INVESTIGATION OF HOW COMPETING CULTURES WITHIN IAVI PLAY OUT IN A DEVELOPING COUNTRY CLINICAL TRIAL SETTING

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Introduction

We started our research from the premise that the International AIDS Vaccine Initiative (IAVI) – as an organisation – creates an environment and sets itself the task of gap filling and knowledge integration, including conduct of clinical trials. This is due to its mandate at set up as a Product Development Partnership (PDP) to remove the disconnect between basic and applied research and clinical development stages. In this way PDPs are seen to overcome an apparent market failure whereby traditional pharmaceutical companies did not get involved in drug and vaccine development for diseases affecting low income countries where profit margins are low. At the same time, the emphasis on clinical trials initially followed IAVI’s emphasis at start up of also focusing on advocacy and being seen as aiding the international development scene. These two areas of activity (promoting science and conducting advocacy) play out within the organisation being impacted by existence of competing cultures\(^1\) within the organisation and its partners.

We can identify a number of competing cultures and resulting storylines within IAVI and its partners. Studying how these cultures play out within a micro arena, such as the clinical trial research setting, provides a way of getting to grips with the contestation that is created. Highlights the main negotiations and differences played out due to meeting of different cultures. It also, as this paper highlights and fitting with certain arguments within institutional sociology, highlights the power and politics flows within innovation activities and the linkages between the micro and macro social. At same time taking this approach also investigates and adds further to literature on how clinical research functions.

The theoretical starting point for this paper is beyond knowledge integration. There is a significant amount of literature on institutionalism and its impact on organisational function within firms and networks. Furthermore there is a body of literature on routines and practice and its benefit or problems created to the successful working of firms and partnerships. However, in both cases, this has not been considered through the lens of clinical trials yet. Another literature (medical anthropology and science studies) has however highlighted the role of routines and practices on clinical research and the impact it has on work functioning. This paper attempts, via micro level case study analysis, to bring these together and say something new about clinical research and clinical trials in developing countries. In so doing it questions the legitimacy of IAVI’s gap filling role at this level.

The paper discusses these issues by first introducing the cultures that predominate within IAVI’s New York office and the potential ‘cultural nightmare’ that is created and needs managing. To simplify the discussion we split these cultures crudely and broadly

\(^1\) By culture we refer to the work of Geertz and Schultz. Geertz defines culture as “a historically transmitted pattern of meaning embodied in symbols, a system of inherited conceptions expressed in symbolic form by means of which men [sic] communicate, perpetuate and develop their knowledge about and attitudes towards life” (Geertz, 1973, p. 89). Schultz discusses studying culture within organizations in this way. He writes, “Opposed to the study of both formal and informal organizational behavior, a cultural way of studying organizations is to study the meaning of organizational behavior – or, more specifically, the meanings and beliefs which members of organizations assign to organizational behavior and how these assigned meanings influence the ways in which they behave themselves” (Schultz, 1995, p. 55)
into two sets of alternative ‘cultures’ based at one end of a spectrum around an emphasis on the business of vaccine science and at the other the needs and role of IAVI as an international development organisation. The paper then discusses the way a number of storylines dominate ways of acting within IAVI’s clinical trial research partners in Kenya play out mirroring the issues at the heart of the competing cultures dominating within the IAVI New York Office. The paper concludes by questioning the degree to which this mirroring highlights a dominance of and introduction of IAVI’s cultures into the Kenyan setting and the implications that the findings have on IAVI’s gap filling activities.

The tree hugger, the sandal wearer and the pinstripe suit: a “cultural nightmare”

The offices of IAVI on first impressions are those of a non-governmental organisation rather than a pharmaceutical or biotechnology company. There is no glass and steel but a prominence of soft creams, African prints while glossy pictures of smiling children adorn the walls. Yet IAVI often portrays itself within the AIDS vaccine development and the global health arenas as a ‘virtual pharmaceutical company’. IAVI is based on what could be termed an international development or global health mission of finding and making accessible an effective and affordable AIDS vaccine but increasingly attempts to work using the same methods and processes, particularly in relation to its research and development activities, in the way a pharmaceutical company would (Chataway et al, 2007). IAVI manages these competing demands through a very effective communications strategy (Chataway and Smith, 2005; 2007).

IAVI is the name used to describe both the not-for-profit organisation set up in New York in 1996 and the wider network of partners that IAVI as a not-for-profit (NFP) works with. This wider network is often referred to as a public-private product development partnership (PDP). Based on our interview data and reviewing various grey literature, we have observed how IAVI (the NFP) is made up of several different types of individual. These individuals highlight the difficult balancing act IAVI has to maintain between its origins as a NFP and its need to work using the similar mechanisms of the pharmaceutical company.

These different groups of personnel were described by various individuals within IAVI as the ‘tree huggers of policy’ and the mission oriented scientists with 1960s enthusiasm and dress sense (described by one interviewee as ‘sandal wearing’) while we have added to this, based on our ethnographic observations and analysis of the interview data, the business minded, pinstripe suit wearing pharmaceutical company executive. This makes for a “cultural nightmare” IAVI’s Chief Operating Officer told us when trying to keep all demands from individuals in check.

What is interesting about being able to identify these different individuals is that they provide a physical image against which to visualise competing cultures or ideas and beliefs that can be found within IAVI as a NFP, and as we shall discuss later its partner organisations within the wider IAVI PDP. These individually held beliefs influence and impact the way IAVI conducts its activities, the staff it recruits and the vision of itself gained by others as well was the internal dynamics of the relations between staff and departments in the organisation and the wider NFP.

Thus, IAVI is made up of the ‘tree-huggers of policy’ as used by one interviewee to describe those who come from the NFP sector. These individuals tend to work in
departments of IAVI that are not on a day to day basis involved in the scientific issues – the research and development work – of IAVI but the policy, advocacy and what is referred to as the ‘country and regional programs’ (CRP) department which has oversight of developing country programmes including advocacy and vaccine preparedness activities.

There is also an emphasis on the mission of IAVI, particularly by the scientist members of the IAVI team. A relatively small number of scientists are involved in AIDS vaccine related work; it is also quite a close knit community where people have worked in the same organisations with each other over time, moved on to new places and still encountered the same people. There is an impression given in the grey literature developed in the run up to IAVI’s 10th anniversary celebrations where senior staff members and key members of the AIDS vaccine community outside IAVI were interviewed, that particularly the senior scientists at IAVI were sustained by their ‘passion for the fight’. They were still working within the 1960s framework of public sector science where the greater scientific good prevailed over secrecy and rivalry; the idea of ‘collegiate science’ dominates the minds of sandal wearing scientists. The emphasis was on altruism of the scientific cause rather than on award and glory particularly relating to publishing demands.

However, in recent years IAVI has become much more aware of the need for a business approach to science and its operations more generally. The type of staff employed over its 10 years existence has changed over time and there has been a relatively recent influx of what could be termed ‘the pinstriped suit brigade’ who place intellectual property, efficiency and industrial methods of working as primary. Business style language has come to dominate discussions of IAVI. Thus as one member of the business development team of IAVI told us that as IAVI staff initially ‘only came from academia or NFP’ worlds they ‘won’t understand the importance of IP’. The business type approach is also evident in the way IAVI portrays itself to the outside world. IAVI’s Chief Executive Officer who is a physician who has worked in developing countries and global health advocacy talks of IAVI as being a ‘virtual pharmaceutical company’ or it working as ‘the private sector with a public sector soul’.

The result is a ‘cultural nightmare’ that needs to be carefully managed to avoid high turnover of staff and a way of ‘sustaining the passion’ as one senior executive of IAVI put it in order to manage the tensions between those that are mission oriented (reducing the burden of HIV/AIDS through development and access to an effective and affordable vaccine) and those who see the scientific goal of an AIDS vaccine as primary and business models as the means to achieve this end. This complex situation can be partly explained by IAVI’s origins, its funding streams and its need to manage a diverse set of partners from a range of different sectors. In particular, it is also partly the result of trying to be an organisation that spans the whole value chain of product development from bench to bedside.

As already mentioned, IAVI was set up by Seth Berkeley, a physician with a background of working in developing countries who has become an advocacy practitioner for all AIDS vaccine related activity. Thus, as founder and CEO of IAVI, Seth Berkeley, was featured on the front cover of a 2000 edition of Newsweek magazine with the caption, ‘Can this man stop AIDS?’ Starting out in 1996 as an advocacy organisation, IAVI has moved further and further into conducting R&D bringing in house many activities.
(Chataway et al., 2007). However IAVI still sees its role very much as an advocate for the AIDS vaccine ‘fight’ more generally, and therefore places an emphasis on highlighting important policy questions related to the financing or eventual distribution of an AIDS vaccine through the work of its policy department as well as trying to focus the scientific agenda through the routine publication of its ‘Scientific Blueprint’ document that outlines the scientific view of the field and outlines recommended strategies for scientists to move forward. Its advocacy role does evoke criticism from other players in the field and, as we have highlighted here, there are also tensions within IAVI regarding these different roles that IAVI as a NFP entity plays.

The emphasis placed in advocacy and the role more generally an AIDS vaccine will play on the global health agenda is also related to the need to ‘appease’ its funders who are mostly bilateral donor agencies (particularly the UK’s Department for International Development) and philanthropic organisations (particularly the Bill and Melinda Gates Foundation). Thus its funding is not structured in the same way as a pharmaceutical company based on shareholders or similar to a biotech company which often rely on venture capital investment. Yet at the same time, IAVI works with a number of pharmaceutical and biotechnology companies and scientific groups from academia who place an emphasis on the primacy of science. IAVI, the NFP, has to manage the expectations and demands of these various partners that make up the PDP known also as IAVI. There has also in the past been the need to manage a further set of expectations. These are the expectations of the developing country based research organisations who have partnered with IAVI, the NFP, in order to conduct clinical trials of promising AIDS vaccine candidates. We will discuss this specific relationship between IAVI and developing country research organisations in more depth below.

These competing agendas both from external influences on IAVI as well as different staff backgrounds results in an array of ideas and beliefs which often compete with each other. Very crudely these can be placed at various places along a spectrum with what can be termed the extreme corporate business and science driven culture at one end and an equally extreme NGO/ donor international development NFP culture at the other (see figure 1).

Figure 1 – spectrum of competing cultures

![Spectrum of Competing Cultures](image-url)
One mechanism that IAVI and individuals within IAVI use to manage these competing cultures is to actually to keep them separate when thinking about how work takes place. For example when investigating the set up of the CRP department we found that it was awarded a separate grant – unrelated to the R&D work of IAVI – that was principally for IAVI to conduct vaccine preparedness activities in a number of developing countries where clinical trials were likely to take place or had already taken place. There was acknowledgement by CRP staff of the difficulty for scientists to understand the need for CRP, particularly the preparation work needed in order to establish a viable clinical trial site. Overtime, as the CRP department has established itself and understanding has been gained between the different individuals and cultures involved, we were informed that an ‘integration model’ had developed that linked both the demands of CRP work with those of the R&D department within IAVI, the NFP. There was now established understanding that vaccine preparedness was crucial in advance of clinical trials to take place. Unfortunately, due to difficulties within AIDS vaccine science over the last year (c.f. Kaiser, 2008), there has been a return to more upstream models of work which emphasize the importance of lab based research, questioning the status of more late stage vaccine candidates. This will have implications on the role, function and more importantly emphasis on and ‘power’ of clinical research and trial activities over the coming years within IAVI.

IAVI’s senior staff argue that its ability to work with the competing tensions – to harness them – is part of the reason for IAVI’s success. Speaking to the COO and the Senior VP of R&D about this, they argued that IAVI’s success was due to their ability to ‘marry pharma and developing country perspectives’:

COO: ‘IAVI showed the way to do clinical trials. Political and social relations are the basis of running clinical trials, and not a by product.

VP: Yes, this is not the approach that a pharmaceutical company would necessarily have. They are enabling. It is a similar thing with the public policy department, the policy agenda gives us a better foundation for our activities. Doing clinical trials is more than shooting in and then out of a country... We want to be able to take decisions as Merck, but in a smaller organisation. We started with an extramural approach to vaccine development, where we were supposed to be the glue and provide some project management. But then we found out that there are things that can done more efficiently if they are done inside [of IAVI].”

However, this is not the view taken by a number of other actors within the AIDS vaccine field. Those on the outside of IAVI the NFP and its wider PDP, view IAVI’s attempts at ‘taming’ and utilising the two competing cultures (and in turn its competing roles) as being a reason for its own lack of success and suspicion granted it by others. Thus, one European AIDS vaccine researcher we spoke to highlighted how IAVI is often seen more as a result of the political issues that it ‘throws around the arena’ rather than the scientific weight it carries placing it more within the political lobby around the controversy and demand for an AIDS vaccine than within the scientific lobby. While a top scientist at the NIH working on AIDS vaccine development told us that IAVI was unable to be seen as neutral because it has this split personality. It can not be seen to speak for the ‘advocacy’ field because of its emphasis one science but in the same way it is unable to speak effectively for the scientific community because of its advocacy work as well.
These competing cultures and storylines can be found within other PDPs which work on different global health diseases. Preliminary research by colleagues at Innogen highlights that the Malaria Vaccine Initiative (MVI) similarly has to balance the dominating international development and global health culture that determined its origins within a larger NGO, PATH, with the business culture and demands of its industrial partner, GSK. This is highlighted in the published work of PATH’s CEO (c.f. Elias, 2006). Interviewees within IAVI also acknowledged that other PDPs were fighting similar battles internally. When discussing the ‘IAVI model’ and the change from an advocacy organisation to one in which milestones, project management and more specific R&D roles were developed in recent years, IAVI’s COO pointed out that the International Partnership on Microbicides (IPM) was also similar to IAVI in this approach but that it was still more similar to industry, even talking of ‘outsourcing’ of work activities.

‘Culture’ influencing organisational activity: IAVI’s developing country activities as an example

From the above we can see that IAVI has a number of competing cultures which have determined the way it has functioned, grown and is perceived by individuals working inside and external to IAVI. Diane Vaughan (1996) has highlighted similar findings in her disaster studies work looking at the Challenger explosion. She argues that culture becomes a medium through which institutional values and beliefs are conveyed, enabled and reproduced but that also people are carriers of culture, enabling the institutional environment to penetrate organisational settings. Vaughan writes that globally dominant organising beliefs and practice (or ‘institutional logics’ to use a term that DiMaggio (1997) developed) originate “in the environment (professions; industries; American society)” but are in turn affected by “practical activity” and are “reproduced in the course of that activity.” (Vaughan, 2002: 26). Thus she uses the example of NASA engineers whose institutional logic of professionalism created cultural beliefs regarding the cost/safety trade-offs in their everyday work routines. Both the institutional logic of professionalism and the related cultural belief regarding cost/safety tradeoffs were mutually reinforcing to each other. This is similar for example to the way culture and activity interacts in the way the CRP department in IAVI was developed. The social setting can reproduce collective beliefs to greater or lesser extents and different organisations vary in the degree of institutionalisation of these beliefs that takes place.

Following on from this and as will be outlined in more depth below, we can see the different cultures impacting on and reproducing within a variety of different arenas outside of the IAVI New York office. As has already been highlighted, there is recognition within the wider AIDS vaccine community of this tension between competing cultures. This paper is interested in highlighting how these cultures are reproduced and reinforced through the work of IAVI within the environment at which it works in developing countries. This argument builds on the concept of ‘institutional isomorphism’ (DiMaggio and Powell, 1983) or the forces that result in the creation of similarities between organisations due to need for resources, few alternatives and these where success is.

Thus as we will highlight next IAVI’s activities at NY level impact on the role and function of its partners in developing countries and in particular the storylines that prevail which in turn impact the way activities take place. These tensions between different cultures are played out and reinforced by similar storylines at various levels of the PDP and within...
IAVI, the NFP, as we shall discuss in the next section below. A storyline (c.f. Hajer, 1997) refers to ‘ways of explaining’ situations. Similar to the concept of rhetoric, metaphor or narrative, it is the idea of the creation of overarching notions that people identify with, contribute to, and use to bring others together towards a common understanding. These operational level mirror and, are influenced by, the overarching cultures that abound within the IAVI partnership. As we shall discuss below, there are a number of operational level storylines related to the way clinical research takes place in developing countries that relate to the relationship between clinical research activities, healthcare provision and capacity building. The discussion of these storylines are nuanced but can to some extent be simplified along the lines of the competing cultures dominating within IAVI at the NY level but also in the regional offices of IAVI.

We investigated this by conducting a micro-level study of IAVI’s activities in Kenya, particularly its partnership activities with two clinical trial sites. One member of our research team conducted a sustained period of fieldwork over 3 months in order to collect primary data in this respect. During this time, Hanlin conducted interviews with key personnel working in the two main research organisations contracted by IAVI to conduct AIDS vaccine clinical trials and related clinical research: KEMRI and KAVI together with intensive periods of observation of activities within the trial sites. This involved time spent ‘hanging around’ (Bernard, 2006; Massey, 1998) the research organisations, watching what was happening, having informal discussions with staff and generally observing what was going on. All of this fieldwork was then later followed up with further interviews both in person and by phone. Data collected in the form of interview transcripts and fieldnotes were analysed using a form of grounded theory approach whereby prominent themes are drawn out from the data and used as a framework around which coding of all data sources then took place. The development of the thematic framework highlighted the existence of these competing storylines and their relationship to the competing cultures found to exist within IAVI’s head quarters in New York.

By way of background information on this micro level case study we shall briefly introduce the partnerships in Kenya that were studies. IAVI started partnerships with developing country research institutions in the late 1990s when it funded the first African based clinical trial of an AIDS vaccine candidate in Kenya. Since then it has opened regional offices in three regions of the world to enable it to more effectively coordinate its activities in developing countries and has partnerships with several developing country based research organisations. Different developing country research organisations have different contractual relationships with IAVI even when they are based in the same country. Therefore for some, such as the Kenyan Medical Research Institute’s (KEMRI) Kilifi Centre, are contracted by IAVI to conduct a specific clinical research activity. Others, such as the Kenyan AIDS Vaccine Initiative (KAVI), are contracted through a longer term negotiated arrangement whereby IAVI supports the research centre in its entirety (staffing, overheads, consumables) for a set period of time (in this case, five years). In both cases however, there is recognition that while both sides talk of ‘partnership’ IAVI has contracted the research centres to complete a series of pieces of work for them (various clinical research trials). The different contracts relate to the different levels of support each centre needs based on the initial levels of expertise and equipment existing within the centre.
The cultures prevailing within IAVI’s New York office were found to influence discussions – storylines – at developing country level and the clinical trial activities that took place within them funded by IAVI through the research centres. The tension between cultures plays out in two different storylines found to co-exist within the partner organisation in Kenya that were studied. These tensions between cultures, mirroring the cultures found within the New York office headquarters between the business science culture on the one hand and the international development dominated culture on the other, were found to play out around storylines in Kenya referring to the issues of:

a. Ethics, the relationship between and relative emphasis placed on research over healthcare and;

b. Short term vs. long term capacity building

In particular, the storylines revolved around a difficulty of emphasising healthcare provision activities with research activities and associated capacity building questions within the constraints of existing research and ethical review guidelines developed within Kenya for AIDS vaccine clinical trials. This is related to a shift in the focus of national level health research activities towards the ethics and regulation of clinical trials and capacity building activities. These storylines mirror the tensions evidenced within IAVI’s New York office. The internal tensions (see Figure 1) around the emphasis on the science of vaccine development over questions of sustainability of activities within developing countries that exist between the prominent ‘business’ orientated culture and the ‘international development’ orientated culture within the New York office are mirrored in questions – the storylines – that dominate within the activities of IAVI’s contracted clinical research organisations and its wider arenas within Kenya.

This set of storylines revolves around the difficulty acknowledged with separating clinical trial research activities and healthcare activities. In the discussions and observations our researcher made during visits to Kenya she was struck by the attempts made to separate discussions and activity of clinical research and healthcare provision alongside the difficult reality of actually doing so. The starkest example of this was highlighted by the physical inability to split research and care activities despite attempts in some places to try to make them separate entities.

For example, when our researcher visited KEMRI’s site in Kilifi she was struck by the physical positioning of the research buildings with the district hospital. KEMRI’s buildings were hidden from the main town by the brow of a hill and a high wall when you got to the top of the hill. The buildings themselves were new and shiny, in her field notes she wrote of it looking like a spaceship totally out of place with the bush scrub landscape and wet, pot-holed town beside it. Most interesting was the way it was connected physically with the district hospital; by a number of covered walkways all on a downward slope that led from various exits from the research buildings to different sections of the hospital. The walkways all took you through a gate (guarded) in the wall that separated the two sections of the site (research from care). Similarly, KAVI is located within the university buildings linked by a walkway to the main Kenyatta National Hospital building on a hill above the centre of Nairobi.

What is interesting about these descriptions is that they highlight the physical linkage between research and care activities which are so often seen as separate (Elston, 1997). Mary Elston talks about the physical separation between University College London and University College Hospital above ground but underground a number of
tunnels join the two together. The Kangemi and Mtwapa sites involved in IAVI work are however different with research and care activities taking place in the same compounds, sometimes in the same buildings.

It is unsurprising perhaps that these two sites are the flagships for the design of future research sites by IAVI as they show the physical marrying of both activities. Unfortunately at none of the sites was there agreement that the perfect relationship between research and care existed and our researcher was never able to find out what a 'perfect' balance of research and care should be in relation to these sites, although more recently there have been papers (Fitzgerald and Wassuna, 2005; Weijer and LeBlanc, 2006) written and a session at the 2007 International AIDS Society conference that have tried to discuss this relationship more generically. IAVI itself has also started to address this issue (Berkley, 2003) and has published treatment and care guidelines on its website (www.iavi.org) in 2007.

In particular there appeared to be a variety of different attitudes and opinions dominating within the IAVI partnership regarding the degree to which an emphasis should be placed on care activities and their integration of research activities with existing local healthcare facilities.

Researchers struggled with the idea that capacity building was not part of their activities – they were there to do research only. Discussions with those at KEMRI in particular highlighted that this was not uncommon. Researchers talked about various colleagues who placed research and its results first and foremost in their activities. This echoes the New York IAVI office tensions between what we termed earlier the ‘business culture’ and the ‘international development culture’. It is possible to find such comments outside of the AIDS vaccine field too. For example, in the New Scientist in 2006 in relation to malaria research a scientist is quoted as saying “Our clinics cannot replace a failing public health system... We’re here to do research” (New Scientist, 2006).

A more pragmatic response our researcher received was that care was only provided because they needed somewhere to do the research and this was inside a care facility. Examples of such facilities were the CCRC in Kilifi District Hospital and Kangemi health facility. As such, the care activities were seen by some interviewees talked to as simply a 'by-product' of the research activities. So for example the IAVI manager saw care provision as a part of the research process; being seen as a necessary part of what doing research entails:

“I would say that we, our primary mandate is scientific research. I believe that there are elements of health care provision that go along with that scientific research and to the degree that health care provision is necessitated by the scientific research we provide it. I think, it is something we are talking about a lot here and I think it's really important for the organisation to be very clear in terms of what their objectives are. I think especially when they work in research work in a resource-poor environment.” [IAVI6; emphasis added]

In a similar tone, over half the people our researcher spoke to (from not only within the research sites but also in the policy arena and IAVI itself) saw the need to offer referral pathways for the provision of follow on healthcare as being necessary on practical grounds. One reason given was that it was felt that the facilities at the research sites did not have the resources, particularly the personnel needed to conduct healthcare
provision activities. Related to this was the demand for care services from the local community who often saw the research sites as health care provision facilities.

More often than not however, our researcher was given a moral argument regarding the need for IAVI research sites to become involved in care provision; sentiments such as the trial sites “can’t not do it”. The argument was that IAVI’s research activities implied a duty of care because some IAVI studies involve HIV positive cohorts. This was reinforced by an attitude that positive changes were being made with vaccine literacy work around the trial sites towards attitudes, knowledge and practices towards HIV/AIDS. This was linked to an IAVI led argument that facilitating support of local healthcare provision and referrals should enhance community awareness and understanding regarding the AIDS vaccine research work. In particular, IAVI stressed the development of integrated approaches that moved away from the trial sites providing treatment and care directly to HIV positive trial participants and screen outs. The focus was on working together to build up local healthcare facilities to provide VCT, ARVs and general healthcare services. Thus the IAVI manager highlighted that there was a personal imperative to the issue – a moral stance needed to be taken such that you “can’t not do it”:

“It’s good for the community, it’s the right thing to do. But is it the right thing for IAVI to do and where do you put the boundaries on it? Myself, informed by the organisation’s overall objectives, the way I define it is that IAVI is bound to provide health care services for individuals who participate in our trials, I think that in terms of individuals who come forward to participate in trials who screen out if they’re HIV tested, we’re bound to provide either health care or a fast referral pathway that is beyond just a blank sheet of paper that we don’t know where to go with it or whether or not they use it. We need to be sure that there are other referral pathways that people are using. I think that’s sort of, the first is absolute. The second is one of the most important, the screen outs, in terms of IAVI’s objectives, are the second, in order of importance. People always say people deserve health care because they’re people, not because they participate in trials. And that’s exactly right.” [IAVI6; emphasis added]

However, a number of actors from a variety of different perspectives (clinical research, IAVI and government) clarified their positions by acknowledging that at some point a distinction had to be made between what was necessary care support for research activities and what should be left to the healthcare domain more generally. This is also reflected in IAVI research site policy whereby clinical care is provided to trial participants and not to their dependents and also relates to decisions within IAVI to work with local healthcare providers to improve care provision more generally to allow for robust referral pathways that reduce the strain on IAVI clinical research sites to become equivalent care provision centres. This was usually couched in terms of resource allocation as per the comments of the IAVI manager spoken to:

“But for an organisation with limited funding and a research mandate, again, where do you put those boundaries? I mean, KAVI is in Nairobi so where are the boundaries? Screen outs, family of volunteers and then the third is the rest of that overall community. So in a place like Kangemi where there are very key services provided in site, the primary service provider is the Nairobi City Council. IAVI’s objectives are to provide services for our volunteers, but we have a limited amount of staff at those trial sites and in such a resource poor setting and such a poor population… Boy, out there, there are huge… and people are not well and they have a lot of needs. They would swamp the research if you include the screen outs in terms of the number of individuals that are providing… So
what IAVI’s objectives are is to build up the capacity of the Nairobi City Council to be able to accommodate those you screen out. I mean, because they are HIV positive or because they have other health care issues.” [IAVI6; emphasis added]

Thus discussions and observations during fieldwork presented us with a variety of different attitudes towards the ethics of clinical research that have created an alternative set of storylines about what is important for the day-to-day operational activities of the partnership in a developing country such as Kenya. These storylines in turn impacted the way activities took place within the CT sites. In particular they were found to be acted out through the way clinical trials and research took place via the routines and standard operating procedures (SOPs) that were introduced, in particular relating to the type of healthcare provision that was provided. They also were acted out through the type of training protocols that were put in place, specifying the type of capacity building that took place.

Thus, as outlined above, trial SOPs regulated the type of healthcare provision that would be provided. Often improving healthcare provision was a by product of the trial activities. Therefore, it has been successful in terms of strengthening the linkages between research and healthcare – in a way that pertains to the current emphasis on research ethics – as outlined in this quote below from a hospital manager:

“It has been successful lets say because of the linkages between the research component and the care component. And the research component actually is more interested in identifying (depending on which research they are doing) it’s more geared towards prevention. So, for a public health concern, that comes in handy. And two, there are some research protocols that’s related more in picking the HIV negative and the HIV positive. But in the course of so doing then we find that patients who are identified as HIV positive are actually enrolled into the care programme. So the integration is good at that level. Then, number two, at the level of the clinic, there is also very good element of integration in terms of personnel, although this is not constant, it keeps on changing, and that’s something that we need to iron-out to ensure that care and research run smoothly.” [Policy11]

However, the desire to conduct good research and the idea that research activities should remain paramount often resulted in care provision being seen as an added extra rather than as a first and foremost necessity. As outlined above, there was an attitude that the sites were clinical research sites first and healthcare facilities second.

Secondly, training protocols specified the type of internal capacity building that took place. The main points that are pertinent to this discussion are as follows:

1. There was an emphasis on staff capacity building that related to trial protocols

Just as there was a division amongst staff regarding the degree of healthcare that was essential provision within the research setting, so too was there a division amongst staff regarding the degree to which IAVI’s activities should be seen to have a capacity building element to them regarding staff development. There was a divide between attitudes regarding the simple need to just provide grounding in the research skills that were needed for a trial being undertaken over longer term capabilities building that would enable the research site to become sustainable and self-sustaining in the long term.
2. Skills training revolved around Good Clinical and Laboratory Practice training

The result was that an emphasis was more often than not placed on training relating to ensuring competence in routines and standard procedures that were needed for specific trials. Often this was emphasised as being the result of budgetary restraints (‘we have a limited budget and need to focus on our end point, what’s needed to get a vaccine out’). However, it was also recognised that different staff capabilities were needed and this changed the type of training that was required. For example, in terms of laboratory staff, one lab director we spoke to said:

“…technicians too have to have lots of different backgrounds. Quality Assurance skills are the most important (if they want to do PhD this isn’t the place for them). Technicians are almost 9-5 and its all about doing the same thing every day and just doing it better. Clinical research is inquisitive versus clinical trials which is 9-5, disciplined and attention to QA [quality assurance] and QC [quality control]. Clinical research is more post-doc heavy under a team leader. Physically the two teams are in two different areas but want them to think about themselves as one team but really they are two different breeds of animal.”

The rote nature of a lot of clinical trial research in developing countries – the need to focus on SOP compliance and not deviate from the norm – meant that at times our researcher in Kenya heard similar arguments from personnel she spoke to about clinical trial research.

3. Long term issues created

The question of sustainability of research sites links to wider national health research capabilities issues. There is a widespread ongoing discussion regarding the degree to which PDPs such as IAVI link into existing healthcare and science based infrastructures (Elias, 2006; Makgoba and Tucker, 2008). IAVI appears to be aware of this and increasingly it talks openly in its literature of its capacity building activities, however, the tension within the organisation appears to remain as discussed above.

Discussion: Studying culture within micro level ‘sites of contestation’

These alternative storylines outlined in this micro level case study highlight a number of questions that relate to the way culture and organisations are often studied and thought of. These storylines highlight a difference of opinion between staff and alternative ways activities and training took place within the clinical research sites in Kenya. These mirror issues at the heart of tensions between cultures within IAVI, the NFP (see Figure 1). The question raised by this is whether they really represent an example of where cultures from within IAVI the NFP have come to dominate within its partner organisations in Kenya? Or to put it another way, is this a case of ‘institutional isomorphism’? To answer these questions we need to consider the interrelationship between the macro and micro levels, the relationship between organisations and institutional logics and power and politics flows. If there is an issue of replicating cultures, this micro level study then raises questions on the way clinical trials themselves are conducted in developing countries particularly relating to issues of sustainability of clinical research capabilities. These issues will now be discussed by way of a concluding section, raising questions for further research and attention in the last year of our project.

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The relationship between the macro and micro

Questions about how the macro environment affects and determines what happens at the meso (organisational) and micro (individual) level have been asked by those from within science studies in terms of the interrelatedness between these different levels and, in particular, the relationship between the micro-social and the macro-social (Knorr-Certina and Cicourel, 1981; Latour, 2005). In particular, they ask does one influence the other? Does it occur as a result of a chain of events, up from the micro-level or down from the macro-level?

Similar questions have been raised by this case. In particular the case highlights the fact that there is a relationship between environmental processes (cultures) and organisational mechanisms; organisations do not occur in a vacuum (Vaughan, 1997). However, what has not been clearly defined until now – although alluded to within the paper – is the degree to which IAVI defines the context within which clinical research activities take place in Kenya. As we shall discuss in a moment, recently there have been questions raised to the degree to which IAVI as a partnership is really a form of ‘scientific imperialism’. As we have evidenced elsewhere (Chataway et al, 2007) IAVI by acting as a knowledge integrator and broker defines the way information flows through the partnership. For example in Chataway et al (2007) we discuss the role of the core materials of IAVI. These documents designed by IAVI New York staff become the mainstay of community mobilisation activities conducted by the clinical research sites in Kenya and are then tailored to meet individual country needs as determined by the staff in Kenya. However, the case of training of research site staff in Kenya and the issues of healthcare provision raised above highlight a more top-down process of management and decision-making. In these cases, IAVI as the NFP predominately determines what training takes place and the protocols for healthcare referral that clinical trial sites undertake.

The relationship between organisations and institutional logics

IAVI’s dominance of training protocols towards the needs of the clinical trial at the expense of long term capacity building for professional development of Kenyan staff highlights a high degree of institutionalisation within the partnership. Institutional sociologists have been said to see ‘routines and scripts, not norms and values,’ as ‘the source of macrostability’ (Vaughan, 2002: 26). Thus the argument goes: the greater the degree of institutionalisation, the greater the cultural persistence and the lack of resistance to change. Vaughan uses the example of air traffic controllers being dominated by conducting activities by rote and common sense as an example of where genuine innovation does not take place because of the degree of institutionalisation around a set of procedures dictating the way air traffic is guided. This importance on training so that one conducts activities by rote rather than promoting independent or group innovation is highlighted by the tension between different forms of capacity building emphasised within IAVI and more particularly within the research sites themselves.

In this way, routines and scripts are seen to create stability through the creation of formalised systems. However, as the micro level study of clinical trial research in Kenya highlights institutional logics held within organisations are impacted by external
environmental pressures and international social setting and action. Thus even when these internal institutional logics stress rote learning and replication of activities on a day to day basis, the ‘messy’ nature of life gets in the way and complicates matters. Vaughan calls this the ‘dark side of organisations’ that creates instability.

This argument is mirrored by a literature that has studied the workings of clinical research and clinical trials in more depth from a critical medical anthropology science studies inspired perspective. Thus Michael Berg has written about clinical research as focusing highly on forms of training such as Good Clinical Practice and its use as a protocol for guiding research activities as opportunities for standardising and guiding of processes to take place that provide opportunities for coordination and the creation of order out of ‘messiness’ (Berg, 1998). However, he goes on to argue that within the order, instability is created, as negotiation is required to ensure tools such as GCP procedures and protocols are taken up. As argued by Harper (2005), samples, equipment, data and volunteers do not always act as the protocols suggest they should, often resulting in unintended outcomes. This makes it is necessary for discussion to take place about the processes or activities undertaken and the data gained.

Power and politics flows

This raises questions over the power and influence that different actors hold within the clinical trial setting and more widely between IAVI and the clinical research organisations it works within countries like Kenya. Is IAVI supporting, even imposing, the right training regimes for clinical trial staff or to what degree are these decisions made within the clinical trial organisations themselves?

Such questions reflect the need for further discussion on the influence of institutional logics on the creation of sustainable research cultures and capabilities in developing countries. In particular, they raise the question of the extent to which ‘scientific imperialism’ (Makgoba and Tucker 2008) takes place. The idea previously discussed of Dimaggio and Powell’s concept of ‘institutional isomorphism’ fits well here and potentially provides a framework for discussing these issues further. To recap, this concept focuses on the creation of similarities between organisations due to need for resources, few alternatives and this is where success is. It may provide the basis on which we can investigate in more depth important questions regarding the chances for change in the role of developing country based research organisations and the value such change would bring. The assumption being that these organisations are ‘moulded’ into emphasising the same institutional logics as the Northern partner institution because they require the resources and success that partnering with IAVI can bring.

However, as Vaughan highlights, Friedland and Alford (1991) state that differences between institutional logics and their competition can precipitate change while the ‘nesting of institutional logics’ can have a stabilising effect. However, this also depends, she says, on the extent to which organisational settings allow for institutionalisation or rather how social settings effect the reproduction of collective beliefs. The implications for this discussion, is that up until now there has been an emphasis on the dominance of IAVI in ensuring the replication of its own competing institutional logics or cultures within the storylines and activities of the clinical research organisations in Kenya. In a Latourian sense there has been a case of ‘enrollment’ taking place here whereby the
dominant organisation has used key issues of quality of clinical research and the
dominance of scientific requirements to ensure the research organisations and their staff
take up the same competing cultures. However, this negates the fact that there are
potentially other issues – national issues affecting Kenya’s healthcare and science
system – that impact the way the clinical research organisations react to IAVI’s contract
work. Hanlin found during her fieldwork that the Kenyan research climate was
influenced by overriding public suspicions regarding clinical trial research (further
documented in the work of Geissler and Pool, 2006) and a competing tension within
national health policy circles regarding the need to place an emphasis on HIV/AIDS
treatment activities over prevention activities (under which AIDS vaccine research was
seen to come under).

Thus, what is interesting here is perhaps how the ‘conflicting cultures’ of IAVI are in a
certain sense ‘the same’ (science/research/business vs policy/advocacy) at the
headquarters level in New York and at the clinical trial sites, however they take a
somewhat different form. At the headquarters level they seem to be more an issue of
status, organizational independence and funding. However, at the clinical trial sites the
issues seem more linked to ethical debates over long-term benefits (deriving from
scientific research) against the immediate healthcare needs of a very poor population.

Clinical trials in developing countries

Linked to the last issue is the question of where next for clinical trials in developing
countries of AIDS vaccine research, particularly relating to the degree of sustainability
that is created around the clinical research sites futures. The main question then
becomes, ‘what happens when IAVI money runs out?’ This is a particularly relevant
question as the recent failures of high profile AIDS vaccine candidate trials has led to a
call for a return to the laboratory and a move away from clinical development activities by
those involved in AIDS vaccine research, including IAVI (as evidenced by IAVI’s recent
emphasis on its new Brooklyn laboratory). IAVI supports KAVI in its entirety for a five
year period based on its current contract but KEMRI is supported only in relation to the
clinical research studies IAVI contracts it to perform. There are obvious implications for
both centres in terms of staff job security but also wider issues created regarding the
countries level of scientific expertise in this area. This has been built up to a high level –
an international regarded level through the reporting of trial results on the international
conference scene and in publications – however the question remains, ‘what happens
after IAVI?’ Is there sufficient capacity within Kenya to absorb staff from the AIDS
vaccine research sites into other research areas (such as malaria vaccine work) or can
the centres themselves retain their identities towards AIDS vaccine drug trials and
research? In some respects because IAVI has placed an emphasis on the ‘gold
standard’ (Timmermans and Berg, 2003) of GCP training within clinical research, staff
and the centres themselves have a set of transferable skills, however, in other respects
AIDS vaccine clinical research is specific to the AIDS vaccine arena and the skills learnt
and used are less transferable. The implications of this are questions for a different
research project, however, they raise the overarching question regarding the implications
of IAVI’s gap filling role. IAVI may have been successful at gap filling on the
international AIDS vaccine research scene however, as a consequence of this, has it in
fact created new gaps within the developing countries in which it works such as Kenya;
creating a new capacity building gap?
References


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