be utilised for HIV R&D.
- ✚ Recommendations made by the IAVI Policy Briefing of 2013 concerning increased spending on health R&D and monitoring of the use of such funds are still highly relevant.
- ✚ In addition to low levels of government expenditure, HIV R&D is also hampered by low levels of Foreign Direct Investment (FDI) in health R&D in Africa.
- ✚ Significant potential exists to leverage more private African-based philanthropic funding for health /HIV R&D.
- ✚ Shifts in the international development funding landscape may result in create a greater expectation of developing world governments to fund their own health R&D.



9. RECOMMENDATIONS



Civil society needs to more closely engage with the African R&D agenda if any progress is going to be made. Governments alone are not pushing the agenda significantly and need to be held accountable by a funded, up-skilled, informed continent wide civil society movement. AAI's Accountability Framework would structure this response to ensure greater *Transparency* around data, expenditure and evidence to track performance; forums of *Dialogue* need to take place with all stakeholders to ascertain and feed into the discussion around the evidence, and develop a comprehensive manageable and implementable roadmap and then real *Action* needs to take place with monitored deliverables and timelines.



African health and HIV civil society should:

- Broaden and develop its capacity to the extent that it can meaningful engage with government in terms of being able to:
 - Clearly identify the specific gaps in HIV R&D that need to be addressed by government;
 - Provide fully costed proposals as to precisely the level of funding needed to meet these gaps;
 - Articulate the precise mechanisms and structures that will facilitate the funds being utilised for the purpose for which they are allocated; and
 - Clearly demonstrate how such increased public financing of R&D will be likely to have secondary economic benefits for the country.
- Strongly support government investigation at the highest level (including senior figures in treasury, finance, etc.) into potential new and /expanded domestic revenue raising to support health R&D. These may include sources suggested in the catalytic framework (such as tobacco and alcohol tax, airport levies, bonds, trust funds etc.) and sources identified by the Kenyan Ministry of Health.
- Widely publicise in multiple government and non-government fora the commitments of African governments as set out in the catalytic framework and the common position of 2016. Develop national and regional-wide strategies to hold government to account to the specific commitments made in the framework. Prime among such commitments is that governments must fully implement their costed National Strategic Plans for HIV, TB and Malaria to ensure the efficient utilisation of the allocated resources.



- ✚ Strongly support the paradigm shift outlined in the *Catalytic Framework* towards African-led initiatives for funding disease responses. Consistently underline the framework's commitment to increasing domestic financing for innovative health mechanisms to fulfil AU and global commitments, and emphasise that this must necessarily entail greater public investment in HIV R&D.
- ✚ Work with governments to form a position in which proportion of all health funding in the national budget is reserved for health R&D. The Bill on this matter currently before the Kenyan Senate may be a good model on which to base a template for national advocacy.
- ✚ Investigate what support it can bring for African governments to respond to the call (by WHO and the *Global Commission on HIV and the Law*) for a binding international treaty on health R&D.
- ✚ Consistently convey to policy makers the consequences of the lack of public investment in R&D placing African countries, and the continent, at a strategic disadvantage in which so many developmental and economic opportunities are lost.
- ✚ Similarly, emphasise the lack of local capture of foreign-funded health R&D research results and outputs leading to the “export” of the outcomes and knowledge with little local benefit. Further emphasise that greater African government-funded R&D will help prevent the exit of such knowledge and outputs and maximise its local public utility.
- ✚ Using examples from Brazil, China, India and other nations, consistently demonstrate to policy makers that investments in health R&D for innovation helps stimulate economic growth and industrialisation.
- ✚ Drawing from the Kenya AIDS Research Agenda and other sources build and widely promote the case that investment in increased HIV R&D will result in a substantial long-term savings and multiple-fold cash returns.
- ✚ Make the case for, and actively work towards, greater collaboration between R&D outfits and government which, among a range of mutual benefits, will help develop a more conducive environment for R&D and the utilisation of results/outputs.
- ✚ Recognise that highly effective and transparent national governance is synonymous with the fulfilment of regional and international obligations. Accordingly, support the broader civil movement for improved standards of overall governance and the implementation of better government accountability mechanisms.
- ✚ Strategize to cultivate well placed champions of civil society's agenda for greater budgetary commitment to HIV R&D. (Depending on the political structures and processes specific to a country, such champions could be key parliamentarians, ministers or ministerial advisors, key figures in the presidency, health department, etc.).
- ✚ Widely discuss and promote the idea that African-led and Africa-funded HIV prevention R&D (including Microbicides, VMMC, PrEP, treatment-as prevention and preventative vaccines) will greatly increase the successful utility of the outputs of such R&D for the African context.



- ✚ Work to ensure that the role of health R&D in helping address and solve national health challenges and priorities is properly assessed and publicly recognised.
- ✚ Further investigate possibility of developing an AU-wide umbrella body whereby health R&D money is channelled to address agreed-upon set of objectives with built in mechanism to evaluate, audit and track R&D funds.
- ✚ Advocate that government commitments to HIV R&D to be integrated into the annual county budget cycle and discussions. Support and contribute to moves to improve the tracking of health / HIV R&D expenditure noting that this is crucial for transparency and accountability.
- ✚ Develop capacity and a strategy to effectively engage with media in terms of promoting the case for greater HIV R&D.
- ✚ Consider in depth what types of broader partnerships and alliances it can enter into to promote increased public investment in HIV R&D. Strategize and coordinate to achieve the manifestation of such partnerships.
- ✚ Ensure that advocacy strategies are developed and implemented not just nationally but also regionally to also hold the AU and the AUC to its obligations.
- ✚ Strategize to work more closely with communities and networks on the ground to educate them as to the critical need for greater health R&D investment by government for people such as themselves and the country.
- ✚ Advocate, as part of a broader alliance, for the establishment and resourcing of regional centres of excellence, as envisaged in the STISA, and that such centres address as a priority the STISA objective of better *understanding of endemic diseases such as HIV/AIDS*.
- ✚ Lend support to government and the AU to hold the international community (including the Global Fund) accountable to their HIV-related R&D commitments.
- ✚ Strongly advocate to government that (as identified in the 2015 AVAC report and other sources) HIV R&D must inform the best possible delivery of HIV prevention products and ensure that those products meet the needs of, and reach, end-users. Further, emphasise that this underlines the importance of African-led and funded HIV R&D particularly with regard to options such as VMMC, microbicides, female condoms and PrEP.
- ✚ Give explicit support full implantation of the 2013 IAVI Policy Briefing's recommendations to develop a framework and set of indicators for monitoring health R&D expenditure; ensuring that each country has specific budget line for health R&D in their annual budget framework; and that each country be required to prepare a biannual report on health R&D status and financing,
- ✚ Convene key senior government figures, private sector representatives and other stakeholders to address the issue of the low levels of Foreign Direct Investment (FDI) in health / HIV R&D in Africa and strategize towards the goal of attracting greater FDI. The AU should address this as a continent-wide challenge.



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Additional sources

- Material gleaned from presentations, panel discussions, focus groups and general discussion at the Civil Society Meeting on HIV Prevention R&D, May 17 & 18: Nairobi, Kenya
- Numerous informal interviews and discussions with HIV researchers and civil society activists.





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