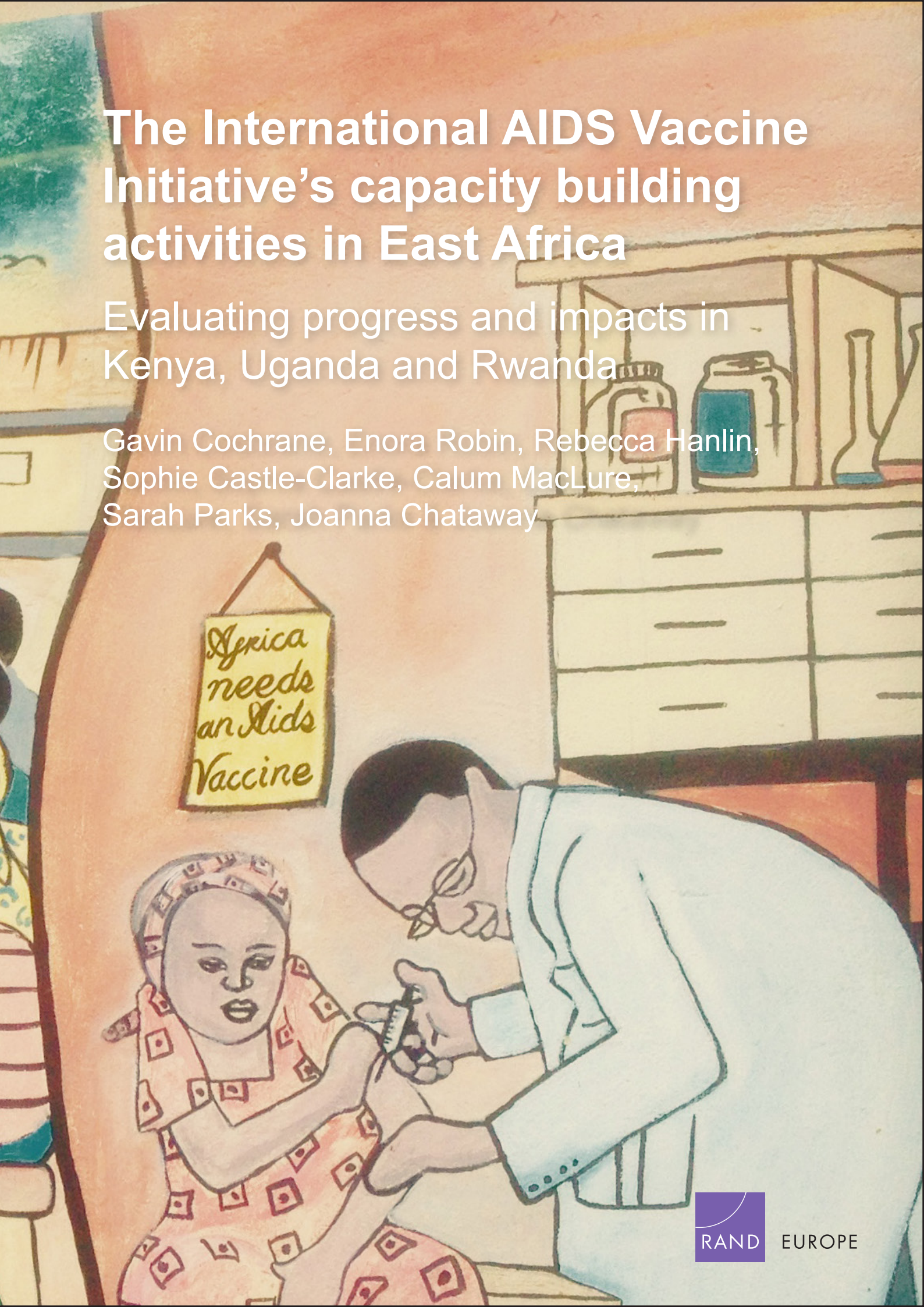


The International AIDS Vaccine Initiative's capacity building activities in East Africa

Evaluating progress and impacts in Kenya, Uganda and Rwanda

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Sarah Parks, Joanna Chataway



Africa
needs
an Aids
Vaccine

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Preface

The International AIDS Vaccine Initiative (IAVI) is one of a number of PDPs created to bridge the gap between scientific and technological potential and the health needs of populations in LMICs. The remit of IAVI is to ensure the development of a safe, effective, accessible, preventive AIDS vaccine for use throughout the world. This work involves a wide range of stakeholders in industrially developing and developed countries.

IAVI's capacity building activities aim to strengthen the ability of its partners to conduct clinical trials and also to enhance a variety of other areas ranging from scientific and technological capacity through to organisational, advocacy and broader development capabilities. In essence, IAVI's capacity building activities aim to build and strengthen health research systems that are conducive to HIV vaccine discovery and to increase preparedness for a vaccine's eventual licensure.

IAVI's geographic remit related to capacity building includes both Eastern and Southern Africa as well as India. This evaluation of IAVI's capacity building activities is focused on East Africa and uses a multi-method approach, combining both desk-based research and fieldwork. The project aims to improve understanding of the type and scope of capacity building that IAVI has conducted and its impact at national and regional levels. IAVI's capacity building work in East Africa was funded by a diverse array of donors – a full list can be found on IAVI's website (www.iavi.org).

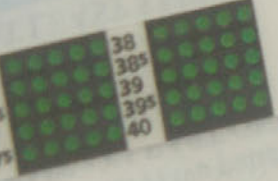
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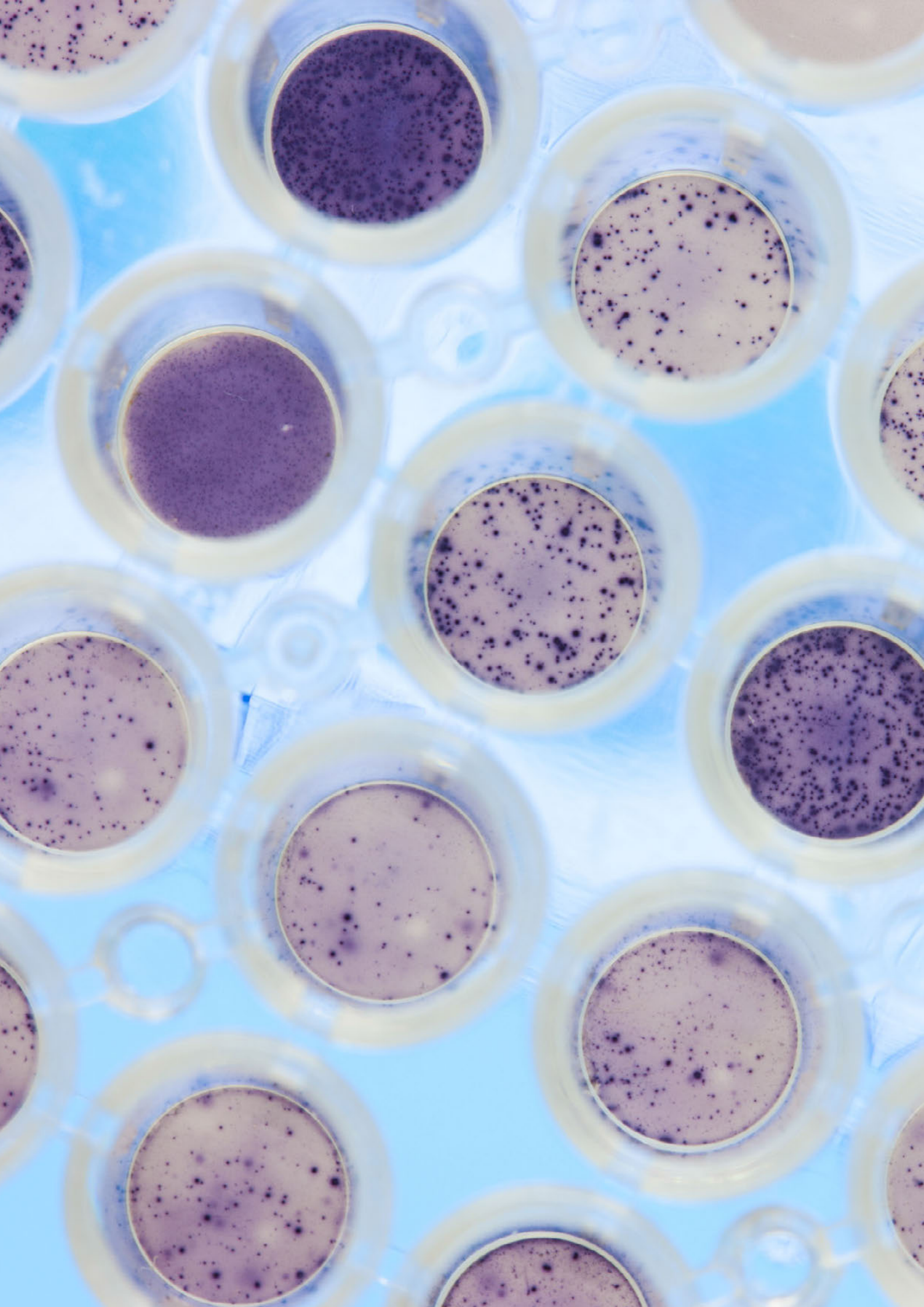
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Summary

The last twenty years have seen an increased focus on research capacity building and capacity strengthening efforts in development interventions, by a variety of organisations such as donor governments, multilateral agencies, science funders and product development partnerships (PDPs). These interventions aim to help build new or develop existing research capacities in low- and middle-income countries (LMICs) in order to reduce dependency on research conducted in high income countries and to address local needs (Jones et al. 2007). The International AIDS Vaccine Initiative (IAVI) is one of a number of PDPs created to address the risk of vaccine development for scientifically challenging pathogens. IAVI is committed to bridging the gap between scientific and technological potential and the health needs of populations in LMICs by demonstrating the feasibility of an HIV vaccine to ensure industry resources for advanced development and licensing. The remit of IAVI is to ensure the development of a safe, effective, accessible, preventive AIDS vaccine for use throughout the world. To achieve this mission, IAVI's work involves a wide range of stakeholders in industrially developing and developed countries. IAVI's capacity building activities aim to strengthen the ability of its partners to conduct clinical research and vaccine trials and also to enhance a variety of other areas ranging from scientific and technological capacity through to organisational, advocacy and broader development capabilities. In essence, IAVI's capacity building activities aim to build and strengthen health research systems that are conducive to vaccine discovery and to increase preparedness for a vaccine's eventual licensure.

However, empirical evidence about the impact of IAVI's capacity building in developing countries is fragmented and far from comprehensive (Chataway & Hanlin 2008; Hanlin et al. 2007; Vian et al. 2013). This is perhaps surprising given the recognised importance of different forms of capacity building and the need to strengthen health research systems. Efforts by IAVI and its partners to continually build capacity make the need for this evaluation even more relevant, as increasingly competitive funding environments mean that demonstrating strong rationales and evidence of success, is increasingly important.

This evaluation therefore seeks to address the following research questions:

1. How has IAVI conceptualised capacity building? How has this changed over time?
How does practice match up with this theory of change?
2. What examples stand out with regards to IAVI's capacity building in East Africa, specifically in the areas of:
 - a) Human resource development (to conduct research and to support research)
 - b) Research capacity: technology transfer and infrastructure development
 - c) Community and policy level activities
3. Are there specific communities and segments of society where IAVI's work has led to significant improvements in policy and health service delivery?

4. Have IAVI's capacity building activities fed into attempts to strengthen capacity in the healthcare and health research systems in the countries in which they have worked?
5. Is IAVI making particularly notable and important contributions to health innovation and research capacity compared to other organisations in this field?

We identified four key categories into which IAVI's capacity building activities can be placed and which will be used as the units of analysis for this evaluation. These are highlighted in Figure s1 below. Note, while observations in this report are limited to IAVI's work in East Africa, the below framework may be relevant for future evaluation of IAVI's capacity building programs in Southern Africa and India. We define 'capacity building' as including 'any efforts to increase the ability of individuals and institutions to undertake high quality research and to engage with the wider community of stakeholders' (ESSENCE 2014:7). Unlike previous studies, it therefore seemed appropriate to include advocacy and community engagement activities within our assessment of capacity building.

	Individual	Institutions and local communities	National - Regional	International
Scientific skills and training	Building the research capacity of existing staff	Establish high quality standards /centres of research excellence	Contributing to improving visibility of African research	Harness partnerships to expand base on HIV vaccine R&D
Research infrastructure	Supplying researchers with lab equipment	Building state-of-the-art research infrastructure	Strengthening national research capabilities	Pooling resources with the global research community
Community engagement	Counselling and access to healthcare for volunteers	Education and awareness programmes for communities	Creating platforms to facilitate civil society engagement	Shaping the international agenda on key populations
Advocacy	Communication skills for policy audience	Evidence-based advocacy training for civil society groups & communities	Providing technical assistance to national AIDS plans	Ensuring sustained investment in HIV vaccine research

Figure s1: Conceptual framework for IAVI's capacity building activities

Box 1 below highlights how IAVI's conceptualisation has evolved over time as well as the findings across each of the four key categories outlined in Figure s1 above and how these activities have had an impact on key population groups in each of the three countries.

As a result of its clinical research activities in East Africa, IAVI's mission to develop an HIV vaccine has become increasingly connected to wider health research systems

Box 1: Key insights into the progress and impact of IAVI's capacity building activities

IAVI's conceptualisation of capacity building

- As a core component of developing an AIDS vaccine that meets the needs of those most vulnerable to HIV, IAVI has incorporated capacity building as a key feature of its strategy in Africa. IAVI's conceptualisation of capacity building remains broad and both internal and external factors appear to have influenced its evolution over time (Section 4.1).

Scientific Skills and Training

- IAVI has made a significant contribution to training interventions to support scientific excellence and Good Clinical Practice for AIDS vaccine clinical trials and epidemiology studies, in particular through the provision of GCP and GCLP training and short courses for over 800 participants.
- IAVI has begun to provide direct support to build further research capacity, through technology transfer of assays and techniques as well as advanced degree support (MSc, PhD) and mentorship that will enable East African scientists to lead AIDS vaccine research and development programs (Section 4.2).

Research infrastructure

- IAVI has established a network of partners with the necessary clinical, laboratory and IT infrastructure to conduct high-quality clinical and epidemiological research and assess the safety and immunogenicity of vaccines. This infrastructure has demonstrated its application for both upstream AIDS vaccine research and other diseases (Section 4.3).

Community engagement

- IAVI has successfully developed integrated community engagement platforms to ensure that its research reflects community interests, safeguards participants' rights and translates research findings in an effective manner (Section 4.4).

Advocacy

- IAVI has played an instrumental role in bridging the gap between researchers and policymakers and engages with governments to ensure that HIV vaccine research is an important component of national policy agendas and aligns with national research priorities (Section 4.5).

Impact of IAVI's work on key populations

- IAVI has been successful at engaging and accessing key populations for research, including fishing communities in Uganda, MSM in Kenya and discordant couples in Rwanda. Data from research has been shared with civil society and policymakers and is beginning to contribute to health policy change (Section 4.6).

strengthening. Since it began operations in the region, IAVI has made a significant contribution to training interventions aimed at supporting scientific excellence and Good Practices (Clinical, Clinical Laboratory and Participatory) as well as investing in infrastructure and laboratories at clinical research centre (CRC) partners. In addition, IAVI has created platforms for engaging with local communities and policymakers on issues related to HIV and vaccines. IAVI's advocacy and communications strategies are based on an underlying belief that the very significant investment needed in HIV/AIDS research was contingent on demand from those who most needed new research in the area - i.e. by populations and their political representatives in developing countries worst affected by the disease. This demand, in turn, would depend in part on greater awareness of and involvement in HIV vaccine research. A key factor in the success of IAVI's scientific capacity building in the region is its ability to act as a broker between researchers, policymakers and local communities. Strong leadership and a commitment to facilitating

Box 2: Key scientific achievements made by IAVI-sponsored research

- Development of the largest acute infection cohort in Africa, which found:
 - That HIV disease progression/viral control varies by sub-type, with subtype C more aggressive than subtypes A and D;
 - The emergence of broadly neutralizing antibody (bnAb) responses approximately 3 years after acute infection;
 - The intense selection pressure on the characteristics of transmitted founder viruses and relationship of virus replicative capacity to disease course.
- Identification and characterization of high-risk populations, methods to reduce risk, and suitability for intervention trials (MSM, FSW, Fishing Communities, Discordant Couples);
- Participation in a cross sectional study of HIV+ samples that led to the identification of around 50 new bnAb and launched renaissance in bnAb identification
- Determination of regionally relevant African blood value clinical trial reference ranges

South-South collaborations between CRCs have also been important in enabling IAVI to both build capacity and make progress towards their larger mission. Increased research capacity across the CRCs has also meant that East African researchers have made a significant contribution to some of the key scientific achievements by IAVI-sponsored research to date, highlighted in Box 2 above.

The findings from our interviews with key stakeholders at IAVI highlight the diversity of factors which have influenced the evolution of their capacity building activities in East Africa. Box 3 presents some of the key overarching themes emerging from IAVI's activities, as well as some considerations for IAVI's future capacity building, based on our findings and observations.

While IAVI's progress in building scientific capacity in Africa appears to have been widely acknowledged in previous evaluations, we have observed an increased emphasis on capacity building as a core component of their strategy in East Africa. This shift may be due, in part, to a proactive effort to more closely align IAVI's work with donor priorities. IAVI's challenge for future capacity building activities will depend on how it balances a broader focus whilst maintaining its core mission of developing an HIV vaccine. These two aims are of course not mutually exclusive. However, as IAVI diversifies its portfolio of activities, demonstrating the impact of its work and securing further funding will be helped by a better understanding and articulation of: (i) what IAVI considers to be its core capacity building activities, which require monitoring and strategic objectives; (ii) where its activities have a spillover effect in further strengthening capacity; and (iii) which activities are outside its remit.

Although clear challenges still exist in ensuring sustained investment, accessing marginalized populations and demonstrating progress in capacity building, the experiences of IAVI to date suggest that substantial progress is being made towards wider health research systems strengthening in the region. The efforts to discover an HIV vaccine have been, and will continue to be, a global endeavour, relying on strong

Box 3: Key scientific achievements made by IAVI-sponsored research

The value of long-term networks

- The creation of a strong network of CRCs in East Africa that collaborate on AIDS vaccine research, training and publications provides an integrated platform to conduct research of expanded scope and complexity. It is also helping to develop professional opportunities for researchers and is strengthening the regional scientific community
- IAVI's long term presence has helped enhance its reputation as a trusted partner both for research sites and for local communities and policymakers

Distributed leadership and a commitment to engagement with diverse stakeholders

- Leadership has proved an important enabler of success in IAVI's capacity building efforts, including increasing utilization of partners in leadership and advisory roles in the global AIDS vaccine field.
- IAVI has recognised the importance of flexible partnerships and good communication between a range of stakeholders to building effective and sustainable capacity in HIV vaccine research
- IAVI's commitment to translating research into policy has facilitated meaningful engagement with policymakers and local communities

Demand-driven capacity building

- IAVI's bottom-up approach, whereby CRCs are responsible for identifying their own training needs and research priorities, and local communities are engaged in the whole research process, has been a strong enabling factor in IAVI's capacity building activities

Internal and external challenges to capacity building

- IAVI faces a number of external challenges that are inherent to the context in which their capacity building activities take place
- IAVI's capacity building activities have expanded over time and the organisation will need to consider how it balances a broader focus whilst maintaining its core mission of developing an HIV vaccine.

Considerations for future capacity building activities

- Success in IAVI's move towards supporting basic research in Africa will be dependent on its ability to facilitate clear, sustainable career pathways
- Coordinating efforts with other capacity building actors in the region may offer the opportunity to pool resources and share experiences
- IAVI should consider the remit of its future capacity building activities, in terms of what it intends to support and where it can help support others
- Specific M&E indicators for evaluating capacity building activities may help IAVI to demonstrate progress to donors
- Balancing flexibility and the formalisation of partnerships may help to clarify expectations and objectives
- More emphasis could be placed on developing non-research training skills at the Clinical Research Centres

international research collaborations and increasingly African scientific leaders. As we move into a post-2015 agenda and begin to focus on improving the sustainability of health research systems in sub-Saharan Africa, organisations such as IAVI can play an important role in developing and advocating improvements in the African research landscape.



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Abbreviations

AIDS	acquired immune deficiency syndrome
amfAR	American Foundation for AIDS Research
AVAC	AIDS Vaccine Advocacy Coalition
bnAb	broadly neutralizing antibody
CAB	community advisory board
CDC	Centers for Disease Control
CGMR-C	Center for Geographical Medical Research-Coast (at KEMRI)
CLO	community liaison officer
CONRAD	Contraceptive Research And Development Program
CRC	clinical research centre
CVCT	couples voluntary counselling and testing
DFID	UK Department for International Development
DNDi	Drugs for Neglected Diseases initiative
EVI	European Vaccine Initiative
FIND	Foundation for Innovative New Diagnostics
GALCK	Gay and Lesbian Coalition of Kenya
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
GPP	Good Participatory Practice
HIL	Human Immunology Laboratory
HIV	human immunodeficiency virus
IAVI	International AIDS Vaccine Initiative
ICT	information communication technology
IDRI	Infectious Disease Research Institute
IPM	International Partnership For Microbicides
IPPPH	Initiative for Public Private Partnerships for Health
JCRC	Joint Clinical Research Center
KAVI-ICR	Kenya AIDS Vaccine Initiative Institute of Clinical Research
KEMRI	Kenya Medical Research Institute

KII	key informant interview
KMCC	Knowledge Management and Communication Capacity
KWTRP	KEMRI Wellcome Trust Research Programme
LGBTI	lesbian, gay, bisexual, transgender and intersex
LMIC	low and middle-income country
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
MSc	masters of science
MSM	men who have sex with men
MVI	Malaria Vaccine Initiative
MVP	Meningitis Vaccine Project
NASCOP	National AIDS & STI Control Programme
NGO	non-governmental organisation
PDP	product-development partnership
PDVI	Pediatric Dengue Vaccine Initiative
PhD	doctor of philosophy
PPP	public private partnership
PSF	Projet San Francisco
TB	tuberculosis
UAC	Uganda AIDS Commission
UFFCA	Ugandan Fisheries and Fish Conservation Association
UHMG	Uganda Health Marketing Group
UNDP	United Nations Development Programme
UON	University of Nairobi
USAID	United States Agency for International Development
UVRI	Uganda Virus Research Institute
VHT	village health team
WAC	World Aids Campaign
WHO	World Health Organization

1. Introduction

The International AIDS Vaccine Initiative (IAVI) is one of a number of product-development partnerships (PDPs) created to bridge the gap between scientific and technological potential and the health needs of populations in low and middle income countries (LMICs). These partnerships bring together academic institutions, public institutions, the private sector, non-governmental organisations (NGOs) and international donor agencies to develop health innovations to benefit LMICs in a wide range of disease areas (HIV, malaria, tuberculosis and other neglected diseases). IAVI's principal aim is to ensure the development of a preventative vaccine for HIV/AIDS. IAVI was set up in 1996 as a not-for-profit organization head-quartered in New York with the aim of promoting the discovery and development of an effective and affordable AIDS vaccine. IAVI is supported financially by national governments, foundations and the private sector and works in five African countries (Kenya, Rwanda, South Africa, Uganda and Zambia), as well as India, Europe and parts of the United States.¹

The 2000s saw a growing recognition of the need to evaluate the performance of PDPs (and other health-related public-private partnerships). In 2004, the Initiative for Public Private Partnerships for Health (IPPPH) concluded that, 'judging success is important to funders and requires the development of comparative performance measures' (Widdus & White 2004:2). Evaluation also helps PDPs demonstrate effectiveness of their work more clearly to the outside world at a time of increased financial pressure on international health and development organizations' activities. Despite this, there has been little work developing appropriate performance measures, and those that do exist do not cover many areas of capacity building (Hanlin 2011).

The mission of IAVI is to ensure the development of a safe, effective, accessible, preventive AIDS vaccine for use throughout the world. To achieve this mission, IAVI's work involves a wide range of stakeholders in industrially developing and developed countries. IAVI's capacity building activities aim to strengthen the ability of its partners to conduct clinical research and vaccine trials and also to enhance a variety of other areas ranging from scientific and technological capacity through to organisational, advocacy and broader development capabilities. In essence, IAVI's capacity building activities aim to build and strengthen health research systems which are conducive to vaccine discovery and development and to increase research systems' preparedness for a vaccine's eventual licensure.

1.1. Objectives of this evaluation

Empirical evidence on the impact of IAVI's capacity building in developing countries is patchy and far from comprehensive (Chataway & Hanlin 2008; Hanlin et al. 2007; Vian

1 <http://www.iavi.org/where-we-work-map>

et al. 2013). This is perhaps surprising given the recognised importance of different forms of capacity building and the need to strengthen health research systems. Efforts by IAVI and its partners to continually build capacity makes the need for this evaluation even more relevant; In addition increasingly competitive funding environments mean that demonstrating strong rationales and evidence of success is increasingly important.

Articulating and documenting the rationale for IAVI's capacity building activities allows a thorough examination of experience and expectations from multiple stakeholder perspectives. These may include field-based institutions, researchers, community advocates, policy makers and healthcare organisations. Over time, such an evaluation approach allows organisations to understand the outputs and impacts of their efforts, and to test whether the underlying assumptions behind an intervention and strategy are valid.

This evaluation has therefore sought to address the following research questions:

1. How has IAVI conceptualised capacity building? How has this changed over time? How does practice match up with this theory of change?
2. What examples stand out with regards to IAVI's capacity building in East Africa, specifically in the areas of:
 - a) Human resource development (to conduct research and to support research)
 - b) Research capacity: technology transfer and infrastructure development
 - c) Community and policy level activities
3. Are there specific communities and segments of society, such as men who have sex with men (MSM), fishing communities and discordant couples where IAVI's work has led to significant improvements in policy and health service delivery?
4. Have IAVI's capacity building activities fed into attempts to strengthen capacity in the healthcare and health research systems in the countries in which they have worked?
5. Is IAVI making particularly notable and important contributions to health innovation and research capacity compared to other organisations active in this field?

While IAVI has a broad geographic remit, including work in Southern Africa and India, the findings from this study are limited to the observation of IAVI's capacity building activities in Kenya, Rwanda and Uganda, particularly at the five clinical research centre (CRC) partners in these countries. CRC's are defined as IAVI's in-country institutional research partners, who are responsible for helping to define and implement the IAVI-sponsored research portfolio, in addition to research conducted with other partners. IAVI's model has involved identifying local research institutions, then developing the necessary capacity to implement relevant research.

This evaluation focuses on East Africa, meaning that we have not included any analysis of IAVI's work in other African countries, such as Zambia or South Africa. The evaluation also focuses on field-based stakeholders, to try to capture perspectives on IAVI's capacity building from those who were intended to benefit from it. The study team is also aware that other issues relating to capacity building and PDPs, in other disease areas or in other contexts for instance, do not fall within the remit of this study. Figure 1.1 below shows the CRCs in East Africa supported by IAVI and the IAVI-supported trials conducted to date. It is important to note that many of the CRCs are involved in a number of trials and studies with other funders as well.

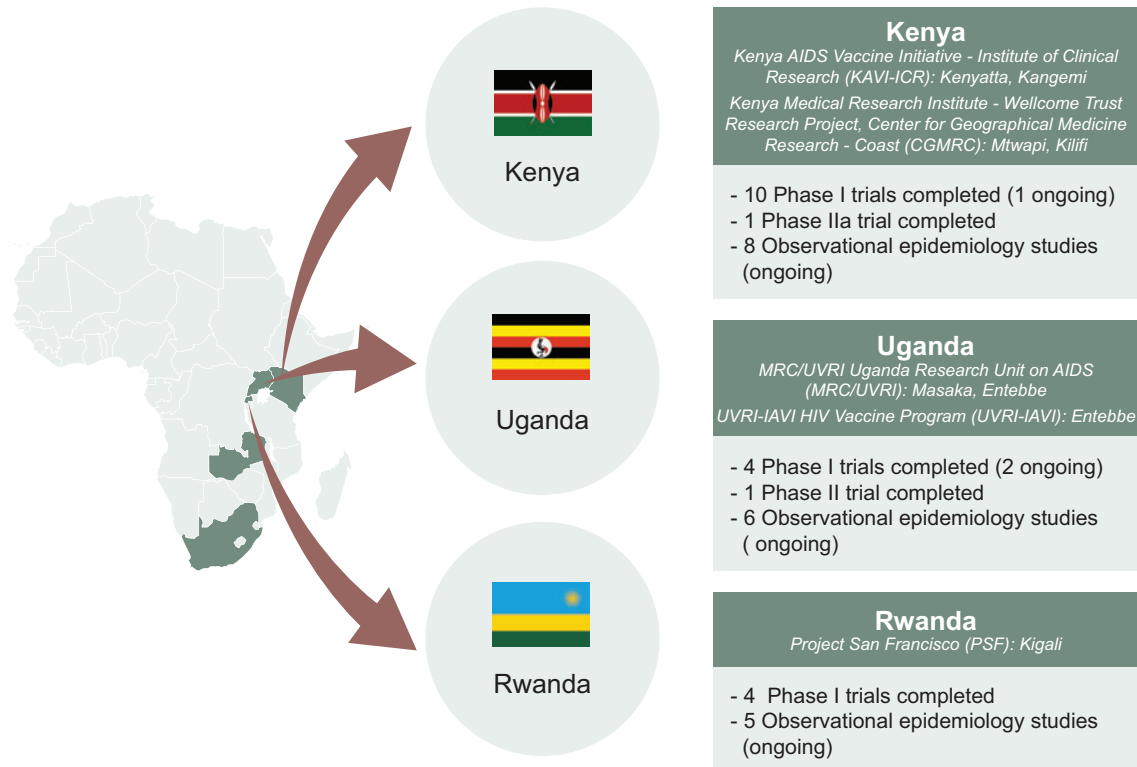


Figure 1.1 Clinical Research Centres supported by IAVI in East Africa²

1.2. Structure of this report

The remainder of this report is structured as follows. Chapter 2 provides a short background to the methodology employed to evaluate IAVI's capacity building activities. Chapter 3 presents IAVI's capacity building activities in the context of PDPs and other capacity building stakeholders. Chapter 4 presents the findings of the evaluation in relation to (i) the development of scientific skills, (ii) the strengthening of research infrastructures conducive to health innovation, and (iii) in relation to community and policy advocacy. The specific impact of IAVI's activities on key populations (fishing communities, discordant couples and MSMs) is also analysed in this chapter. Chapter 5 discusses which factors have enhanced IAVI's progress and impacts, and what challenges the organisation had to face in relation to capacity building in the three countries of intervention. The chapter concludes with some future considerations for IAVI.

² IAVI also supports CRCs in Zambia and South Africa



2. Methodology

This evaluation has been both desk-based and fieldwork-based, drawing on a mix of qualitative and quantitative evidence from diverse stakeholders including IAVI staff, researchers across East Africa, policymakers and local NGOs.

The initial phase of the research involved extensive data collection from previous evaluations of IAVI³ and internal documentation as well as a review of the literature on health research capacity building in Africa. The purpose of the desk research was to build up a picture of IAVI's historical capacity building activities and impacts and also to place them in the context of broader capacity building activities conducted by other donors or institutions in the field. This was supplemented with five key informant interviews (KIIs) conducted by phone or in-person with 5 key representatives from IAVI's senior team.

The second phase of the research involved fieldwork in East Africa, meeting key personnel involved in capacity building activities. A total of 32 KIIs were conducted across Uganda, Kenya and Rwanda with IAVI staff, local researchers at CRCs, non-government organisations (NGOs), healthcare staff, policymakers and community based organisations. Interview protocols can be found in Appendix A.

The purpose of these interviews was to scope out issues relevant to IAVI's capacity building activities and the impacts on key population groups. We were also conscious of the need to include communities and groups, such as fishing communities, MSM and discordant couples, which may have had particular capacity building needs as a result of interactions with IAVI. The interviews were semi-structured and followed a template of open-ended questions, developed from the key insights drawn from the first phase of the research. The interviews were complemented with site visits to all the IAVI CRCs and meetings with laboratory staff. It is important to note that not all interviewees could comment on all issues, as themes were often specific to a particular stakeholder and/or country. Therefore, we did not aim to quantify the strength of different interview responses in this evaluation.

3 In particular previous work by the Innogen Institute (University of Edinburgh and Open University). For example, see Chataway et al. (2006); Chataway et al. (2007); Chataway & Hanlin (2008); Hanlin et al. (2007); Hanlin (2011)



3. IAVI in the context of capacity building

3.1. Capacity building for health research

The last twenty years have seen increased focus on research capacity building and capacity strengthening efforts in development interventions. These interventions aim to help build new or develop existing research capacities in LMICs in order to reduce dependency on research conducted in high income countries and to address local needs (Jones et al. 2007). The overarching goal of these efforts is to enable African researchers and institutions to develop the scientific skills needed to address local health problems and needs effectively (Chu et al. 2014; Whitworth et al. 2008; Zofou et al. 2011). Research capacity building interventions span a number of sectors including education, agriculture and health, among others.

Stakeholders investing in the field are diverse and include donors, international and local NGOs, specialist capacity building service providers based in the North and the South, academic institutions and individual organisational development advisers and facilitators. The diverse range of actors in the field may prove important, as suggested by the WHO report (2005) *'Preventing Chronic Diseases: A Vital Investment'*, which particularly emphasises the need to build on multi-stakeholder partnerships to develop cost effective solutions to the high burden of disease in developing countries (Aikins et al. 2012). With this in mind, while significant levels of investment have been allocated to disease control programmes by organisations such as the Global Fund, over the last ten years, there has also been a growing recognition of the need to address the limited capacity of LMICs to conduct health research. Improving skills and research infrastructures alongside organisational and institutional capacity for conducting research has been acknowledged as an important instrument in creating and strengthening sustainable health systems in the global South (Lahiff et al. 2010; Oomman et al. 2007).

IAVI is part of a joint effort by various stakeholders to support the development and strengthening of health research capacity in developing countries (Gyapong & Ofori-Adjei 2006; Marjanovic et al. 2013; Whitworth et al. 2008). In addition, IAVI helps developing countries create and sustain locally owned solutions to the high and endemic burden of the diseases they face (Lansang & Dennis 2004; Vasquez et al. 2013).

Capacity building initiatives tend to be complex interventions and they can target different levels of the broader health research ecosystem, including at:

- **the individual level**, through graduate or post graduate research and professional training for individual researchers;
- **the institutional level**, through investment in scientific institutions providing essential infrastructure. (e.g. research equipment, labs and ICT facilities) and organisational training (e.g. monitoring and evaluation, leadership training, supervision and financial training);
- **the community level**, through engaging with local populations/specific communities

(e.g. HIV communities) for research activities (e.g. clinical trials), as well as broader communication, prevention and dissemination activities;

- **the policy level**, (national, regional and international) through collaboration and advocacy.

Integrated strategies supporting different levels are central to the development of sustainable research capacity (Vasquez et al., 2013). However, participants involved in capacity building might chose to support just one level or a subset thereof, focusing for example on a particular type of individual or institutional support – depending on their priorities, resources and/or the needs of the country in which they work(Chataway et al. 2006).

3.2. Different approaches to research capacity building

Various approaches have been adopted to implement research capacity building activities. Differences in approaches may result from variation in the governance models adopted between North-South collaborators or donors-recipients; differences in the aims and objectives of a programme (whether its primary focus is on individual, institutional or system-level); and the extent to which capacity building is an explicit or implicit goal. In addition, these differences are not mutually exclusive which further increases the different combinations available to capacity building stakeholders. We discuss some of the more prominent examples in the literature below.

Bilateral approaches are the traditional model. These constitute partnerships between two institutions, usually a Northern institution (mentor) and a Southern partner, and have tended to focus on the training of students, fellowships and joint research projects.⁴ Interesting South–South collaborations have also been observed, mostly in BRIC countries.⁵ However, bilateral approaches have often failed to maintain capacity building efforts in the long run and to address issues of scale. Thus, a weakness of many previous bilateral approaches is that they do not adequately account for the fact that capacity building is a continuous process which can take many years to come to fruition.

As a result, there has been a push towards the development of sustained research partnerships, intended to build mutual trust among participants and facilitate the ownership of research by LMICs (Accordia Global Health Foundation 2010; Jones et al. 2007). While some of these partnerships focus on research, with capacity building as a value-added activity or a spillover, others explicitly focus on building capacity. In both types of partnership there has been an increased emphasis on more shared ownership models, which are thought to lead to more sustainable capacity in the long run. The principles for shared ownership have been detailed by Maselli et al. (2006) including:

- Collaboration between institutions in setting research priorities;
- Regular interactions among stakeholders;
- Clear definition of partners' responsibilities;

4 For a more detailed discussion on this model of capacity building Maselli et al. (2006); Jones et al. (2007); Sewankambo et al (2015)

5 Thorsteinsdottir (2012) presents a number of south-south collaborations in health biotechnology across BRIC countries

- Development of accounting mechanisms for beneficiaries;
- Promotion of mutual learning;
- Enhancement of capacities;
- Data sharing and development of networks;
- Dissemination of results;
- Pooling of profits and merits;
- Translation of results; and securing outcomes.

Some capacity building programmes have adopted a networked approach, which allows for the leveraging of often scarce resources (building on complementarities across the network), incentivises knowledge sharing and helps spread risks across participants (Marjanovic et al. 2013).⁶ These partnerships can involve both North-South and less frequently South-South networks (Gitta et al. 2011), based on local ownership. The funding of South-South collaborative networks appears more risky but potentially more sustainable in the long run (Cochrane et al. 2014). Another model of capacity building is the learning-by-doing approach (Chataway et al. 2006). This differs from the bilateral and networked approach in that learning-by-doing initiatives do not necessarily target capacity building as a core priority, although capacity building underpins their main activities. As such, they can take the form of implementation programmes, clinical trials or drug-discovery programmes in the case of health research.

While this growing interest from donor institutions – and the resulting increase in programmes aimed at building health research capacity – is encouraging, the effectiveness of these varied approaches remains unclear (Uduma et al. 2013). Our report will explore the impact of IAVI's approach to capacity building/strengthening through PDPs in three countries: Rwanda, Uganda and Kenya.

3.3. Building capacity through public-private partnerships

The recognition that the new technologies needed by the poor were not being developed or accessed has led to the establishment of a wide range of global health initiatives based on public-private partnerships (PPPs) over the last three decades. The success of the PPP approach rests on its ability to address these issues through the creation of new organisational structures and cultures which promote collaboration in developing and/or distributing products to those who need them (Chataway et al 2007) The creation of PPPs related to neglected diseases, for example, uses an organisational and institutional model in an attempt to solve the technical and social challenge of developing and diffusing science and technology-based products relevant to the needs of developing countries (Chataway et al. 2007). As attempts to meet the challenge have evolved, organisational and institutional models have become more refined, with a subset known as product-development partnerships (PDPs) emerging within the broad umbrella of PPPs.

6 Examples of networked approaches to capacity building include: the Wellcome Trust funded African Institutions Initiative (AII) and recently launched Developing Excellence in Leadership, Training and Science Initiative (DELTA) (<http://www.wellcome.ac.uk/funding/biomedical-science/funding-schemes/strategic-awards-and-initiatives/wtp057105>) and the European and Developing Country Clinical Trials Partnership's Networks of excellence. (Miuro et al. 2013)

Developing products for neglected diseases often requires improving underdeveloped research capacities in endemic countries. Capacity building can empower local research communities to assume leadership roles as well as halting the effects of 'brain drain' from the global South (Olliaro & Wayling 2008).

Capacity can be developed through PDPs in a number of ways:

Partnering

PDPs can partner with local research organisations in endemic countries in order to facilitate knowledge sharing. Partnerships are seen as an opportunity for 'increased access to new ideas and best practices, technical expertise and resources; wider coverage and impact of research benefit; and an increased probability of sustainability recognition and leverage of the research partnerships' (Lansang & Dennis 2004).

Training

PDPs can train local researchers, equipping them with the skills and expertise necessary to conduct clinical research – such as training them in new techniques and in good clinical research standards so that research meets all ethical and regulatory requirements.

Infrastructure

PDPs can invest in infrastructure in order to create sites suitable for clinical trials. Infrastructural investments can be categorised into three main types and outcomes (Olliaro & Wayling 2008):

- Short-term commitments, such as establishing a field site for the duration of a project(s). Sites generated are not generally sustainable.
- The establishment of a project site including infrastructure development which will continue to be useful beyond the end of the trial. A small number of projects could be undertaken here. Sites are generally sustainable for three to five years and establish foundations which outlive the initial trial or intervention.
- The establishment of a research centre providing scientific infrastructure for long-term research. This is based on some permanent core funding, with new projects contributing to the funding. Development is long-term and the centre can be maintained over time with projects contributing funds.

For projects carrying out clinical trials in endemic countries, some level of capacity building both in terms of personnel and infrastructure is often required. The type of capacity building often depends on the type of trial. For example, malaria drug trials require sites capable of small trials with access to relatively small numbers of adults and children, whereas malaria vaccine trials need sites from which researchers are able to access and manage very large numbers of infants – the target population for vaccination (Moran et al. 2010). Similarly, the lack of sites with adequate facilities and access to patients in numbers large enough to conduct sufficiently representative clinical trials has traditionally been a hindrance in studying interventions for African trypanosomiasis (Olliaro & Wayling, 2008).

Advocacy

PDPs can engage in advocacy activities in order to place the need for research (and research capacity building) on the political agenda. However, undertaking capacity building activities is not straightforward. Olliaro and Wayling (2008, 33) point out that 'strengthening research capacities may jeopardise already weak systems by diverting scarce human resources and disrupting work'. They also point out that some of the 'big funders' including the Bill and Melinda Gates Foundation and the Global Fund to Fight AIDS, Tuberculosis and Malaria are reluctant to support initiatives to develop and sustain capacity (Olliaro & Wayling, 2008). While this may be the case in some instances, it is important to note that there is a range of attitudes to capacity building amongst the donor community, with government donors increasingly asking for capacity building to be an explicit aim of projects seeking their grants.

With these difficulties in mind, PDPs have adopted a number of different ways to build required capacity in endemic countries. In some cases this has been a natural consequence of undertaking R&D in developing countries, whereas in others it has been a direct goal. We have sought to understand the different ways in which PDPs contribute to capacity building and how their effects may differ.

Table 3.1 below highlights the different capacity building approaches adopted by PDPs, as stated on their websites and in academic literature. We reviewed all active PDPs (as opposed to PPPs more generally) listed in the Health Partnerships Database in order to create a PDP typology of capacity building activities, which is used to form a framework for analysis.

Table 3.1 Product-development partnerships' capacity building activities

Name of PDP	Capacity building explicitly stated as a goal?	Work with local researchers/ communities to share knowledge	Provide training	Provide infrastructure	Partake in advocacy	Countries/region of intervention
Aeras Global TB Vaccine Foundation	Yes	X	X	X	X	Past and current clinical studies: 7 in Africa 4 in Asia 3 in the US and 4 in Europe
Contraceptive Research And Development Program (CONRAD)	No					
Drugs for Neglected Diseases initiative (DNDi)	Yes	X	X	X		Strong emphasis on Africa, and Latin America to a lesser extent
European Vaccine Initiative (EVI)	Yes	X		X	X	East and West Africa
Foundation for Innovative New Diagnostics (FIND)	Yes	X	X	X		Main focus: Africa, followed by India and South East Asia (far less sites) and then to a lesser extent Latin America
International AIDS Vaccine Initiative (IAVI)	Yes	X	X	X	X	East Africa, Southern Africa, India
Infectious Disease Research Institute (IDRI)	No	X				
International Partnership For Microbicides (IPM)	Yes	X	X	X	X	East and South Africa
Malaria Vaccine Initiative (MVI)	No	X	X	X		
Medicines for Malaria Venture (MMV)	No	X	X	X		
Meningitis Vaccine Project (MVP)	No	X				
Pediatric Dengue Vaccine Initiative (PDVI)	No				X	
Sabin PDP (previously the Human Hookworm Vaccine Initiative)	No				X	
TB Alliance	Yes	X	X			Kenya, South Africa and Zambia

The table shows that of the seven PDPs that do not explicitly name capacity building as a goal, only two (MVI and MMV) provide some sort of capacity building, here in the form of training and infrastructure. The others rely on working with local partners and advocacy activities. By contrast, of the PDPs which do name capacity building as an explicit goal, all provide training, infrastructure or both. From this distinction alone, it can be seen that there is a notable difference in the way capacity building is approached.

The International AIDS Vaccine Initiative

Capacity building activities in Kenya, Uganda & Rwanda

The International AIDS Vaccine Initiative (IAVI) have made a significant contribution to training interventions for supporting scientific excellence, invested in infrastructure and laboratories at CRCs and have engaged with local communities and policymakers on issues related to HIV and vaccines.



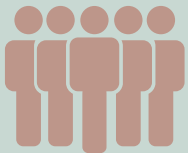
\$134

IAVI have invested over \$134 million in Africa since 2003



5 clinical research centres

IAVI supports 5 Clinical Research Centres in East Africa through providing training and financial assistance to build or refurbish the state-of-the-art laboratories



800
people

Over 800 people have been trained in Good Clinical Practice and Good Clinical Laboratory Practice



112
organisations

IAVI have successfully developed platforms for community engagement with 112 organisations in the region

26,629

volunteers have been involved in clinical trials and epidemiological studies, raising awareness of HIV research in the region



24%

of all publications of IAVI-supported research have an affiliation with an East African institution

4. Progress and impact of IAVI's capacity building activities

Key messages

We identified a broad range of capacity building activities supported by IAVI, which can be grouped into four key categories: (1) Scientific skills and training; (2) Research infrastructure; (3) Community engagement; (4) Advocacy and policymaker engagement. In addition, we also reflect on the impact of these activities on at-risk populations and how IAVI's conceptualisation of capacity building.

IAVI's conceptualisation of capacity building

- As a core component of developing an AIDS vaccine that meets the needs of those most vulnerable to HIV, IAVI has incorporated capacity building as a key feature of its strategy in Africa. IAVI's conceptualisation of capacity building remains broad and both internal and external factors appear to have influenced its evolution over time (Section 4.1).

Scientific Skills and Training

- IAVI has made a significant contribution to training interventions to support scientific excellence and Good Clinical Practice for AIDS vaccine clinical trials and epidemiology studies, in particular through the provision of GCP and GCLP training and short courses for over 800 participants.
- IAVI has begun to provide direct support to build further research capacity, through technology transfer of assays and techniques as well as advanced degree support (MSc, PhD) and mentorship that will enable East African scientists to lead AIDS vaccine research and development programs (Section 4.2).

Research infrastructure

- IAVI has established a network of partners with the necessary clinical, laboratory and IT infrastructure to conduct high-quality clinical and epidemiological research and assess the safety and immunogenicity of vaccines. This infrastructure has demonstrated its application for both upstream AIDS vaccine research and other diseases (Section 4.3).

Community engagement

- IAVI has successfully developed integrated community engagement platforms to ensure that its research reflects community interests, safeguards participants' rights and translates research findings in an effective manner (Section 4.4).

Advocacy

- IAVI has played an instrumental role in bridging the gap between researchers and policymakers and engages with governments to ensure that HIV vaccine research is an important component of national policy agendas and aligns with national research priorities (Section 4.5).

Impact of IAVI's work on at-risk populations

- IAVI has been successful at engaging and accessing key populations for research, including fishing communities in Uganda, MSM in Kenya and discordant couples in Rwanda. Data from research has been shared with civil society and policymakers and is beginning to contribute to health policy change (Section 4.6).

4.1. Categories of capacity building activities

We have identified four key categories into which IAVI's capacity building activities can be placed and which will be used as the units of analysis for this evaluation of work in East Africa:

- Training in scientific skills
- Provision of research infrastructure
- Community engagement and mobilisation
- Advocacy and policymaker engagement

We define 'capacity building' as including 'any efforts to increase the ability of individuals and institutions to undertake high quality research and to engage with the wider community of stakeholders' (ESSENCE 2014:7). Unlike previous studies, it therefore seems appropriate to include advocacy and community engagement activities in our assessment of capacity building. As previously mentioned, capacity building can also occur at different levels, including the individual, institutional and systemic, a fact which should also be considered with regard to IAVI's capacity building activities. Figure 4.1 shows how the four categories of IAVI's capacity building activities outlined above map onto these different levels.

	Individual	Institutions and local communities	National - Regional	International
Scientific skills and training	Building the research capacity of existing staff	Establish high quality standards /centres of research excellence	Contributing to improving visibility of African research	Harness partnerships to expand base on HIV vaccine R&D
Research infrastructure	Supplying researchers with lab equipment	Building state-of-the-art research infrastructure	Strengthening national research capabilities	Pooling resources with the global research community
Community engagement	Counselling and access to healthcare for volunteers	Education and awareness programmes for communities	Creating platforms to facilitate civil society engagement	Shaping the international agenda on key populations
Advocacy	Communication skills for policy audience	Evidence-based advocacy training for civil society groups & communities	Providing technical assistance to national AIDS plans	Ensuring sustained investment in HIV vaccine research

Figure 4.1 Conceptual framework for IAVI's capacity building activities

These elements are closely interrelated when establishing a conducive environment for conducting clinical research and in this chapter we discuss how IAVI has contributed to each of these different areas. First, through investment in diverse training programmes and supporting research studies, scholarships and fellowships for African researchers (Section 4.2). Second, through investment in the physical infrastructure (laboratories, clinical infrastructure, ICT systems) needed to support high-quality research and researchers (Section 4.3). Third, through investment in community engagement initiatives to ensure long-term buy-in, progress and the relevance of research in HIV (Section 4.4). Fourth, through advocacy aimed at engaging with policymakers and raising the visibility of HIV on policy agendas (Section 4.5). Finally, we discuss how IAVI's capacity building activities have had an impact on key population groups in each of the three countries (Section 4.6).

Before discussing in detail findings related to each element of capacity building, we discuss how IAVI's conceptualisation has evolved.

4.2. IAVI's conceptualisation of capacity building

Previous work has emphasised the different ways in which IAVI has built capacity, using both formal training and engagement with good practice and established standards along with 'learning by doing', achieved through partnership and collaboration. As a PDP, IAVI has been able to contribute to strengthening health research systems in developing countries, not only by building research infrastructure and training clinical research staff but also by actively engaging communities, policymakers and other international organisations involved in HIV vaccine research (Chataway et al. 2006).

IAVI's success in developing the capacity to conduct clinical trials in East Africa was also discussed in a World Bank evaluation (Druce et al. 2009). This found that IAVI had been a global leader in conducting vaccine research designed for East Africa, and applauded the collaborative manner in which IAVI 'set up high quality capabilities for effectively testing HIV vaccines in developing countries' (Druce et al. 2009, 8).

However, these studies also noted that while IAVI had made substantial efforts to build capacity in developing countries, the conceptualisation of capacity building in IAVI's mandate was unclear. In discussing this with internal staff at IAVI, Hanlin et al. (2007:72) noted that:

while there were those who saw capacity building as a key part of IAVI's activities and a need for developing partners to be 'true' partners with ownership over activities, others saw it as a consequence of its general activities

In our interviews with IAVI staff, one interviewee noted that IAVI should have been better at promoting its capacity building work, although at the time it was difficult given the lack of a formal programme.

While capacity building activities have broadly continued along a similar trajectory in recent years, IAVI now have a much more formalised position on capacity building. This may be due, in part, to a desire to more concretely define the intersection between capacity building necessary to achieve IAVI's mission and the larger development objectives of many of IAVI donors. The focus is on building scientific and technological capacity in regions most affected by the pandemic, in the hope of contributing to the

sustainability of vaccine research, as well as meeting broader development goals. According to IAVI's website,⁷ capacity building activities are focused on providing both physical infrastructure and training:

Beyond equipping clinics and laboratories in the research network, IAVI also has overseen the training of research center staff to ensure that they conduct their work in accordance with the highest of scientific and ethical standards – and with the meticulous care required by regulators who approve new vaccines

Despite moves towards a formalised position, IAVI's conceptualisation of capacity building remains broad. Rather than stating explicit objectives designed to capture all aspects of PDP capacity building activities, capacity building goals cut across a number of the organisation's areas of activity. For example, elements of capacity building can be seen in all three of IAVI's overarching objectives in their Strategic Plan 2011–2015. These include:

- Accelerating the development of AIDS vaccines by identifying opportunities and gaps in the field and ensuring that IAVI invests its resources in areas that add most value;
- Harnessing partnerships to expand the diversity and number of novel AIDS vaccine candidates;
- Building support for AIDS vaccine development.

It is also important to note some significant changes in the way the organisation functions, which have influenced its conceptualisation of capacity building both within IAVI and externally. These changes are outlined in Table 4.1 below⁸:

Table 4.1 Factors affecting IAVI's conceptualisation of capacity building

Internal Changes	External Changes
<ul style="list-style-type: none"> • More understanding of capacity building's importance internally - IAVI's work has become more enmeshed with a variety of other efforts to strengthen health systems in developing countries. • A shift towards supporting more pre-clinical research - The quest for an effective vaccine has proved even more challenging than originally predicted and in recent years IAVI has needed to refocus activities with relatively increased investment in basic science. • A cultural shift that increases collaboration and consultation with other researchers and organizations – The need to pool resources and build on existing capacity has meant that IAVI is increasingly working with other capacity building organisations and has been flexible in enabling CRCs to conduct work with other donors in other areas. 	<ul style="list-style-type: none"> • Changes in HIV research – Breakthroughs in HIV research – such as the RV144 vaccine, the discovery of new broadly neutralising antibodies, and the success of anti-retrovirals (ARVs) – have had a profound impact on the global landscape of HIV vaccine research. • Limited growth in funds for HIV vaccine research – The current fiscal climate has reduced the resources allocated for HIV vaccine research. IAVI's drop in funding in 2008 reflects a wider trend towards reductions in both HIV vaccine research funding and funding for PDPs more generally. • A greater demand from donors to support and demonstrate capacity building in developing countries – Several major donors to IAVI, such as USAID and DFID, increasingly require efforts to build capacity to be a core component of any grant application. In addition, donors are now asking IAVI to quantify the impact of capacity building.

⁷ <http://www.iavi.org/what-we-do/science/capacity-building>

⁸ A number of these points are outlined in IAVI's Strategic Plan 2011-2015

IAVI's activities have expanded over time to go far beyond skills development and now encompass community empowerment, training for healthcare workers and broader capacity building objectives at the systemic level (supporting government institutions involved in HIV research and prevention at the local, national and regional level).

One of the IAVI employees interviewed noted that there is now more understanding internally of the importance of capacity building. It was noted that there had previously been difficulties in balancing the focus between finding a vaccine and the wide range of work that goes into finding an HIV vaccine. Now building scientific capacity in the region is not so much seen as a spill-over effect of looking for an HIV vaccine, but as a core component of IAVI's activities and necessary for achieving their mission. While the lack of a more rigorous conceptualisation has not prevented IAVI from building sustainable capacity in East Africa, it may have implications for future efforts to evaluate and demonstrate the impact of its capacity building activities.

4.3. Training interventions to support scientific excellence and Good Clinical Practice

Since it began working in Africa, IAVI has recognised the need for research capacity building by supporting a number of activities at partner sites in the region. These aim to ensure that local research staff have the necessary skills and are able to conduct research that meets international scientific and ethical standards. This has predominantly focused on applied research skills, such as direct training, support and hands-on experience in clinical trials as well as Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) training (Section 4.3.1). In recent years IAVI has begun to approach scientific training in a more holistic fashion, with the aim of building capacity in the region with lasting value for the communities and countries participating in vaccine research. Building on previous activities, IAVI has started: (i) offering training courses to a wider audience, including other African researchers outside their partner sites (Section 4.3.1); (ii) building a training program to support PhD and MSc training, in addition to continuing applied research courses (Section 4.3.2); (iii) contributing substantially to the evidence base on HIV vaccine research by supporting African scientists' publication of peer-reviewed journal articles (Section 4.3.3); and (iv) sophisticated technology transfer and training to allow greater African involvement in more upstream vaccine design research.

4.3.1. Short-courses: GCP/GCLP training and other short courses have contributed to improved scientific skills in the region

In order for a vaccine trial centre to conduct clinical trials to an international standard, requirements include GCP standards, standard operating procedures and data management, and support services for volunteers such as referrals, counselling and family planning (Kochhar 2013). The establishment of GCP compliant research centers and state-of-the-art, GCLP-accredited laboratories with well-trained staff has therefore been central to IAVI's mission in East Africa.

GCP training is designed to equip researchers with the skills and knowledge necessary to enable them to carry out clinical research to the required international standards. Since 2002 IAVI has conducted 35 GCP training courses at CRCs in East Africa, with over a thousand participants attending (just over 71 per cent of the total number of participants

trained in GCP by IAVI globally).⁹ In addition, a further 90 participants have been trained in GCP online. Figure 4.2 below shows the breakdown of GCP trainings in each East African country by year.

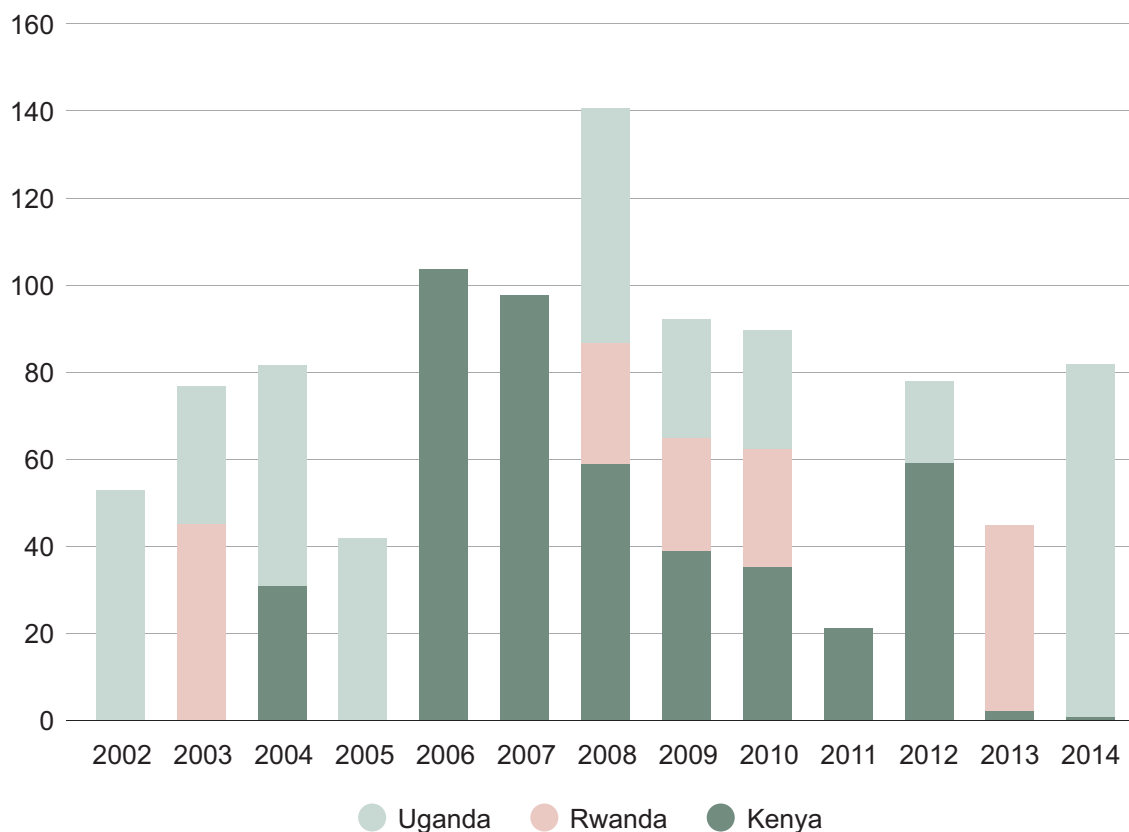


Figure 4.2 Number of participants in IAVI supported GCP training courses across East Africa

In addition to GCP training, IAVI has also invested in GCLP training for laboratory scientists and technicians at CRCs to facilitate the accreditation of their laboratories. This training is based on legal requirements used in Europe for conducting clinical trials, and CRCs are required to pass two annual audits in order to be granted full accreditation.¹⁰ Since IAVI began to invest in GCLP training in 2004, all sites have now received full GCLP accreditation. Figure 4.3 shows the number of participants attending GCLP training courses in East Africa.

IAVI has also supported a number of in-country short courses on a variety of topics including bioethics, quality management systems, immunology and project management. Although a number of interviewees noted that while IAVI has made great progress in scientific skills training, more emphasis could be placed on non-research training skills such as financial management and research administration.

⁹ A further 14 GCP courses have been conducted in India, Zambia and South Africa.

¹⁰ <http://www.cyto.purdue.edu/cdroms/gh/HTML/program/media/IAVILab.pdf>

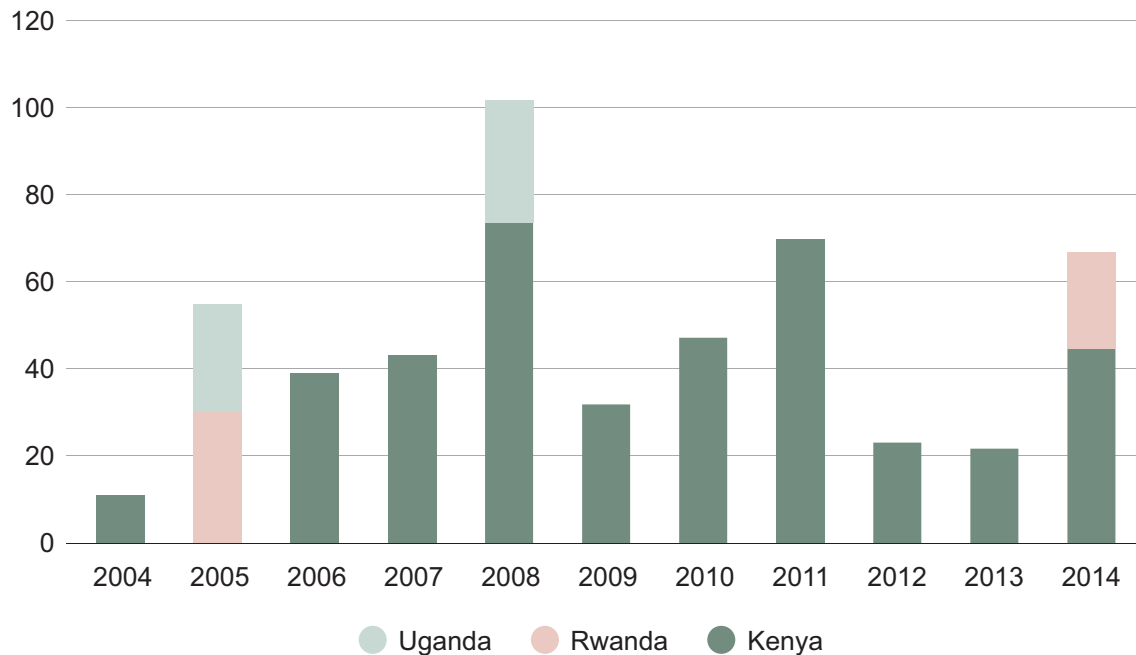


Figure 4.3 Number of participants in GCLP training courses across East Africa

Previous evaluations of IAVI's work have all noted that training was universally endorsed as a valuable activity for African HIV vaccine research. The success of IAVI's training in scientific skills, beside the number of people trained, has been achieved in various ways.

Firstly, IAVI's Human Immunology Laboratory in London – which is responsible for coordinating laboratory training activities across IAVI's network and monitoring the integrity of data generated by CRCs – has verified that the quality of clinical and immunological analyses coming from CRCs are consistently on a par with their counterparts in the US and Europe.¹¹ Establishing a foundation of GCP and GCLP standards with staff at the CRCs has also contributed to all East African CRC labs being awarded GCLP accreditation, allowing them to leverage further funding for clinical trial research and establish themselves as centres of excellence in the region.

Secondly, IAVI has invested in a 'train-the-trainer' approach to their GCP training. This ensures that training, rather than being restricted to IAVI staff is available to researchers, policymakers, health-workers, community groups and other non-IAVI staff. According to one interviewee this is hugely beneficial for the sustainability of clinical research in East Africa as it mitigates the risks of high staff turnover and infrastructure limitations associated with clinical research in the region, and ultimately increases East African capacity to conduct high-quality clinical trial research. As well as local health-workers and community based organisations, local researchers at CRCs have trained participants from other organisations, including:

- Global health NGOs and donors: US Centers for Disease Control (CDC) and

11 http://r4d.dfid.gov.uk/PDF/Outputs/IAVI/IAVI_Annual_Report_2010_ENG.pdf

Prevention, European & Developing Country Clinical Trials Partnership, IntraHealth International, Walter Reed Project;

- Other PDPs: Drugs for Neglected Diseases initiative (DNDi), Aeras Global TB Vaccine Foundation;
- Local universities: National University of Butare, Makerere University, University of Nairobi;
- Government officials: Ugandan National Council for Science & Technology, Joint Clinical Research Center (JCRC) in Uganda, Ministry of Health officials.

GCLP accreditation was seen by many interviewees as an important step in becoming globally recognised as a centre of excellence for clinical trial research. For example, researchers at KAVI-ICR obtained a grant from the Canadian government to build on the capacity developed by IAVI by creating a number of training courses for researchers working throughout the region, including for CDC and DNDi.¹² Projet San Francisco (PSF) have established themselves as the leading national laboratory for clinical trials and have been asked by the government to help train government health workers and to conduct further research.

4.3.2. Longer-term training studentships and fellowships: IAVI has recently begun to move towards supporting more basic research

Vaccine research is a long process, underpinned by basic research. Some HIV researchers argue that the evidence base on which vaccine research depends is still too limited to permit the development of a vaccine, and that increased investment in basic research is required to overcome this stumbling block (Esparza & Bhamarapavati 2000; van Regenmortel et al. 2014). This paradigm shift has been recognised by IAVI, who has invested heavily in basic research and more recently has expanded that work to include African collaborators.

IAVI has provided direct support to basic research through MSc and PhD training and mentorship, and has also given indirect support through flexible work arrangements, allowing researchers to pursue academic qualifications and short courses on scientific writing. To date, over 30 CRC staff have obtained degrees either locally or abroad with IAVI support and an additional 18 are currently pursuing Masters and PhD's with IAVI support. In addition to supporting degree qualifications for junior staff, IAVI is beginning to provide small amounts of funding through a formal awards process (known as 'investigational awards') to enable investigators to conduct their own research; research related to HIV vaccine design and IAVI's epidemiological interests are prioritized. This is in addition to a number of larger-scale investigator-driven research projects that are already part of the IAVI portfolio. One interviewee noted that while 'you could argue that is a bit outside IAVI's scope, you could reason that with any broader community engagement that is one component of working with society'.

More recently, IAVI and the CRCs are partnering with Emory University on the Vaccine Immunology Science and Technology for Africa (VISTA) programme, funded by USAID.

The VISTA programme aims to support capacity building for basic research and leadership in HIV vaccine design. In particular the programme includes traineeships for African scientists in molecular virology (at Emory University) and immunology (at IAVI's Human Immunology Laboratory at Imperial College London and African CRCs).¹³

On the whole, almost all interviewees at the CRCs felt that IAVI's increased support for basic research was valuable to their work, was appreciated by their staff, and was ultimately necessary both for future HIV vaccine research in East Africa and to develop the next cadre of scientific leaders in the region. According to one interviewee, by moving to support more basic research IAVI are improving job satisfaction, as people are being offered the opportunity to build on the applied research skills obtained through participation in clinical trial research. Other interviewees also felt the move was crucial for the sustainability of the CRCs, as developing a critical mass of staff with PhDs and other academic qualifications is essential for winning external grants and fostering the next generation of scientific leaders.

However, some interviewees were concerned that challenges may emerge in staff retention once researchers were trained, and that opportunities to provide additional resources to more qualified staff were limited. In addition, the difficulties faced by project leaders in sparing key staff members for the length of time PhDs require was also seen as a challenge when it comes to future efforts at increasing basic research training. While much of the training takes place in-country, a number of interviewees suggested that IAVI should consider establishing mechanisms that would encourage staff to return to their home country/institution after completing research training that takes place abroad

4.3.3. Training is contributing to improving the visibility of African researchers and African research

An optimum evidence base is critical for effective research on HIV/AIDS in Africa. Moreover, given the burden of disease faced by the continent, increasing emphasis is being placed on the need to improve the contribution of African-led research (Chu et al. 2014). Historically, African research has only made a small contribution to global HIV research and has been characterised by high levels of international collaboration (Tijssen 2007; World Bank 2014). In recent years, the contribution of African research to the wider evidence base on HIV has increased significantly, with a tenfold rise in the number of publications on HIV/AIDS research from 2000 to 2009 (UNECA 2013). However, scientific outputs remain low compared to other regions of the world. A range of participants, including PDPs, have been involved in efforts to address this gap and facilitate the development of African scientific output.

IAVI has been successful in generating knowledge and contributing to the development of a robust evidence base for HIV vaccine research. This has been achieved by supporting the publication of research in peer-reviewed journals, policy briefs and conference proceedings. Between 2008 and 2014, IAVI contributed to 371 peer-reviewed journal articles, of which 88 (24 per cent) have an author from an African institution and 63 (17 per cent) have an author at an East African CRC.¹⁴ Figure 4.4 shows how IAVI's publication output compares to other PDPs.

13 <http://www.iavi.org/newsletter/2015/505-international-womens-day-2015#vista>

14 Data generated from Web of Science using bibliometric funding acknowledgements. As of 14th January 2015

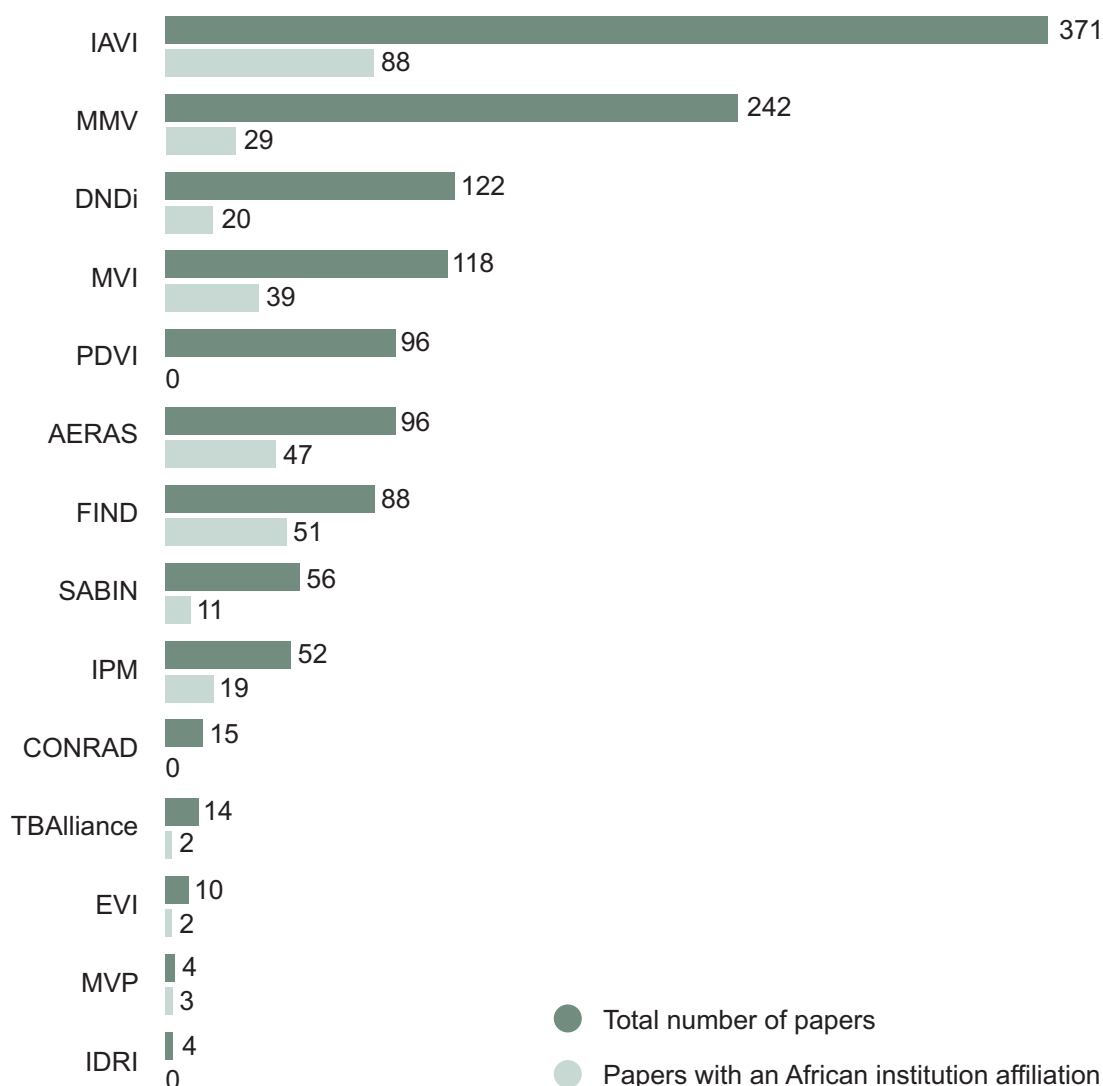


Figure 4.4 Number of peer-review journal papers by PDP (2008–2014)

It is important to highlight the fact that comparative data between PDPs requires interpretation with caution. Comparisons across PDPs are fraught with difficulties due to the variation in size of PDPs and the number of years they have been active. In addition, challenges arise given both the differences in geographical location of epidemics (e.g. HIV/AIDS compared to malaria) and differences in overall global R&D expenditure on different diseases (e.g. HIV/AIDS receives more than twice as much as any other neglected infectious disease in global R&D investment) (Cardoso et al. 2014). Nevertheless, what is interesting to note from Figure 4.4 is the volume of scientific output being produced by PDPs and the potential for African research to make a significant contribution to this evidence base.

Despite progress in producing papers with African institutional affiliations, IAVI has recognised that African researchers are underrepresented as lead authors. Of the 63 papers with an African institutional affiliation only 33 per cent have an African researcher as a lead author. In an attempt to address this disparity, IAVI has begun to invest in a series of workshops and training sessions aimed at improving the scientific writing skills

of junior African researchers and laboratory personnel (Rubens 2013). Since 2009, IAVI has financed four scientific writing workshops which have trained 84 researchers in East Africa, focusing on improving skills in abstract, manuscript and grant writing through both one-day workshops and longer residential training courses. IAVI will also partner with the University of California San Francisco (UCSF) through a NIH-funded initiative, International Traineeships in AIDS Prevention Studies (ITAPS). The aim of this is to provide scientific manuscript writing and mentorship development training for CRC staff that blends onsite and online training. Internal assessments of these trainings suggest that the workshops were well received, and participants have gone on to have abstracts accepted for peer-reviewed journals and conference presentations (Rubens 2013). These findings were supported by interviewees, who stressed the importance of scientific-writing workshops both for the sustainability of research efforts in Africa, and to ensure that the next generation of African researchers are equipped to win grants and contribute to the global evidence base on HIV research. However, possible incentives to publish should be considered given that many IAVI researchers work in a clinical rather than academic research setting. Researchers in East Africa have also made a significant contribution to some of the key scientific breakthroughs made by IAVI-sponsored research, which are highlighted in the Box below.

Key scientific achievements by IAVI-sponsored research

- Development of the largest acute infection cohort in Africa, which found:
 - That HIV disease progression/viral control varies by sub-type, with subtype C more aggressive than subtypes A and D;
 - The emergence of broadly neutralizing antibody (bnAb) responses approximately 3 years after acute infection;
 - The intense selection pressure on the characteristics of transmitted founder viruses and relationship of virus replicative capacity to disease course.
- Identification and characterization of high-risk populations, methods to reduce risk, and suitability for intervention trials (MSM, FSW, Fishing Communities, Discordant Couples);
- Participation in a cross sectional study of HIV+ samples that led to the identification of around 50 new bnAb and launched renaissance in bnAb identification
- Determination of regionally relevant African blood value clinical trial reference ranges

4.4. Developing research infrastructure

4.4.1. Building state-of-the-art research laboratories in East Africa

Without adequate research infrastructure, the capacity to conduct clinical trials in Africa is limited. Since IAVI began working in East Africa it has recognised that a conducive research environment with state-of-the-art technology is essential to the delivery of high-quality research. IAVI established collaborations with five CRCs in East Africa (see Table 4.2 below) to accelerate the testing of candidate vaccines. Across each of these CRCs, IAVI has provided financial assistance to build or refurbish the state-of-the-art laboratories, clinical facilities and information technology systems needed to conduct high-quality clinical research and assess the safety and immunogenicity of vaccines. An overview of each CRC is given below.

- **Kenya AIDS Vaccine Initiative Institute of Clinical Research (KAVI-ICR)** is a part of the College of Health Sciences at the University of Nairobi (UON) and has been involved with HIV prevention research, specifically focused on HIV vaccines, since 1998. KAVI's main offices are situated at the Kenyatta National Hospital (KNH), which is the teaching hospital for the UON. KAVI also has another clinical trial site located at a community-based clinic situated at the Kangemi health center.¹⁵
- **Center for Geographical Medical Research-Coast at Kenya Medical Research Institute (KEMRI-CGMR-C)**. In 1989 the Kenya Medical Research Institute (KEMRI), one of Africa's leading health research institutions, formed a landmark partnership with the Wellcome Trust and the University of Oxford, to establish a research programme on the coast of Kenya, the KEMRI-Wellcome Trust Research Programme (KWTRP), which is based within the KEMRI Centre for Geographic Medicine Coast (CGMR-C). Over 25 years, the programme has grown to become a major Programme with about 800 staff working across Kenya. In 2003, IAVI began supporting researchers at the KWTRP to conduct HIV research. The group was among the first to identify, mobilize, and recruit MSM for longitudinal studies in Africa, estimate HIV incidence among MSM, and develop strong community support from local health stake holders.¹⁶
- **Uganda Virus Research Institute –International AIDS Vaccine Initiative Joint Program (UVRI-IAVI)** was established in 2001 as a collaborative partnership between the Uganda Virus Research Institute (UVRI) and the International AIDS Vaccine Initiative (IAVI). The Program was developed to conduct HIV vaccine trials, feasibility studies, capacity building and other activities in preparation for future large scale HIV vaccine trials.¹⁷
- **Medical Research Council/Uganda Virus Research Institute Uganda Research Unit on AIDS (MRC-UVRI)** was officially launched in 1989, establishing offices and laboratories at the UVRI site in Entebbe. In 2005 the Program was upgraded to a Unit and in 2009 the bilateral memorandum of understanding between the Governments of Uganda and the UK, regarding the operations of the MRC-UVRI Research Unit on AIDS, was extended for 10 years. Its main research activities are located in Masaka, Kalungu, Kampala and Wakiso districts of Uganda.¹⁸ IAVI began partnering with MRC-UVRI in 2003.
- **Projet San Francisco (PSF)** Projet San Francisco (PSF) was founded by Dr. Susan Allen in 1986, and is the longest-standing HIV research organisation in Rwanda. Together with the ZEHRP sites in Zambia, they form the Rwanda-Zambia HIV Research Group (RZHRG). The RZHRG main office is located within Emory University in Atlanta, Georgia. IAVI began working with PSF in 2003. PSF maintains three couples voluntary counselling and testing (CVCT) sites in different districts of Kigali, as well as a mobile unit which changes location monthly.¹⁹

15 <http://kaviuon.org/about-us/about-kavi>

16 <http://www.kemri-wellcome.org/index.php/en/about>

17 <http://uvri.go.ug/index.php/divisions/12-about-uvri/59-uvri-partner-programs>

18 <http://www.mrcuganda.org/about/our-mission>; <http://uvri.go.ug/index.php/divisions/12-about-uvri/59-uvri-partner-programs>

19 <http://www.rzhr.org/Kigali.html>

Table 4.2 East African CRCS supported by IAVI

Clinical Research Centre	Location	IAVI Partner since	Type of affiliation
Kenya AIDS Vaccine Initiative Institute of Clinical Research (KAVI-ICR)	Nairobi, Kenya	1999	Academic; University of Nairobi
Uganda Virus Research Institute –International AIDS Vaccine Initiative Joint Program (UVRI-IAVI)	Entebbe, Uganda	2001	Government
Projet San Francisco (PSF)	Kigali, Rwanda	2003	Academic; Emory University
Center for Geographical Medical Research at Kenya Medical Research Institute (KEMRI-CGMR-C)	Mtwapa and Kilifi, Kenya	2003	Government
Medical Research Council/Uganda Virus Research Institute Uganda Research Unit on AIDS (MRC-UVRI)	Masaka, Uganda	2003	Government

Interviewees noted a number of important features of the construction and outfitting of vaccine trial facilities at the CRCs. These included facility construction, the provision of high-tech laboratory equipment (such as ELISpot readers and Flow Cytometers) to allow for more sophisticated immunology assessment, IT systems to improve data management and sample-tracking, HIV-testing facilities, and reception areas, consultation and counselling rooms for trial participants. Given the challenges presented by frequent power outages in many East African countries, IAVI has also supplied generators to provide continuous backup power to essential equipment such as storage freezers.²⁰ These investments, along with the training of staff discussed above, contributed to the success of all CRCs in obtaining GCLP accreditation.

According to several interviewees, this distinguishes IAVI from other donors as they have not only funded research projects but have also invested significantly in the physical infrastructure at research centres. One interviewee at PSF noted, ‘Almost all of the infrastructure development is as a result of IAVI whereas other donors tend to only support research’. In addition, by providing the necessary infrastructure locally, so that immunology work can be done on site, IAVI has challenged the traditional model of conducting clinical research in Africa, whereby samples are taken from volunteers in Africa and shipped to labs in the US or Europe to be analysed.²¹

20 <http://www.globalgiving.org/pfil/538/projdoc.pdf>

21 <http://www.cyto.purdue.edu/cdroms/gh/HTML/program/media/IAVILab.pdf>

Strengthening pre-existing centres and coordinating with other participants to share resources was also noted by interviewees as a significant factor in establishing sustainable research infrastructure in the region. In particular, efforts to share resources with other PDPs, such as the recent collaborations between the HIL and Aeras, and partnership with pharmaceutical companies to provide clinical research capacity, offer a sustainable solution to resource limited settings, as well as offering the opportunity to share lessons learnt and best practice.

IAVI's Human Immunology Laboratory (HIL) at Imperial College London has been instrumental in coordinating the laboratory infrastructural development of partner CRCs in East Africa. The lab acts as a hub linking IAVI's network of CRCs worldwide, supplying the network with essential materials, enabling on-site evaluation of immune responses to candidate AIDS vaccines, providing and coordinating training programmes for clinical staff and 'acting as a central resource to compare and prioritise candidate AIDS vaccines based on validated immunological assays'.²² IAVI also support an innovative 'matched equipment' system, whereby all the labs at the CRCs and at the HIL use identical equipment, so that support and advice can be provided quickly to troubleshoot faulty equipment. In addition, through the VISTA programme the HIL is helping to support traineeships in immunology and virology to build more basic research capacity at CRC's. More broadly the VISTA programme aims to expand knowledge using existing and new samples from unique cohorts across Africa to advance basic research capabilities through a comprehensive technology transfer and training program

Interviewees also reflected on some of the challenges associated with developing research infrastructure at the CRCs. Concerns relating to land ownership have been highlighted by representatives from several research sites. The KEMRI-Wellcome clinic is currently located on government-owned land, which makes the site's sustainability uncertain. PSF in Kigali will soon be relocated following the government's decision to rezone the area for new estate developments. The lack of opportunities to expand existing sites has been given as a limiting factor for capacity building, trial, and health and healthcare service-related activities.

In addition some interviewees noted that delays in the procurement of laboratory materials are a recurring challenge and tend to slow down research projects.

4.5. Community engagement and mobilisation

IAVI's commitment to engaging with local communities has been a key component of its activities throughout Africa, and is clearly demonstrated in East Africa. IAVI and CRC engagement is driven by the recognition that communities affected by HIV play an important role in HIV research and should therefore be engaged throughout the research process. Moreover, sustained engagement with local communities outside of clinical trials has a range of potential benefits. Firstly, it is likely to improve awareness of HIV in key populations and their local communities; secondly, it may strengthen access to national healthcare delivery systems, and thirdly, it may help ensure involvement of key populations

22 <http://r4d.dfid.gov.uk/PDF/Outputs/iavi/IAVIFactsheetRandD.pdf>

in clinical trials and ease concerns about research ethics. IAVI and CRC partner findings have supported social science research by investigating various issues. These have included stigma and discrimination; barriers and opportunities for involving MSM and FSW; gender-related barriers to clinical trial participation; the social impact of trial participation; and the informed consent process all of which have helped provide a deeper understanding of local communities and the most at-risk populations (see Section 4.5 below).

IAVI's conceptualisation of community engagement as a way to empower key populations (as well as to gain a deeper understanding of cultural constraints or contextual barriers to the implementation of vaccine trials) has shown a significant degree of innovation. As a result, IAVI's understanding of community engagement has broadened and covers a wide spectrum of initiatives. This section aims to introduce the three key areas that characterise IAVI's engagement with communities in East Africa, and its main achievements to date.

4.5.1. IAVI has successfully developed platforms for community engagement

IAVI has invested in the creation of platforms for engaging with communities at different levels, within and across various community networks in Rwanda, Kenya and Uganda. They have also sought to achieve the same impact more broadly across East Africa through integrated regional initiatives.

At the local level, IAVI has engaged with communities by working with and supporting CRC's to establish, maintain, and financially support community advisory boards (CABs) for vaccine trials and epidemiological studies. In 2012 IAVI published Guidelines on CAB Development to support CRC's in building and maintaining CABs and ensure a measure of consistency across the network. In establishing effective CAB networks across CRC's, IAVI has identified common issues faced by research teams and CAB members, helping to ensure that research safeguards the rights of participants and reflects community interests. CABs bring together multiple stakeholders interested in or affected by the research, including:

- Religious leaders
- Representatives of local authorities and experts in law enforcement
- People living with HIV
- Medical professionals
- Groups representing key populations (e.g. MSMs, youth, sex workers, fishing communities).²³

Since 2003, IAVI has supported eight CABs across all CRC partners with 112 members. The composition of each CAB is shown in Table 4.3 below.

²³ For instance, IAVI has built links with the Gay and Lesbian Coalition of Kenya (GALCK), a group with participants from advocacy, service providers and support services (continuum of care) in Kenya. In Uganda, IAVI works with UFFCA, an organisation representing fishing communities.

Table 4.3 Composition of Community Advisory Boards at each CRC²⁴

CRCs community team	Number of CAB members	CAB composition	Year est.	Other advisory mechanisms in place
KAVI KNH	18	Religious leaders, youth, women leaders, NGO representatives, medical rep, past volunteers, lawyers	Since 2003/4	Peer leaders
KAVI-Kangemi	11	Youth, police, religious leaders, women leaders, social workers, health sector reps, NGO reps of people living with HIV, prison social workers	Since 2003/4	Peer leaders Former trial participant group
KAVI-Kangemi (MSM Advisory Committee)	7	MSM sex workers, religious leaders, NGO representatives	Since 2003/4	Peer leaders Former trial participant group
UVRI-IAVI Entebbe	14	Journalist, religious leaders, educators, business person, medical doctor, former participant, HIV services counsellors	Since 2002	Peer leaders network Village health teams
MRC-UVRI-Kampala	12	Sex workers, police, counsellor, people living with HIV, district representative, local council rep, hospital representative, peer leaders	Since 2009	Monthly meetings with managers of bars and lodges
MRC-UVRI- Masaka	13	Journalist, religious leaders, educators, business person, medical doctor, former participants, VCT counsellors	Since 2003/4	Peer leaders network Village health teams
KEMRI-CGMR-C	20	Religious leaders, women living with HIV, disabled youth, local chiefs, security, bar owners reps, Boda boda reps, health facility reps	Since 2011 to replace prior CAB (in existence since 2003)	Coastal Adults Sexual Health Outreach Worker (CASHOWs) Peer leaders representatives of MSM and sex worker NGOs
Projet San Francisco	17	Medical workers, pastors, educators, journalists	Since 2005	Regular meetings with community leaders

In some cases certain communities are not well represented within the CAB. This can be caused by the marginalisation of some groups in a given country. In such cases CRCs are encouraged to set up separate groups to include marginalised groups in the research process. For example, in Kangemi, when MSMs could not be included in the CAB due to tensions with religious leaders, KAVI-ICR set up a separate group for MSMs.

Each of the CRCs has a dedicated community liaison officer (CLO) in charge of ensuring regular communication with CABs. CAB members have received numerous training courses including Good Participatory Practice (GPP) training, vaccine and research literacy, gender training, communication skills and MSM sensitivity training where appropriate. IAVI has trained community liaison officers and civil society organisations

24 Data provided by IAVI

from East Africa in using social media to disseminate information on HIV prevention research to a wide audience. CRC's have provided CABs with access to basic resources including space to meet (usually at CRCs), financial support for travelling to the meeting (given that some of the communities are located in remote areas), and equipment and administrative support to organise the regular meetings.

At the national level, interactions and regular meetings of CABs in a given country have been encouraged by IAVI. In Uganda, IAVI facilitates meetings between five CABs from different research centres across the country to discuss HIV prevention research and share insights. Community representatives are also encouraged to engage with national and local policy makers (see Section 4.6). IAVI coordinates both high-level platforms with policy makers and grassroots platforms for engaging with communities. At the regional level, IAVI organises annual meetings for CAB members and CLO's to come together to share their own experiences, challenges and lessons learned across various contexts. This has greatly benefitted CAB members, as highlighted by several interviewees.

4.5.2. IAVI has contributed to the empowerment of communities through research and advocacy training

IAVI's engagement with communities aims to strengthen their capacity to actively participate in scientific research and to understand wider global and public health issues related to HIV research. CAB members are consulted throughout the research process, from protocol development through to the enrolment of participants for vaccine trials. IAVI and CRC's provide CABs with educational material related to the specific research they are involved with, as well as information on broader scientific issues related to HIV research. CLOs are also in charge of keeping channels of communication open, including making sure that CAB members have access to CRC staff should they have a query or concern. The CABs are not only consulted but are also given the tools to participate effectively and critically in the research process. This usually takes the form of short vocational training courses for research participants covering topics ranging from mobilisation to HIV testing and skills development.

IAVI has also encouraged collaboration between researchers and representatives of key populations at a national level. In Kenya, IAVI has supported the development and training of the G-10, a national research advisory group with the mandate to coordinate LGBT-related research issues and enhance collaboration between the community and researchers, including using data to influence policy and practice in the field. IAVI supported CGMR-C and the Gay and Lesbian Coalition of Kenya (GALCK), through the G-10, to organize and convene consultative meetings with Gay, Men who have Sex with Men and Transgender (GMT) groups to strengthen CGMR-C's stakeholder engagement with key populations. A sub-set of the G-10 based at the coast, Utafiti Pwani, was formed to engage with researchers on behalf of these groups. The partnership was launched by CGMR-C with co-authorship of a paper "collaborating with GMT organizations on HIV prevention and care research in Coastal Kenya" which was published in the KEMRI Bioethics Review Newsletter.

IAVI has also provided selected partners from key population groups with training on evidence-based advocacy, focusing on empowerment, communication and writing skills. One of our interviewees explained that IAVI had been instrumental in bringing basic science to civil society groups and, ultimately, to policymakers. Examples range from local organisations such as GALCK to organisations like the World AIDS Campaign

(IAVI is a member of the campaign's steering committee), a regional platform which holds governments to account for health outcomes.²⁵ Other examples include Kangemi (Kenya), IAVI and KAVI-ICR organising training for peer leaders around the importance of HIV research. GPP training organised in collaboration with AVAC for all CRCs and IAVI has also delivered empowerment training to representatives of the MSM community.

4.5.3. IAVI has been particularly active in educating healthcare professionals

IAVI has been particularly instrumental in raising health and healthcare practitioners' awareness of HIV prevention and has contributed to their understanding of key populations in East Africa. This has been achieved through the organisation of continuing medical education programs for health professionals through local hospitals and health facilities. The training aims to ensure local health care providers, as key community gate-keepers, are well-versed about research taking place in-country, and able to respond to questions and concerns that may be raised by potential volunteers or the general community.

In Kenya, CGMR-C, with IAVI support, developed an online training program for health care providers working with MSMs. This program was developed with and endorsed by the National AIDS and STI Control Program (NASCO) and included on their website. To date, almost 1200 practitioners have been trained by CGMR-C, and positive effects of this training documented (Dijkstra et al. 2015).²⁶ IAVI also supported AVAC to develop an online course on Good Participatory Practice (GPP) to ensure that community staff are well-versed in these international standards.

In Rwanda, PSF has been at the forefront of sensitivity training for clinical staff working with discordant couples. One interviewee noted that this sort of training-based, bottom-up advocacy campaign created a social norm for couples testing. Telling couples that they were discordant and providing condoms resulted in a 70-80 per cent reduction in transmission simply due to increased condom use. This also made it possible to narrow the focus of research on how transmission happens.

4.6. Advocacy targeted at policymaker engagement

IAVI's capacity building efforts have also been directed at strengthening the wider policy environment and increasing policymakers' awareness of public health issues related to HIV. This is crucial given the long-term effort and high level of commitment required to develop an HIV vaccine. More generally, effective responses to the HIV crisis in Africa are heavily dependent on engaging national governments (Harman, 2009). Ultimately, IAVI aims to increase governments' financial commitment to HIV research while ensuring that public policies support health research and encourage HIV prevention, education and access to treatment without discrimination. In East Africa, government spending on health research is particularly low, although the situation varies across countries (Kenya, for instance, has dramatically increased HIV spending over the last couple of years) (African Union & UNAIDS 2013). IAVI has therefore invested in sustained advocacy efforts to put HIV prevention, the needs of Key Populations and vaccine research on the political agenda.

25 For more information, see <http://www.worldaidscampaign.org>

26 Updated figure from interviewee at KEMRI-CGMR-C

IAVI's main advocacy collaborator at the regional level is AVAC. The two organisations have worked together on the formulation of an African advocacy plan focusing on the development of a global AIDS vaccine. The partnership has been formalised through joint mission statements and vision documents, whose priorities have been developed in collaboration with KAVI, MRC-UVRI, UVRI-IAVI, WAC, and the East African National Networks of AIDS Services Organisations. This helped persuade governments to include priorities related to AIDS vaccine development in key strategy documents, to express these priorities at important regional forums and to discuss them with high level stakeholders.

IAVI has had success in translating research into policy in a number of areas. In Uganda, IAVI is a member of the national prevention committee, a multi-stakeholder initiative which contributes to the wider political agenda. A representative of the Ugandan AIDS Commission highlighted IAVI's contribution on issues related to key populations, particularly fishing communities and sex workers. They emphasised that IAVI had been instrumental in informing policy by providing evidence from socio-demographic and epidemiological studies on these populations. The upcoming Ugandan HIV Prevention Strategy (an update of the 2011–2015 strategy), which the national prevention committee develops in partnership with members of parliament, draws directly on IAVI's recommendations for fishing communities. IAVI had previously participated in the Ugandan AIDS Commission National Priority Action Plan (2011/12 –2012/13).²⁷ Our interviewees noted that fishing communities are now a priority on the Ugandan political agenda. In Kenya, interviewees mentioned how IAVI's work has become a critical component of national HIV strategies, their work with NASCOP to provide information for the Kenya HIV Prevention Revolution Road Map and the Kenya National AIDS Strategic Framework, being two such examples.²⁸

IAVI has also engaged with government more directly through capacity building activities targeting government officials. Interviews with policymakers in each country suggested that this training has aimed to help government officials (primarily from health ministries) to use research outputs and translate them into policy briefs and/or policy papers.

In 2003, IAVI partner PSF worked closely with the Rwandan government to help design policies targeting discordant couples as a relevant and effective approach to reducing the prevalence of HIV. Similarly, IAVI-sponsored work with MSM in Kenya has sparked interest and recognition from the government of Rwanda and other donors that MSM are a key community for their work. This has resulted in a system for referrals, new guidelines for the most at-risk populations and improved understanding of key risk factors in MSM (such as transactional sex and alcohol intake). In addition, the Rwandan government has recently commissioned a survey in order to improve its understanding of the MSM community. The survey will be led by IAVI's partners at the PSF site in Kigali.

4.6.1. IAVI is active in disseminating research and raising awareness of HIV research

IAVI aims to build capacity in civil society and strengthen links between civil society and policymakers, contributing expert advice on ways in which African governments can

27 <http://uganda.um.dk/en/~media/Uganda/Documents/English%20site/Danida/National%20Priority%20Action%20Plan.pdf>

28 <http://www.gbvhivonline.com/wp-content/uploads/2014/04/HIV-prevention-roadmap-report-draft.pdf>

incentivise R&D. IAVI works with local partners to disseminate information about their activities at international conferences, providing financial and technical support and training for policymakers, communities and civil society.²⁹ In addition to international platforms, IAVI have also used innovative dissemination mechanisms to engage with local communities. For example, IAVI collaborated with Lightbox - a socially conscious local media production company in Kenya - on a project to raise awareness of new prevention technologies and vaccines for young people. A short documentary was shot in Kenya and South Africa, featuring IAVI research staff and young people discussing new prevention technologies. The documentary was presented to researchers, international funders and policy makers at the Cape Town HIV Research for Prevention conference in October 2014. IAVI's work with Lightbox sparked interest from a number of other donors, including AERAS, which works on developing TB vaccines. In addition, IAVI has sponsored videos on work in fishing communities and with MSM, with a particular focus on community engagement activities.

In parallel, IAVI has also been involved in media capacity building, organising training for journalists throughout East Africa about HIV issues. In Uganda, this work was done in collaboration with the Uganda AIDS Commission.³⁰ IAVI engaged the Kenyan media by providing training for radio journalists and media briefings and sponsored several workshops for journalists in Kigali. Further, IAVI supported partner AVAC to conduct both local media trainings and trainings/briefings associated with various conferences. These activities allowed IAVI to communicate more effectively about the research conducted and raise media awareness around HIV.

4.7. Impact of IAVI's work on key populations

4.7.1. Fishing communities in Uganda

Fishing communities are amongst the highest-risk groups for HIV infection. In Uganda, HIV prevalence in fishing communities is 28.8 per cent, much higher than the national prevalence of 7 per cent. High prevalence can be attributed to a number of interlinking factors, including: mobility, the amount of time spent away from home, daily cash income, ready availability of commercial sex in fishing ports, and a subculture of risk-taking and hyper-masculinity among fishermen (Allen & Seeley 2004, Kiwanuka et al. 2014, Seeley et al. 2012). Women in fishing communities are at particularly high risk, as they are often in a subordinate economic and social position. Much of this research in Uganda has been conducted by IAVI partners MRC/UVRI and UVRI-IAVI, and has been instrumental in identifying HIV risk and larger public health needs of this under-served population.

High HIV incidence affects both individuals and the sustainability of fisheries. At the individual level, loss of time due to illness or caring for another can lead to labour shortages both for money-earning activities and household tasks. Many families rely on farming as well as fishing to support themselves, with income from fishing used to

29 Key conferences mentioned by interviewees included: AIDS Vaccine Literacy Training delivered at the Gender AIDS Forum in Durban in 2008; panel discussions, satellite session, and pre- and post- conference training for community advocates at the International AIDS Society (IAS) conference in partnership with the Desmond Tutu HIV Foundation, the Global Youth Coalition on HIV/AIDS and the Black AIDS Institute; and a two-day advocacy training workshop during the 5th BRICS Summit in Durban in March 2013 with the World AIDS campaign.

30 IAVI annual progress report, 2004

purchase agricultural materials. Consequently, a reduction in income from fishing often means a reduction in agricultural production, and diminished access to food. HIV-affected families are also subject to stigmatisation, which may make it difficult for them to access the credit needed to purchase land or fishing equipment.

At a community level, various HIV-related factors can negatively affect economic performance. These include loss of staff with key skills and knowledge, absenteeism due to illness, and poor morale due to fear and uncertainty about HIV. Furthermore, the loss of knowledge gained by experience, combined with the higher general likelihood of death, can reduce incentives for longer-term and inter-generational stewardship of resources (Allison & Seeley 2004). IAVI has been working closely with key organisations to engage with fishing communities in Uganda. Adopting a multi-stakeholder approach to community engagement, IAVI and partners are working with health service providers, local authorities, international NGOs and representatives from the community through grassroots organisations to access and provide testing and care options to fishing communities. These multi-stakeholder partnerships have allowed IAVI and CRC partners to build trust with communities, which has been crucial to effective engagement. This is particularly significant given that, according to one interviewee, prior to IAVI's engagement there were no accessible health services for these communities.

Our interviewees noted that this multi-stakeholder approach has been crucial in finding innovative ways to access to this very mobile and hard-to-reach community. One example has been through their partnership with the Uganda Health Marketing Group (UHMG),³¹ IAVI has helped address some of the challenges related to access and their research has also helped to identify unmet needs. According to one interviewee:

IAVI have opened our eyes to the needs of women in these fishing communities. Previously we had never provided family planning services to these communities and now a large number of people are enrolled and we are expanding our operations to other islands in the region.

The partnership contributed to the provision of services to islands with high HIV prevalence, resulting in 56 women accessing family planning services and 2253 people being tested across 13 islands, of which 412 were tested positive and directed to care.³² In addition, through building on their pre-existing networks, IAVI also supported the establishment of new referral systems and mechanisms for connecting people living with HIV to the care they need.

IAVI's close links with government officials and policymakers in Uganda have also had an impact on fishing communities. IAVI is a member of the national prevention committee in Uganda, which serves as a building block for the wider government agenda on HIV. In addition, IAVI has collaborated with the Uganda AIDS Commission (UAC)³³ on various media events advocating HIV vaccine research, as well as convening a national Fisherfolk Summit for key stakeholders to discuss strategies to accelerate provision of HIV prevention

31 UHMG is a social marketing company aiming to provide access to affordable healthcare solutions, more information is available on their website: <http://www.uhmg.org>

32 Data received through correspondence with UHMG

33 The Uganda AIDS Commission (UAC) was established in 1992 by an act of parliament to coordinate the implementation of the national strategy to combat HIV/AIDS; for more information, see <http://www.aidsuganda.org>

to fishing communities. This led to the development of a roadmap to guide the provision of HIV/AIDS services in fishing communities. The roadmap emphasised the need for comprehensive collection of demographic data, community involvement in the design of interventions, improved access to health centres at key sites, expanded healthcare provision beyond HIV/AIDS services, and sustained dialogue with policymakers.³⁴ According to several interviewees the roadmap being presented to members of parliament and other key stakeholders has contributed to fishing communities being highlighted as a priority population in the National Strategic Plan for HIV/AIDS.³⁵

IAVI's work with grassroots organisations, such as the Ugandan Fisheries and Fish Conservation Association (UFFCA),³⁶ has allowed them to access infected populations and provide access to health services, testing and educational material about HIV issues. One interviewee reported that these 'different channels for engagement have helped improve fishing communities' knowledge of HIV and prevention tools as well as access to testing, treatment and family-planning services on some of the islands'. IAVI has also recently supported training in HIV research and prevention services for village health team (VHT) members and peer leaders from fishing communities spanning three districts and 12 villages,³⁷ providing them with the knowledge needed to improve the efficiency of HIV prevention services in their communities, as well as building wider awareness of HIV counselling, testing, education and sensitisation.

In addition, IAVI have also supported campaigns to raise visibility more broadly, such as the 'Minibuzz' campaign,³⁸ designed by the Knowledge Management and Communication Capacity initiative (KMCC).³⁹ The campaign, carried out in December 2013, consisted of a series of videos aimed at fishermen and their broader communities which discussed behaviours and attitudes towards HIV, as well as providing information related to treatment and prevention.⁴⁰ The partnership has facilitated direct engagement with fishing communities and has also helped to foster discussion about stigma and perception with people from outside the community.

4.7.2. Men who have sex with men in Kenya

Men who have sex with men (MSM) are a regularly overlooked yet high-risk group for HIV infection in Africa. The stigma faced by many MSM across sub-Saharan Africa has made them a particularly difficult group to access. However, there is growing recognition of the importance of engagement with MSM (Sanders et al. 2007; van Griensven 2007) as they are a particularly high-risk group for various reasons. Firstly, HIV prevalence is higher among MSM than among the population as a whole. Secondly, incidence rates are higher

34 <http://uffca-ug.org/wp-content/uploads/2015/01/brief-report2.pdf>

35 <http://uganda.um.dk/en/~media/Uganda/Documents/English%20site/Danida/NATIONAL%20STRATEGIC%20PLAN%20FOR%20HIV%20%20AIDS%20201112%20%20201415.pdf>

36 A national advocacy organisation funded in 1994 and based in Kampala

37 <http://www.iavi.org/newsletter/2014/494-world-aids-day-2014>

38 The 'Minibuzz' campaign comprises short videos showing people from local communities sharing their views on specific HIV related topics.

39 KMCC is a communication organization set up in 2012 to facilitate the uptake of HIV prevention and information strategies, more information is available on their website: <http://www.kmcc.org.ug/>

40 Videos available on KMCC website and here (Fishermen Fighting HIV part 1; HIV Myth Busting in fishing community; How do fishermen spend their free time?)

from male-to-male sexual activity (Price et al. 2012). Thirdly, MSM are more likely than other groups to have sex with multiple partners, often including women, which indicates that MSM may play an important role in the dynamics of HIV transmission (Onyango-Ouma et al. 2005).

In Kenya, MSM populations come from a wide variety of socioeconomic and ethnic backgrounds (Onyango-Ouma et al. 2005). MSM behaviour is illegal, and the community is subject to social stigma and widespread discrimination. Consequently, MSM have difficulty finding healthcare providers trained to meet their specific sexual health needs, and they are less likely to approach providers for specific advice due to fear of discrimination, 'outing' and/or exposure to criminal charges. MSM populations have shown willingness to be involved in HIV research to help improve their sexual health (van Griensven 2007).

Similar to the fishing communities in Uganda, many interviewees noted that research and community engagement activities carried out by CRC partner KEMRI-Wellcome (CGMR-C) with support and sponsorship from IAVI, have contributed significantly to efforts to address MSM-specific health needs. In 2005, the team at CGMR-C was the first African site to receive ethical approval for and to develop an MSM trial cohort.⁴¹ Since then, over 1,400 MSM have been tested at the centre and over 1,000 have participated in research, contributing significantly to knowledge about behaviour and epidemiology in this high-risk population, both in Kenya and throughout Africa.⁴² Interviewees highlighted that "IAVI was one of the first organisations to work with MSMs in Kenya, during a time of structural exclusion from many other aspects of society". This has not been without substantial challenges, given the socio-political context surrounding homosexuality in the country.⁴³

CGMR-C have worked particularly with MSM communities in coastal Kenya, developing and refining community engagement mechanisms for their MSM work, including inviting representatives from MSM communities to take part in discussions regarding research activities at different stages, from research design and protocol development through to dissemination. As mentioned in section 4.5, an MSM advisory group was invited by CGMR-C to co-author an article which was published in the KEMRI Bioethics Review Newsletter. It was reported that these activities contributed to the empowerment of MSM organisations by providing them with channels to raise challenges, share experiences and discuss research priorities. Many interviewees reported that CGMR-C and IAVI's role in facilitating dialogue and helping to bring organisations together was crucial. As one interviewee noted, 'it allows us to be agents of our own change'.

It was also noted that CGMR-C's work with MSMs goes beyond its direct engagement with representatives from the community, in that they have also been implementing initiatives aimed at reducing stigma around MSMs and facilitating their access to health and healthcare. One example is MARPS-Africa, a virtual training course using computer-

41 Approval to enroll men and women who reported anal sex in the past 3 months was requested. This became a de-facto MSM cohort.

42 <http://www.kemri.org/dmdocuments/The%20KEMRI%20Bioethics%20Review%20Volume%204%20Issue%203.pdf>

43 For example, the CRC at Kilifi was attacked by anti-homosexuality protestors in 2010, resulting in people being dragged out from the waiting room of the clinic and beaten. <http://www.bbc.com/news/10320057>

assisted learning. CGMR-C, in collaboration with the Kenya National AIDS and STD Control Program (NASCO) and supported by IAVI developed the modular on-line training tool in 2011, which provides awareness and sensitivity training to healthcare workers about MSM health issues.⁴⁴ To date almost 1200 healthcare workers (including over 500 government employees) have completed the training and a recent study found that the 'training, which combined self-directed and facilitated group learning, increased health worker knowledge and reduced homophobic attitudes up to three months after training' (van der Elst et al. 2013). In addition, some interviewees noted that support for MSM health needs has improved as a result of the training. For example, one interviewee reported that:

There are now MSM support groups. They are interacting with their colleagues to exchange experiences with their colleagues and talk about how to treat MSM.

Interviewees also noted that the active involvement of NASCO in promoting the training through their website has been very beneficial.

Since we have included NASCO in our work, for example the healthcare worker training, the sensitisation training for medical workers, frontline workers who deal with patients, [it has been] really well received at the national level

In addition to supporting community engagement work at CGMR-C, IAVI has worked nationally to engage the LGBT community. IAVI has developed a strong partnership with the Gay and Lesbian Coalition of Kenya (GALCK), which acts as the national umbrella body for LGBTI organisations working on issues of rights, health and social welfare.⁴⁵ This has allowed IAVI to work with various MSM organisations in Kenya by creating platforms for engagement with key stakeholders, including helping to develop the LGBTI national research advisory group, the G-10. In addition, IAVI has supported other LGBTI platforms, such as the GHPN-Ke and an MSM symposium, all of which provide advice and feedback to in-country research programs related to LGBTI issues.

In addition, these forums for engagement also provided training for local organisations and NGOs on the use of evidence-based research for advocacy purposes, and on soft skills for advocacy. One interviewee noted that IAVI's work with MSM representatives has also been used in national HIV prevention strategies, illustrating the organisation's commitment to working hand-in-hand with communities to influence policy. For instance, it was noted that "IAVI is unique in the sense that they link research to policy" and that "now it would be surprising if policymakers [in Kenya] did not know about key populations, which is thanks to IAVI".

IAVI's position as a trusted partner of the Ministry of Health's National AIDS & STI Control Programme (NASCO) has been crucial in highlighting the needs of MSMs in Kenya, and interviewees reported that IAVI research has been critical in having these issues included in national strategies, guidelines and policies. Recent examples include NASCO's Most at Risk Populations Surveillance Report (2012),⁴⁶ the aforementioned HIV Prevention

44 For more information, see <http://www.marps-africa.org>

45 <http://www.galck.org/>

46 <http://nascop.or.ke/library/Marps/MARPs%20BOOK%20REPORT%20.pdf>

Roadmap (2014 - 2030),⁴⁷ and a best-practice guidance document, *Respect, Protect, Fulfill*, outlining the challenges and opportunities for conducting HIV research with MSMs, which IAVI developed in collaboration with amfAR, Johns Hopkins University and the UNDP.⁴⁸

4.7.3. Discordant couples in Rwanda

Discordant couples consist of one HIV-positive partner and one HIV negative partner. In Africa discordant couples have a particularly high risk of HIV transmission because many couples will not know that one of the individuals is infected with HIV. Additionally, there is a low rate of condom use. The high risk of transmission affects both the HIV-negative partner and any resultant children. A number of studies have indicated that the majority of new HIV infections in Africa occur in discordant cohabiting couples (Allen 2003).

In Rwanda 3.1 per cent of couples are known to be discordant (El-Sadr et al. 2011). This is the only country in Africa to have implemented Couples Voluntary Counselling and Testing (CVCT) on a national scale, with more than 90 per cent of pregnant women and their partners now tested and given advice on transmission prevention methods (Ingabire et al. 2013). However, there is still stigma attached to HIV in Rwanda, both by healthcare professionals and the wider community (Jean-Baptiste 2008).

IAVI has supported PSF's work with discordant couples in Rwanda from 2003-2012, building on the long-standing work of researchers from Emory University at PSF, which started in 1986. PSF has contributed to the nationwide spread of couples testing and helped shape national CVCT policy. Since 1988, more than 17,000 couples have been tested, 8,000 people have been provided with screening for sexually transmitted infections, and 940 HIV discordant couples have received general outpatient care at the PSF clinic.⁴⁹

IAVI's support has helped PSF to get funding from other sources such as the Global Fund and the National Institutes of Health for their work with discordant couples. IAVI support has also contributed to wider advocacy and policy objectives, contributing research and evidence that helped PSF to convince government officials that working with couples is an effective approach in helping to tackle HIV. According to one interviewee, 'PSF has continued to promote couples testing on the basis that it has proven to be relatively cheap and effective' and that IAVI's role in advocating with PSF for couples testing has been 'important as IAVI has a powerful voice'. PSF has also encouraged the uptake of CVCT in Rwandan clinics, by providing training to government clinics, which in turn act as entry points into PSF observational studies and clinical trials. Currently, PSF is assisting and monitoring the effectiveness of government programs for discordant couples throughout the country. Outside of Rwanda, PSF is now established as a leading regional centre for CVCT and has conducted training with other IAVI-affiliated sites as well as other African health workers and researchers. According to one interviewee, 'PSF has been able to help over 20 other countries, including countries outside of Africa.'

47 http://www.nacc.or.ke/attachments/article/418/Kenya_HIV_Prevention_Revolution_Road_Map.pdf

48 <http://www.undp.org/content/dam/undp/library/hiv/undp/English/MSMguidance2011.pdf>

49 <http://www.rzhrg.org/Kigali.html>



5. Discussion

The findings from our interviews with key stakeholders at IAVI highlight the diversity of factors which have influenced the evolution of their capacity building activities in East Africa. The section below reflects on these findings, presenting the key overarching themes emerging from IAVI's activities, drawing on lessons from the wider literature about other capacity building initiatives. Finally we present some considerations for IAVI's future capacity building, based on our findings and observations.

The value of long-term networks

- **The creation of a strong network of CRCs in East Africa which collaborate on research, training and publications is helping to develop professional opportunities for researchers and strengthening the regional scientific community.** Research networks provide an opportunity to pool resources and expertise while spreading risks and costs, as well as the opportunity to coordinate activities, learn from experiences and share tacit knowledge through personal interactions and informal engagement.⁵⁰ IAVI's commitment to developing a network of CRCs in East Africa has allowed African researchers and research institutions to gain these opportunities by enhancing training and knowledge throughout the region. According to one interviewee, adopting the 'train-the-trainer' approach has also strengthened the network of CRCs as it allows for sites to build on their comparative advantage, enabling expertise at the CRCs to be diffused across the network. IAVI's strategy of seeking partnerships with established, multi-donor institutions in the region has also allowed for resources and knowledge to be shared. It was felt by many interviewees that this networked, South-South model of research training was key to ensuring the sustainability of HIV research in East Africa.
- **IAVI's long-term presence has been key in its reputation as a trusted partner for both CRCs and for local communities and policymakers.** Despite the proliferation of capacity building activities over the last 20 years, many such efforts are only short- or medium-term commitments, often tied to particular funding. Olapade-Olaopa et al. (2014:s23) note that 'initiatives in Sub-Saharan Africa have suffered from investments that do not cover the time required for a successful transformation'. Many interviewees noted that a key strength of IAVI's approach to capacity building is that they have been in the region for a long time, and this historical presence has enabled equitable research collaborations and trust among key stakeholders in the region. One interviewee from an NGO in Uganda stated that IAVI's reputation and longevity had allowed them access to policymakers and key populations which would otherwise have been very difficult.

50 For further discussion see: Kraut et al. (1988); Katz & Martin (1997); Subramanyam (1983)

Distributed leadership and a commitment to engagement with diverse stakeholders

- Leadership has proved an important enabler of success in IAVI's capacity building efforts.** While the role of leadership as an enabling factor in organisational excellence is widely recognised,⁵¹ its role in building effective research capacity is often underestimated. Strong leadership abilities within research teams at the CRCs, as well as at the IAVI offices in Nairobi, New York and HIL have been key drivers of IAVI's capacity building achievements in East Africa. Many interviewees noted the importance of strong leadership and decisionmakers in establishing good links with policymakers and building trust with local community groups.
- IAVI's commitment to translating research into policy has facilitated meaningful engagement with policymakers and local communities.** A driving force behind IAVI's capacity building activities has been a commitment to translate their scientific research into policy and to ensure that local communities' needs are reflected. IAVI has strengthened links between communities, policymakers and researchers by acting both as an innovation 'integrator' who ensures that scientific research is relevant and inclusive, and as a development 'broker' who brings together key stakeholders to raise the profile of HIV vaccine research (Chataway et al., 2006). This dual role has been crucial to its capacity building achievements.

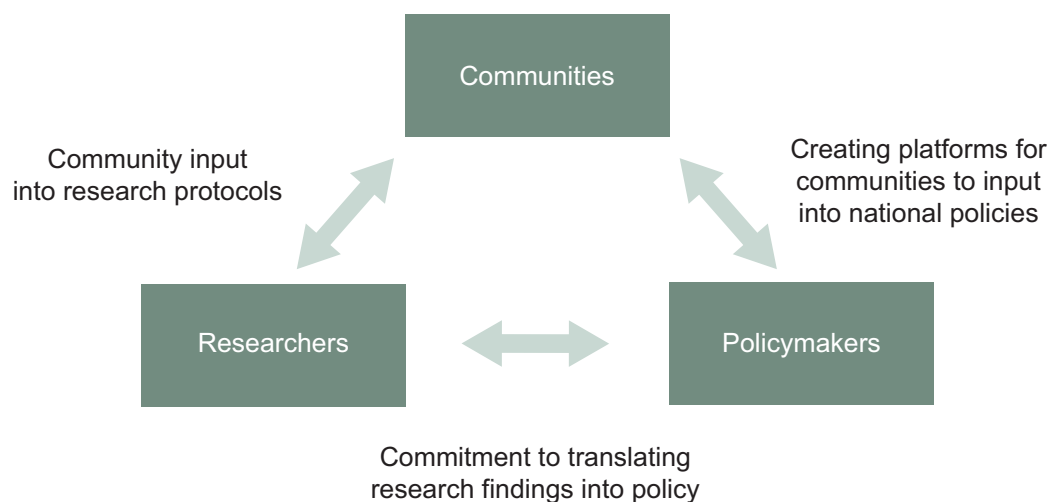


Figure 5.1 IAVI's role as a broker between stakeholders

- IAVI has recognised the importance of flexible partnerships and good communication between a range of stakeholders in building effective and sustainable capacity in HIV vaccine research.** Effective capacity building, in essence, is underpinned by the ability to develop partnerships which enable the sharing of knowledge and the building of mutual trust and ownership. The diverse range of partnerships required for IAVI to build sustainable capacity in East Africa has led to informal partnerships with NGOs, clinical research sites, academic institutions,

other donors and PDPs, policymakers and local government. Flexibility in these partnerships and good communication are frequently cited, both by our interviewees and previous evaluations, as enabling factors in IAVI's capacity building activities. When comparing IAVI to other research funders, feedback included the statement that 'when we started working with other donors we didn't realise how rigid they could be', and that 'if all institutions could have the same sort of relationship that we have with IAVI, things would be much better'.

This flexible approach is rooted in the recognition that each stakeholder group has different expectations and needs. This is demonstrated by the diversity of IAVI's work, which includes supporting the diversification of research activities at CRCs, actively sharing knowledge and resources with other donors/PDPs in the region, and creating platforms for groups in order to increase the visibility of issues affecting the most-at-risk populations. Through this work, IAVI has been able to build sustainable, effective partnerships which harness relevant expertise, improve the quality and impact of research, and allow for resources to be fully utilised.

Demand-driven capacity building

- **IAVI's bottom-up approach, whereby CRCs are responsible for identifying their own training needs and local communities are engaged in the whole research process, has been a strong enabling factor in IAVI's capacity building activities.** Numerous studies have emphasised the importance of ownership in developing sustainable research capacity.⁵² IAVI's strength has been in ensuring that capacity building activities constitute a continuous process of improvement, driven by CRCs. In addition, as a PDP IAVI is uniquely placed among capacity building participants to adopt a holistic approach to issues surrounding HIV vaccine research. This finding resonates with Hanlin et al (2007) who note that 'by working as a PPP, [IAVI] has changed 'ownership' of science, making the process more flexible and emphasising a bottom-up dialogue process while advocating a private sector ethos'.

Internal and external challenges to capacity building

- **IAVI faces a number of external challenges which are inherent to the context in which their capacity building activities take place.** These include challenges related to the lack of integrated health and care systems, social tensions related to the stigmatisation of key populations, lack of reliable infrastructure, issues relating to land ownership and the uncertain funding environment for further vaccine research, all of which make it difficult to conduct research in the region. While addressing these challenges are outside the remit of IAVI, these challenges should be understood with respect to its achievements to date.
- **IAVI's capacity building activities have expanded over time and the organisation will need to consider how it balances a broader focus whilst maintaining its core mission of developing an HIV vaccine.** While there are a number of challenges relating to the external environment in which IAVI operates, an internal

52 See, for example Adewole et al. (2014); Chu et al. (2014) and Marjanovic et al. (2013)

challenge for the organisation, in relation to capacity building, will be the extent to which it broadens or narrows its focus. IAVI's activities have expanded over time and several interviewees expressed the desire for IAVI to do more to integrate research- and care-related activities and to consider a more holistic approach to strengthening health systems through deeper collaboration with players involved in other sectors, such as sanitation, transport and infrastructure. This expanded focus allows for a more flexible and diverse approach to capacity building but also makes IAVI's activities more complex and perhaps less understandable for its partners.

5.1. Considerations for future capacity building activities

IAVI's contribution to CRC networks has yielded positive results and maintaining leaderships and involvement is likely to yield continuing positive results. In the section below, we focus on the potential for improvement of IAVI's capacity building activities, drawing on evidence from the key findings of this study.

- **Success in IAVI's move towards supporting basic research will depend on its ability to facilitate clear career pathways.** IAVI's move towards supporting more basic research, through degree programs, appears to be a necessary step in producing the next generation of African scientific leaders. The success of this support will depend on IAVI's ability to work with CRC partners (and oftentimes their parent institutions) to define clear research career pathways that enable African scientists to develop, conduct and disseminate HIV vaccine research. This may require further engagement with local universities and other research institutes in the region. Clear research pathways may also encourage trainees to return to their home country/institution. In addition, helping to forge partnerships with local academic institutions and building on pre-existing networks of excellence in the region will also be important when considering linking trainees to mentors.
- **Coordinating efforts with other capacity building actors in the region may offer the opportunity to pool resources and share experiences.** Coordination with existing initiatives supporting PhDs and postdocs would also help ensure the sustainability of this type of funding. IAVI could consider engagement strategies with researcher funders, such as the Wellcome Trust and NIH, to avoid duplication of efforts. Integrated solutions to ensure retention of researchers throughout their career pathways need to be considered in collaboration with other donors. For instance, balancing support to different and complementary research projects, where existing skills can be applied to different health research problems, has been presented as a potential solution to the CRC's sustainability, as this diversification would help to attract funding from different donors.
- **IAVI should consider the remit of IAVI's future capacity building activities, in terms of what it intends to support and where it can help support others.** There may be a need for a clearer conceptualisation of IAVI's capacity building activities. As previously discussed IAVI offers a unique 'learning-by-doing' approach to capacity building and in recent years has begun to incorporate scientific training as a core component of its strategy. Clarity on how other aspects of capacity building complement each other, what mechanisms are in place to support each of these, and what aspects are outside the scope of IAVI support, are all questions it may be helpful to consider.

- **Specific M&E indicators for evaluating capacity building activities may help IAVI to demonstrate progress to donors.** Coupled with this is the need for IAVI to create capacity building-specific monitoring and evaluation (M&E) indicators which can be used to set milestones and demonstrate success to donors. Capacity building is frequently becoming a necessary component required by donors, although it is often difficult to evaluate. In order to demonstrate the progress and opportunities encountered with its capacity building activities, IAVI should consider what data it could collect on a continuous basis to make the case for sustained investment in their work in Africa. The work of the Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts (ESSENCE) on Health Research group, which aims to develop common frameworks for planning, monitoring and evaluation of capacity building activities, may provide useful insights into potential indicators (Boyd et al. 2013). Career tracking mechanisms may also be helpful in assessing the outcomes of support to research training.
- **Balancing flexibility and the formalisation of partnerships may help clarify expectations and objectives.** One of IAVI's strengths is its ability to mobilise a wide network of organisations from different sectors (research, civil society, policy, health and healthcare community). While IAVI's flexible and experimental approach to partnerships was received positively, formalising certain types of partnerships and clarifying expectations may be beneficial, and may help avoid delays and miscommunications on some projects. This could be achieved through greater clarity and transparency regarding funding allocation to IAVI's partners.
- **More emphasis could be placed on developing non-research training skills at the CRCs, such as financial management and research administration.** This should go hand in hand with the development of monitoring tools to collect information on activities and achievements in a timely manner. The move towards supporting more basic research offers good opportunities for leveraging additional funding from other donors and agencies in order to conduct broader research projects, although will depend on financial management capacities developed at the CRC level. A broader funding base would help the CRCs become more financially resilient but would also require the development of strong financial and administrative capabilities to comply with different donors/funder requirements. In addition, given the strong leadership skills demonstrated at the CRCs, IAVI may also wish to consider supporting more formal leadership training to ensure its ability to contribute to the next generation of African scientific leaders. In addition, providing access to non-IAVI training, through collaboration with other donors and research centres, and through wider dissemination of existing opportunities across CRCs was also highlighted as something IAVI could improve on.

5.2. Final remarks

Developing effective research is underpinned by the need for individual research skills, adequate organisational and research infrastructure and a supportive local and global policy context (Chu et al. 2014). Efforts to address these gaps, aimed at fostering sustainable research capacity in Africa, have been growing in recent years and increasingly non-traditional players, such as PPPs, are taking a leading role in these initiatives. PDPs in particular offer an interesting model of capacity building, as organisations which offer a learn-by-doing approach to capacity building whilst being driven by the development of health products.

IAVI's mission to develop an HIV vaccine has become increasingly connected with wider efforts to strengthen health research systems, both through its clinical research and other associated activities in East Africa. Since it began operations in the region, IAVI has made a significant contribution to training aimed at supporting scientific excellence and GCP, as well as investing in infrastructure and laboratories at CRCs. In addition, IAVI has created platforms through which to engage with local communities and policymakers on issues related to HIV and vaccines. IAVI's advocacy and communications strategies are based on an underlying belief that the very significant investment needed in HIV/AIDS research was contingent on demand from those who most needed new research in the area, i.e. populations and their political representatives in developing countries worst affected by the disease. This demand, in turn, depends in part on greater awareness of and involvement in HIV vaccine research. Therefore, much of IAVI's achievements in improving scientific capacity in the region have been down to its ability to act as a broker between researchers, policymakers and local communities. Strong leadership and a commitment to facilitating South-South collaborations between CRCs have also been important enablers in IAVI's capacity building

While IAVI's progress in building scientific capacity in Africa appears to have been widely acknowledged in previous evaluations, we have observed an increased emphasis on capacity building as a core component of their strategy in East Africa. IAVI's challenge for future capacity building activities will depend on how it balances a broader focus whilst maintaining its core mission of developing an HIV vaccine. These are of course not mutually exclusive although as it diversifies its portfolio of activities it would be useful, in order to demonstrate impact and sustain future funding, to formulate a better understanding and articulation of three key points. Firstly, what IAVI considers its core capacity building activities, which require monitoring and strategic objectives; secondly, where its activities have a spillover effect in further strengthening capacity; and thirdly which activities are outside its remit. In addition, building a degree of flexibility and diversity into future capacity building activities will be important in responding to emerging needs and absorptive capacity issues.

Although clear challenges still exist in terms of ensuring sustained investment, accessing marginalized populations and demonstrating progress in capacity building, the experiences of IAVI to date suggest that substantial progress is being made towards a wider strengthening of health research systems in the region. The efforts to discover an HIV vaccine have been, and will continue to be, a global endeavour, relying on strong international research collaborations and increasingly African scientific leaders. As we move into a post-2015 agenda and begin to focus on improving the sustainability of health systems in sub-Saharan Africa, stakeholders such as IAVI can play an important role in developing and advocating for improvements in the African research landscape.

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Appendix A: Interview Protocol

Scientific skills and training

1. What IAVI capacity building activities related to training/scientific skills are taking place/are you aware of?
2. How did you get involved with these activities/some of these activities?
3. Who are these activities targeting?
4. Has this approach changed over time?
5. How are training needs identified?
6. How are training opportunities communicated?
7. Which other organisations have you worked with and are involved in scientific training activities in East Africa?
8. What has enabled the success? How did this happen and can you give examples? (Probes: financial investment, human resources investment, governance mechanisms, communication activities)
9. What have the challenges been? Have they been mitigated/managed? If yes, how and can you give examples?
10. What do you see as the opportunities for future capacity building activities?
11. Do you evaluate training courses/collect feedback?
12. What data is collected on training? (e.g. number of courses per year, number of people trained, number of courses in Africa, number of courses outside Africa, staff retention/career tracking, needs assessments)
13. Are there any examples of other training activities you've been involved with outside of IAVI that you think IAVI could learn from?
14. Have you experienced any spillovers from IAVI's capacity building activities? That is, are there any wider benefits outside of HIV vaccine research that you have experienced or observed as a result of your participation in these activities? Can you provide some examples? (E.g. using the capacity built for other research outside of HIV, government interactions with the LGBT community/people living with HIV)

Research infrastructure

1. What IAVI capacity building activities related to technology transfer and infrastructural development are taking place/are you aware of?
2. How are laboratory needs identified?
3. How often do you interact with the Human Immunology Laboratory in the UK on technology transfer/lab equipment maintenance? What is the nature of this interaction? Please provide examples

4. How often do you interact with the Contract Laboratory Services in South Africa on technology transfer/lab equipment maintenance? What is the nature of the interaction? Please provide examples
5. How often do you interact with the other research sites in Africa on technology transfer/lab equipment maintenance? What is the nature of the interaction? Please provide examples

Community engagement, outreach & key populations

1. Could you please describe the community outreach activities you have been involved with/are aware of?
2. What have been the major achievements of these activities to date?
3. What has enabled the success? How did this happen and can you give examples?
4. What have the challenges been? Have they been mitigated/managed? If yes, how and can you give examples?
5. What activities are planned for the near future?
6. Which specific communities are targeted with your outreach activities? What are the challenges and opportunities of working with these groups?
7. To what extent has IAVI funded activities had an impact on these communities? In what ways and why? What were the results?
8. Have any advisory boards been established with support from IAVI at your site? (Community Advisory Boards, Gender Advisory Boards, etc.) If so, please provide the following details: date of creation, name of clinical research center where the advisory is located; members profile and areas of expertise.
9. What has IAVI's role been in supporting Couples Voluntary Counselling and Testing (CVCT) activities?
10. Are there other mechanisms for engagement with different communities that IAVI support? Is there anything additional engagement strategies IAVI should consider?
11. Is there data available on provide information about:
 - Number of people involved in the provision of community outreach programs;
 - Number of people who have had VCT
 - Number of training programs per annum targeting 1) CABs Members; 2) healthcare workers; 3) volunteers;
 - Number of people enrolled in each of these programs (disaggregated per year and gender if possible)

Advocacy & policymaker engagement

1. Please describe the advocacy activities you have been involved with/are aware of to raise the profile of HIV vaccine research?
2. What have been the major achievements of these activities to date?
3. What has enabled the success? How did this happen and can you give examples?
4. What have the challenges been? Have they been mitigated/ managed? If yes, how and can you give examples?
5. What activities are planned for the near future?
6. Have you witnessed support from key decision-makers/government officials for the work IAVI does on HIV vaccine research/community engagement? How has this changed over time? Please provide examples
7. Are you aware of any national/international policy documents that IAVI supported activities have contributed to? Please give examples.
8. What mechanisms have facilitated engagement with policy makers?
9. What are the main barriers to engaging with policy makers? Have these barriers been overcome over time? If so, could you give examples?
10. Have you worked with other organisations involved in capacity building activities? If so, which ones? Please describe the nature of the collaboration
11. Are you aware of any collaboration (formal or informal) with other Product Development Partnerships (PDPs)? If so please describe.
12. What are the main challenges to engaging with other organisations? Has this changed over time? If so, why and how? Please give examples.
13. What are the main enablers to engaging with other organisations?



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