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Saying ‘No’ to PrEP research in Malawi: what constitutes ‘failure’ in offshored HIV prevention research?

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Between 2004 and 2005, the first multi-sited clinical trial tested whether an existing, marketed antiretroviral drug, Tenofovir (TDF), could prevent HIV transmission. Referred to as pre-exposure prophylaxis (PrEP), most of these trial sites prematurely closed down. Two sites located in Cambodia and Cameroon received international media attention. But little attention was drawn to sites in Malawi and Nigeria, where university ethicists and research scientists extensively debated PrEP. This article focuses on events that took place in Malawi where there was a prolonged dispute over the scientific rationales of PrEP and not trial specific ethics referred to as ‘bioethics’. Specifically, the article discusses debates pertaining to three PrEP trial protocols that were refused ethics approval in Malawi between 2004 and 2009. It is argued that HIV science debates in Malawi are embedded in postcolonial politics – geopolitical histories and state and household economic dispossessions that have created the structural possibilities for Malawi to become an offshore destination for HIV clinical research. As such, ethics in this case does not pertain to trial or bioethical ‘failures’. Rather, ethics is located at the scale of imperial relations that give rise to multiple, often invisible, research concerns and constraints.

Keywords: AIDS Clinical trials; PrEP; failure; Malawi and Africa; ethics; imperialism

Introduction

Between 2004 and 2005, the first multi-sited clinical trial tested whether an existing, marketed antiretroviral drug, Tenofovir (TDF), could prevent HIV transmission. Known as pre-exposure prophylaxis (PrEP), several institutions formed partnerships to carry out the research.¹ Family Health International (referred to as FHI in this article, but it was renamed FHI360 in 2011), an international social marketing firm administered the trials. Gilead Sciences, the manufacturer, supplied Tenofovir medication and the Gates Foundation funded most research sites.² The trials were offshored to teaching hospitals and research institutions in Cambodia, Nigeria, Cameroon, Ghana, Thailand, and Malawi. Local HIV negative sex workers and injection drug users (in Thailand) were recruited as trial volunteers due to their perceived high-risk behavior. Most PrEP trials prematurely

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shut down for several reasons. Planned and ongoing trials in Cambodia, Cameroon, and Nigeria respectively ended within months of each other (Mills et al. 2005). Thailand and Ghana were the only sites that concluded the trial. Ghana had inconclusive results (L. Peterson et al. 2007) and Thailand showed promising results (Choopanya 2013) although it was hampered by claims of extreme ethical problems (Kaplan 2009; Jintarkanon 2005).

Two of these trial sites caught international attention – Cambodia and Cameroon (Chase 2005; Chippaux 2005; Grant et al. 2005; Jintarkanon 2005; Lange 2005). In Cambodia, a national sex workers' union, the Womyn's Network for Unity (WNU), made its complaints about the trial protocol clear in national and international press conferences (Forbes and Mudaliar 2009; Sandy 2012; see also Rosengarten and Michael 2009). The most important issue for WNU was side effects. Given their poor earning status and little access to health care, WNU members argued that any possible illness even over the short term could very quickly create hardship and economic instability for their families (Sandy 2012; Forbes and Mudaliar 2009). WNU asked the trial coordinators for 20–30 years of insurance that would cover trial-related illnesses if they were to participate (Forbes and Mudaliar 2009). While trial coordinators appeared to be sympathetic, the trial protocol was not modified to match these requests (Forbes and Mudaliar 2009).

In Cameroon, long-time AIDS activists also raised several similar concerns pertaining mostly to the protocol design. These concerns included the fact that protocol and informed consent documents were written only in English and not French (Cameroon's two official languages); female condoms were not included in the protocol; no provisions were made for the care of trial participants if they sero-converted during the trial; and there were no stipulations on future access to drugs if proven effective (Yomgne 2009). As in Cambodia, activists suggested modifications to the protocol to allay these concerns, which did not materialize. These issues were soon overshadowed by attention brought to the Cameroonian media's misconstrued portrayals of the trials (Yomgne 2009; Mack et al. 2010), which appeared while negotiations were taking place between activists and researchers. Subsequently, the governments of Cambodia and Cameroon shut down the trials. Official reasons for trial closures were not entirely clear in both cases.

Despite the contentious points raised about the research protocol and its design, local actors who raised concerns were consistently portrayed as unable to understand clinical science. Specifically, scientists outside these countries and working within international HIV prevention consortiums insisted that communities required more HIV science education. It was thought that once communities could better understand the principles of HIV clinical research, there would be no unnecessary failure to implement PrEP trials (Grant et al. 2005; Mills et al. 2005; UNAIDS 2007). Such communities were imagined to be AIDS activists and sex workers.

But in Malawi and Nigeria the communities that raised similar and more extended questions about these initial PrEP trials were university ethicists and research scientists. The contentions raised in both these countries received relatively little if any attention in the media and the international scientific literature (Chigwedere 2009; Ukpogong 2009). With this conspicuous absence, our research project endeavored to understand the debates in both these sites. In this article, we focus solely on events that took place in Malawi and analyze why two Malawian ethics committees – one national and constituent of the Ministry of Health, another based at the University of Malawi's College of Medicine – not only denied ethics approval for the planned PrEP study in 2005, but twice again in 2009.

Our ethnographic and archival work took place between 2005 and 2011. At international AIDS conferences and HIV research meetings, we conducted participant observation and interviewed members of international HIV prevention consortiums as well as

feminist activists who first coined the term, ‘microbicide’ – compounds used in the vagina or rectum that were tested for HIV prevention mostly during the 2000s. We interviewed scientists who conducted preclinical PrEP research in the 1990s as well as scientists and ethicists at relevant research institutions – those who designed protocols and those who implemented them at research sites. In Nigeria and Malawi, we interviewed trial workers, state and university ethicists, and trial volunteers. We also followed and analyzed extensive debates on microbicide and PrEP trials taking place on African listservs (see especially [NHVMAG, no date](#)). We conducted a total of 62 informal and formal open-ended semi-structured interviews over this period. Both Peterson and Folayan have worked together on HIV clinical research in Nigeria since 2004. Prior to this study, they both had established different professional connections in Malawi, which included colleagues working on ethics committees as well as those working in HIV prevention research. These connections facilitated access to the research site, including introductions to potential interviewees.³

In Malawi there was a prolonged debate over the scientific rationales of PrEP, which explicitly did not pertain to bioethics – a term used to analyze the standards of clinical practice. This debate circled around differences of opinion between Malawi-based primary investigators (the PIs) and scientists on the Malawi ethics committees (the ethicists). The PIs claimed that PrEP is a potential biomedical HIV prevention strategy that would have important national ramifications; and, as such, they argued that failing to implement an important and needed trial was a substantial setback for research in Malawi. However, the ethicists claimed that PrEP – as a future HIV prevention technology and not the trial itself – is a problematic contradiction to the country’s national HIV treatment policy that could worsen the national HIV problem.

It is argued that debates over PrEP science rationales in the Malawi case are embedded in postcolonial politics that have shaped the structural possibilities of scientific research in the African postcolony. The construct of *failure* has undergirded the arguments and analyses of offshored PrEP research in Malawi and elsewhere – that a trial failed to be implemented; that a national HIV policy could fail; that African publics failed to understand scientific research; or that international PrEP researchers failed to understand African concerns. However, our ethnographic research pointed to a different analytical scale of failure: it is impossible to delink considerations of PrEP as a future prevention technology to other larger issues that the interviewees identified, such as the national economy, research infrastructure and legacies, as well as global HIV prevention and treatment politics.

This article analyzes these points by first describing Malawi’s political and economic histories that created the circumstances for the country to become an offshore destination for HIV clinical research. We then link these contexts to Malawi’s history of state research regulation for which expertise and clinical capacities differently evolved to shape debates over scientific rationales. Second, we describe the three multi-sited PrEP trials that were denied IRB approval in Malawi, while all other sites throughout African and Asian countries gave IRB approval; and we draw on ethnographic fieldwork and interviews to detail the stakes. This article concludes by analyzing the implications of these debates: the concept of failure needs to expand beyond bioethical frames and clinical practices to also include the politics, research visions, structural conditions (Cohen 1999; Hamdy 2012) and especially imperial relations that have made HIV research contentious possible.

AIDS intersections: foreign funding, African economic crisis, and offshore clinical research

Malawi is a southern African country whose colonial and postcolonial history has framed the context of institutionalized medicine and clinical research. Under colonial Nyasaland (now Malawi), those seeking medical training and expertise travelled to medical schools in Northern Rhodesia (now Zambia) and Southern Rhodesia (now Zimbabwe) (Broadhead and Muula 2002). This education migration created a significant brain drain and, in response, the state of Malawi built a medical school – the College of Medicine at the University of Malawi – in the mid-1980s to ensure student retention and institutionalize scientific research (Broadhead and Muula 2002). These efforts required foreign funding and participation, which was obtained from British, West German, Australian, Dutch, and Malawian governments (Broadhead and Muula 2002). These early aid packages mark one of the first iterations of foreign-determined research agendas inside Malawian research institutes. For instance, the curriculum focus was determined by the funders and geared toward community based medicine, which was welcomed at the time and continues to be the foundation of Malawi's medical education (Broadhead and Muula 2002).

But by the early 1990s, foreign aid funding priorities began to change and subsidies for medical institutions were withdrawn (Broadhead and Muula 2002; Wendland 2010). These changes in foreign aid were influenced by politics emerging at the end of the Cold War such that Malawi and other Southern African countries were no longer viewed as needing to be coaxed against Soviet influence. Making matters worse, the repressive actions of the Kumuzu Banda regime (1961–1994) neglected the health and research sectors, leading to steady deterioration (Wendland 2010). Toward the end of his regime, AIDS was hitting Malawi very hard. By 2003, 14% of adults were living with HIV, making Malawi, along with other Southern African countries, the center of the global AIDS epidemic (see Craddock 2000; Kalipeni and Ghosh 2007; Watkins 2004). By the mid-1990s the economy worsened even further largely due to the implementation of the International Monetary Fund's structural adjustment program or SAP (Kalipeni 2004; Wendland 2010). SAPs installed throughout Africa mandated currency devaluation, the removal of public funds, and privatization of health services, which led to worker retrenchment, massive national debt, and tumultuous household poverty (Turshen 1999; Peterson 2014; Mkandawire and Soludo 1998). Malawi's national economy, based primarily on agriculture and a large labor migration into neighboring country mines, grew increasingly stressed. Kepilani (2004) describes how a radical withdrawal of state funds from the public sector, made it extraordinarily difficult for Malawian health and research institutions to be funded and to function (see also Wendland 2010).

As the AIDS crisis and the impoverishment that came with structural adjustment converged, foreign funding to scattered HIV/AIDS non-governmental organizations began to be administered. Such funding haphazardly supported the provision of some health care services that broken health care systems could no longer address (Benton 2015; Nguyen 2010; Smith 2014). Over time, AIDS interventions were justified via discourses that articulated the urgent and growing humanitarian crisis as a predicament of African governments' inability to manage increasing HIV infections. As Vinh-Kim Nguyen (2009) points out, the establishment and scaling up of massive AIDS intervention programs created a paradigm for which entire populations were standardized and targeted for AIDS interventions. He argues that this 'humanitarian assemblage of populations constitutes a global biopolitical laboratory that allows a full range of novel technologies (ranging from

highly individualized biomedical interventions to policies to juridical systems) to be “trialed”...’ (Nguyen 2009, 213).

Following Nguyen’s argument, we concur that PrEP was a significant component of these HIV prevention and intervention logics. As early as 1995, activists, scholars and policy makers working at the intersections of gender and development advocated for novel biomedical HIV prevention research geared toward protecting and empowering women who were disproportionately affected by the epidemic (Heise and Elias 1995; Forbes 2013). The urgency of this gender-based advocacy inadvertently mapped onto the globalization of clinical trials. The tremendous expansion of clinical molecules (made available via technological advances in combinatorial chemistry) were outsourced to the private sector as well as offshored to countries outside of high earning pharmaceutical markets (Fisher 2009; Petryna 2009; Sunder Rajan 2012). This increased clinical trial activity is directly connected to the brand-name pharmaceutical industry’s strategy of expanding pharmaceutical uses and their markets (Dumit 2012). The strategy to sustain market share includes treating chronic diseases (Dumit 2012) such as HIV as well as expanding the use of anti-AIDS drugs, which includes PrEP.⁴

In light of these convergences between the dispossession of African research infrastructures, HIV gendered urgencies, and the exponential increase of clinical trials, Malawi became a desirable destination to host trials as well as to draw on a population of volunteers to carry out clinical research. As a funding gap for medical research and training emerged, institutions in the US (and other countries) stepped in to draw on Malawi’s existing scientific expertise as well as partner with the country’s medical and research facilities. But unlike Malawi’s earlier history, the research institutions did not establish agendas that focused on community-based health. In fact, the country does not have an actual strategic plan geared toward research that addresses national health priorities (Kirigia et al. 2015). Rather, foreign partners established and financed more or less permanent institutions that mostly fund high priority global health research (Muula and Mfutso-Bengo 2007). That is, ‘(m)uch of the research on human subjects in Malawi is in the discipline of infectious diseases, mostly tuberculosis, HIV and AIDS, other sexually transmitted infections, and malaria. Research on non-communicable diseases such as diabetes, hypertension and cancer is almost non-existent’ (Muula and Mfutso-Bengo 2007:35).

Two major Malawi-based US institutions are noteworthy because they were involved in the PrEP trials. The first is the University of North Carolina (UNC) Project–Malawi, which has been collaborating with the Ministry of Health since 1990. It is based at the Kamuzu Central Hospital campus in Lilongwe and employs over 250 research scientists and medical personnel (University of North Carolina Project-Malawi no date). The second is John Hopkins University’s Bloomberg School of Public Health, which partners with the College of Medicine, University of Malawi and the Ministry of Health. This collaboration began in 1988 and focuses primarily on HIV transmission research (Malawi College of Medicine-Johns Hopkins University Research Project, no date).⁵ It is based in the city of Blantyre and employs over 200 staff members that include researchers, nurses, clinicians, and laboratory personnel (Malawi College of Medicine-Johns Hopkins University Research Project, no date).⁶

HIV research projects directed by Family Health International as well as worldwide consortiums including the Microbicides Trial Network and the HIV Prevention Trials Network (HPTN) were designed to ‘evaluate new HIV prevention interventions and strategies in populations and geographical regions that bear a disproportionate burden of infection’ (HPTN no date). The Blantyre and Lilongwe research centers have hosted each of these Networks’ trials in the past. The partnerships must interface with existing

Malawian research regulatory bodies, which became the central locale for debates over PrEP in Malawi.

Offshore research encounters and Malawian national research regulation

Research regulation in Malawi began in 1974 when the National Research Council of Malawi was established by Presidential decree (Ndebele and Mfutso-Bengo 2007). The National Commission on Science and Technology (NCST) was also constituted at that time to promote and regulate research in Malawi (NCST no date). Between 1974 and 1994, the NCST reviewed all protocols for research implementation in Malawi. In 1994, the research protocol review was decentralized to the specific ministry of concern (such as agriculture and engineering) with the exception of health research because of its 'sensitive nature' (Muula and Mfutso-Bengo 2007). Health research involves the recruitment of human participants and therefore requires more detailed scrutiny and review. The National Health Science Research Committee (NHSRC) was then constituted by the NCST to review research protocols on its behalf (NCST no date). The NCST continued to provide oversight function to NHSRC. In this capacity, according to our interviewees on the ethics committees, it has the power to play the role of an arbitrator when disputes over research protocols arise between the ethics committee and researchers.

In 1991, the University of Malawi College of Medicine was established. Initially, research protocols that emanated from this medical school was reviewed by the NHSRC until 1997 when a new Institutional Review Board (IRB) – the College of Medicine Research and Ethics Committee (COMREC) – was established in the medical school (Muula and Mfutso-Bengo 2007). Two members of COMREC sit on the NHSRC committee and two members of the NHSRC sit on the COMREC committee (COMREC no date). The membership overlap was established to allow for a functional interaction between the university and national research regulatory organs. These two ethics committees are expected not only to review health-related research protocols, but also to monitor their implementation (COMREC no date).

We were informed by several interviewees that the collaboration between these two IRBs had worked well in the past, but foreign PrEP protocols submissions brought unprecedented confusions and tensions to light. Specifically, COMREC's mandate is to review research proposals that originate from the Medical School (Muula and Mfutso-Bengo 2007). However, this committee refers all clinical studies of 'national interest' and those with political sensitivity to the NHSRC; examples of national interest studies can include vaccine trials, drug trials, stem cell research, genetic studies, and national surveys (Ndebele and Mfutso-Bengo 2007). According to a member of the National Commission for Science and Technology, most research may constitute 'national interest' but there are additional concerns regarding health and safety. That is, if anything 'goes wrong,' as he put it, a federal agency that approves a protocol puts responsibility on the government rather than the research institution. If a study is deemed of national interest, then a special committee comprising members of both ethics review boards is set up to review protocols (Ndebele and Mfutso-Bengo 2007).

With the arrival of PrEP, a number of unprecedented disputes emerged that were couched within a seemingly peculiar dichotomy that is elaborated upon below: the enrichment of Malawian national research versus the integrity of HIV national policies. These disputes can be linked to Malawi's political history for which clinical, medical, and research institutions have been tied to foreign funding, which has had two effects. One is that foreign financing has provided sustained funds for research as well as opportunities

for increasing international collaborations. Second, there has been a growing development of research and ethics specialists in Malawi whose expertise got institutionalized within medical institutions and state regulation. This expertise arose as a result of long-time experience with community-based medicine and clinical medical practice. But it was especially influenced by the know-how that ethicists developed as a result of the exponential increase in offshored research protocols (Petryna 2009) that were showing up in Malawian and other African institutional review boards.⁷ The simultaneous development of these two factors meant that while Malawian-based scientists could expertly scrutinize foreign research protocols, state research institutions did not have the capacity to define and implement nationally-determined health research priorities. This gap gave rise to unforeseen predicaments in health research – problems that would ultimately stake claims over the question of failure and HIV research.

Tenofovir and Truvada PrEP knock on Malawi's door

In 2004 and in 2009, the University of Malawi, College of Medicine received three research protocols to study Tenofovir (submitted in 2004 and 2009) and Truvada (submitted in 2009) as PrEP. At that time, both pharmaceuticals were existing marketed nucleoside reverse transcriptase inhibitors used to treat HIV infection. None of these research protocols received IRB approval in Malawi. The same protocols were however approved and the studies were implemented in other African countries. Family Health International (FHI, now named FHI360) was supposed to conduct the first 2004 study. A second protocol submitted by FHI in 2009 was called FEMPREP and the planned study drug was Truvada (a combination pill containing the US FDA approved marketed antiretrovirals, Emtricitabine and Tenofovir).⁸ The intention was to assess the safety and effectiveness of the daily use of Truvada in preventing HIV in women who were considered to be at high risk of infection. That same year, the Microbicide Trials Network submitted another protocol called VOICE,⁹ which intended to use Truvada and Tenofovir as study products.¹⁰

The 2004 Tenofovir trial was to be conducted by the University of North Carolina Project Malawi. It was a phase II PrEP study and was initially granted approval on 7 September 2004 by the University of Malawi's IRB, COMREC. During the initial IRB deliberations, questions were raised about the prospect of drug resistance. After UNC addressed COMREC's concerns on this matter, the protocol was approved. Upon approval, formative research within a nearby community commenced, which generated data on the acceptability of Tenofovir as PrEP among potential recruits. Those who conducted this research informed the authors that they identified sex workers located in 90 different brothels, lounges, and bars that they frequented. The implementation of the phase II study was deemed highly favorable.

Yet, on 24 November 2005, about 14 months after the approval of the protocol and before the trial enrolled participants, the NHSRC chair informed UNC via an official letter, that the study's IRB approval had been withdrawn. From the letter, the NHSRC Chair cites 'advice received from specialist HIV management groups of the Ministry of Health (MoH) and a presentation on TDF [Tenofovir] from UNC on 18 November 2005' as reasons for study discontinuation. The withdrawal of ethics approval happened before the recruitment of study participants actually commenced. We were repeatedly told by local PIs that the reasons for withdrawal had to do with 'national interest.' The PIs claimed that there was no other communication beyond this explanation.

Four years later, the FEMPREP and VOICE study protocols were submitted for ethical reviews. Both were submitted to COMREC, which forwarded these applications to

NHSRC because they were both deemed to be of ‘national interest.’ This marked the beginning of what appeared to be several lengthy delays and a great deal of confusion on how the research protocols were handled including how the ethics committees communicate with the researchers. The ethics committees raised several issues with the FEMPREP and VOICE study protocols. According to our findings from interviews with ethics committee members and researchers, the main concern related to the possibility of promoting HIV resistance to the study drug. A second concern had to do with what are known as ‘post-trial benefits’. In this case, these included whether the country of Malawi could easily access the drug if the trial results were successful – an issue not brought up during our interviews but discussed in official IRB documents exchanged between the ethics committees and the PIs. Several open and closed meetings took place over an 18 month period. In the end, the NHSRC refused to give approval for both protocols.

Ultimately, the National Commission for Science and Technology (NCST), which is the overarching national science and research government agency, was asked to arbitrate what was becoming a conflict between the researchers and the national ethics committee. The NCST set up a three-person committee to review the protocols. It also sought external opinions and assessed the situation in other countries that were conducting similar studies. The NCST asserted that concern over resistance to Truvada within the frame of the HIV prevention protocol was not reason enough to stop the implementation of the trials based on the evidence generated from the various reports received. The NCST does not have the authority to override NHSRC decisions; it could only advise the NHSRC to review its decision.

In early 2010, and in a new twist of events, the NHSRC requested that the researchers secure a no-fault health insurance in the case of HIV positive seroconversion and resistance. The intent was to guard against the potential negative impact on study participants’ health that could occur well after the PrEP study had been concluded. The NHSRC stated that this requirement is in line with guidance point 19 of the Council for International Organizations of Medical Sciences International Ethical Guidelines. While researchers for the proposed FEMPREP and VOICE studies managed to secure health insurance for study participants, the NHSRC did not grant approval for either of the trials. Ultimately, the main point of contention remained with the question of drug resistance and, to a lesser extent, also included access to products if deemed successful after being trialed in Malawi. But both drug resistance and post-trial benefits indexed far greater issues shaping research and health outcomes.

The debate: drug resistance, post-trial benefits, foreign funding

In 2004, when Family Health International submitted the first Tenofovir protocol for ethics approval, it did not stipulate monitoring drug resistance if trial participants were to seroconvert. But as later PrEP protocols began to include drug resistance monitoring, researchers were quite reassured by the apparent enhanced safety of these drugs due to the comparably low toxicity and the low levels of drug resistance. Indeed, the researchers in Malawi meant to administer these trials locally echoed to us and in their statements to, and meetings with, COMREC and the NHSRC, that drug resistance was a fairly negligible issue. For example, as one senior trial worker explained:

We did a mathematical modelling on answering that question on resistance. Tenofovir has a very huge barrier for developing resistance. And between Blantyre and Lilongwe we were going to recruit 150 participants on the study drug and another 150 would be on placebo.

Resistance to Tenofovir is much lower than resistance to Combivir and 3TC or D4T and 3TC. So we worked that out of the 150 [trial participants], probably 1 person would develop resistance during the study – 1 out 150. So therefore, there is no way you can say that you unleash a huge resistance burden within Malawi. It's either these participants would be followed rigorously during the study and if we saw any resistance we would send samples to our partners to work out which regimen would be the best suited to this participant. [Therefore] we answered those questions.

But the IRBs were not simply concerned about resistance that could arise within an imagined isolated context of a drug trial. They were concerned about the fact that in Malawi, a country that provides universal access to antiretroviral treatment for HIV infection, Tenofovir, was part of the second and last line therapy in the national HIV treatment policy.¹¹ HIV positive patients usually begin with one treatment combination and when HIV becomes resistant to this first line therapy, the patient will switch to a new HIV drug combination, or a second line treatment. For Malawi, if a trial volunteer was to develop a Tenofovir resistant HIV strain, no treatment in-country would be available to him or her. Another researcher we interviewed indicated that the research team addressed this concern:

We had responded to them and told them that the world moves too fast and the treatment of HIV is moving too fast for anybody to think that treatment which is available today may be the same treatment that could be used next year. More efficacious treatment is coming up. Even if Tenofovir was found to be effective we were sure that by the time a good number of Malawians will need Tenofovir as a 2nd line, Tenofovir will not be 2nd line, there would be something more efficacious than Tenofovir so there is nothing to worry about. But people were worried about it.

One IRB member, echoing several ethics committee members' sentiments, explained at length that ultimately the problem was rooted in managing HIV resistant strains when the drugs needed to do so were not available in Malawi:

We know that [with] any drug, a person will develop resistance as time goes on – that is a given fact... But it's the mode of resistance development, the source of resistance development that is a worry or reason for concern. This is not a treatment trial, it's a trial on PrEP and this is a low income country. As a low income country you are using this 2nd line [treatment] drug regimen for PrEP and there is no mechanisms for substitution in the future from the government coffers. You sacrifice a vital drug in the 2nd line regimen, which is expensive. You see, you are caught in a dilemma – you have to promote science and at the same time you are very poor... We needed to address the issue that if we sacrifice this drug these people will have no option, no alternatives if they resist ... the 1st line ... The issue is about sacrificing the best available alternative. ... To me the issue of resistance is not an issue ... [because] the resistance argument is becoming weaker and weaker.

At this point one of us asked why the resistance argument is actually weaker. He emphasized again that drug resistance for HIV treatment is an expected outcome that a poor country such as Malawi can certainly anticipate, but for which it cannot develop a treatment policy simply because it does not have the funding to do so. It would require, what he called, 'drug sacrifice'. Indeed, national treatment policies in low income countries such as Malawi are determined not only by advances in new treatments but by their affordability for country-wide HIV treatment programs. In most cases, first line drugs are off-patent, generic, and far less expensive. These drugs destined for large HIV positive populations can be more easily secured than many of the second line and most third line

drug treatments (referred to as ‘salvage therapy’), which are patented and far less affordable. At the time of this study, Malawi only had one second line option and no salvage therapy regimen recommendation because such drugs are not affordable.

At least two interviewees mentioned that the national media were discussing the possibility of Malawi losing its next round of United Nations Global Fund financing, the largest funding source for HIV treatment in Malawi. Without such financing people living with HIV and receiving antiretroviral drugs that are funded by the Global Fund run the risk of having their ‘life-long’ treatment terminated. And so the tension between promoting science and good health outcomes while at ‘the same time you are very poor’ is a significant postcolonial ethical dilemma for which the structure of research and HIV financial flows present no easy solutions.

But while ethics committee members were concerned about the politics of treatment, researchers involved with PrEP repeatedly indicated that it would be a big loss to Malawi if PrEP research was not pursued there – a sentiment not echoed by the members of the ethics committees. Many of the interviewees could not strongly pinpoint reasons for these opinions, but two did stand out. One was that if PrEP use in Malawi was officially approved based on studies conducted outside of Malawi, local evidence would still need to be generated to inform PrEP-related drug policies and program roll outs.¹² Perhaps more important to these researchers was the second reason: the politics of international funding that underlie the long-term buoyancy of research institutions. As one researcher put it:

It just set HIV backwards. I think we should have been in there with the rest of the world at the forefront of high tech research. [But instead] we lose out on our capacity building, lose out in terms of our health services system. Research in Malawi is also a big employer ... we have got cadres [at] all levels. We have got nurses, clinicians, we have lab people, we have data people – and all those people lose out. And particularly for the country we lose out in response to what we do in public health problems in a very strong manner.¹³

This researcher echoed what many had articulated to us – that foreign partnerships fundamentally keep skilled labor employed, bolster the integrity of public and population health, and provide an ‘equalizing effect’ (often via state-encouraged technology transfers – data sharing, publication opportunities, and equipment provisions) between wealthy research institutes and Malawian scientific institutions (NCST no date; Muula and Mfutso-Bengo 2007). Thus, there is a lot at stake in ‘losing out.’

In a separate manner, ‘losing out’ was extended to ‘post-trial benefits,’ which were not included in the IRB documents and were a concern for both ethics committees. Post-trial benefits pertain to memorandum of understandings or other official assurances that PrEP can be easily accessed by the trial community or host country if found effective; and in this particular case, this assurance was only relevant if connected to the non-trial related issue of securing an alternative to the second line antiretroviral treatment for trial volunteers who become infected with resistant strains. But offshored PrEP research is rarely connected to post-trial benefits that must engage the politics of global drug marketing where patented drugs are sold on private high-income markets; they are rarely sold on low-income markets and are instead only available via limited free donor programs (Peterson 2014). This disconnect has to do with the fact that drug companies do not play direct roles in PrEP research but rather they donate their pharmaceutical products to clinical trials. This kind of brokerage places several institutions between the drug company and the study volunteers, making it very difficult to assure access to future drugs and health care (Fisher 2009; Sunder Rajan 2007; Petryna 2009).

Conclusion

During the early PrEP trials and debates, discussions of trial failure have been strongly influenced by the urgency to take global action against HIV (UNAIDS 2007). PrEP trial failure has been relegated to a problem of activists and the media who do not understand research and who block or disrupt life-saving research (Chase 2005; Grant et al. 2005; Mack et al. 2010). Failure is also about trial sponsors and PIs' inability to understand scientific and ethical analysis by communities where trials are offshored (Jintarkanon 2005; Ukpong and Peterson 2009). Failure pertains to the functions of (bio)ethics, which has been analyzed by scholars (and edited volumes) as variable, singular and universal, context driven, and embedded in regulation, knowledge production, economic disparities, and political economy to name a few (Cooper and Waldby 2014; Fisher 2009; Geissler 2015; Geissler and Molyneux 2011; Kingori 2013; Petryna 2009; Molyneux and Geissler 2008; Rosengarten and Michael 2013; Sunder Rajan 2012; see also Cohen 1999 and Hamdy 2012). Failure might be inevitable (or not), given the inequalities found between wealthy overseas research institutions and their impoverished neighboring communities and research collaborators (Crane 2013; Farmer 2002; Fairhead, Leach, and Small 2006; Geissler et al. 2008; Gikonyo et al. 2008; Reynolds et al. 2012; Wendland 2008).¹⁴

In analyzing the politics of PrEP in Malawi, we wish to draw upon many of these insights, especially Cooper and Waldby (2014); Fisher (2009); and Sunder Rajan (2009; 2012) who examine the politics of neoliberalism and imperialism when it comes to offshored and privatized research. Our analysis does not explicitly pertain to bioethics or ethical variability. As shown, the Malawi debates focused on PrEP science rationales. These debates were connected primarily to national HIV policies and the ability to secure long-term funding for second-line and salvage therapy; and secondarily, they were connected to the possibility of creating agreeable terms to access marketed drug products that are tested in Malawi. Here, the issues raised did not pertain to trial practices and easily identifiable inequalities. Rather, the question was whether PrEP as a HIV prevention technology (and not a clinical trial) could be reconciled with broader questions of future research agendas, future drugs, and future national health concerns. In taking PrEP debates to this more macro level, the analytical scale of ethics shifts from trial relationships to the post-colonial legacies – geopolitics and economic liberalization – that structure the possibilities of research and health outcomes in Malawi.

How then do we locate 'failure' in this larger field? Genuine desires to develop interventions for HIV prevention must come to terms with the history of Malawi's economic and legal dispossessions and its place in the global economy. That is, failure must be understood within the legacies of imperial power. The debates that pit the enrichment of Malawian national research (and the possibility of 'losing out') against the integrity of HIV national policies (and the possibility of facing 'drug sacrifice') reveal much in this regard. As the discussions demonstrate, some scientists expressed a deep desire to be engaged in 'high tech' research, especially to be at the forefront of cutting edge HIV solutions. For the ethicists, these shared desires come into conflict with the future prospects of HIV treatment. The sustainability of both scientific research and the national HIV treatment policy is largely dependent upon foreign funding. As such, both HIV research and HIV treatment policy are beholden to foreign research agendas in the absence of a national research policy that defines health research priorities for the country.

These contradictions and rather dramatic constraints at the national level must also be reconciled with the politics of PrEP at a more global level. PrEP has been described by international scientists and AIDS activists as urgent and life-saving for especially

marginalized women and sero-discordant couples. This argument converges quite effortlessly with drug development models that increase market share. These models invent new uses of existing marketed products that can extend a drug patent's life. Hence, the Malawi ethics committees' concern over post-trial access to successful drug products must be understood within the broader context of who becomes experimental subjects and who becomes contract labor for products destined for high earning markets located outside of Africa (Cooper and Waldby 2014; Sunder Rajan 2007).

Here we might wonder what it means for a Malawian ethics committee to say 'no' to PrEP research, not once but three times. This is not simply about a failure to listen or understand what is at stake in refusing to approve PrEP study protocols. It is about the way in which imperialist relations are constituted via disparate articulations of scientific expertise and civil society, foreign influence, and the African nation-state (which has not 'failed' as it has made strong claims in the PrEP debates). While there are differently located subjectivities emerging out of this field of power, all actors discursively and materially vie to establish authority over sovereign notions of public health and ultimately the public good. In this context, saying 'no' to PrEP research means understanding the structures of power that make clinical encounters appear completely natural; and as such, they get understood as humanitarian/scientific urgencies rather than about imperial relations.

It is noteworthy that none of our interlocutors used the term 'failure' to describe their perspective on events. But as the early literature on the PrEP trials show, the idea of failure is in constant juxtaposition with assumed normative functions – such as how a trial could successfully work or how bioethics should consider performing within multiple contexts and constraints (UNAIDS 2007; International AIDS Society 2005). For those who have expectations that offshored research can locate itself in some imagined normative sense of things, failure to implement a trial is sudden, shocking, and out of the normal range of experience. But if refusals are located within imperialism itself, then saying 'no' to PrEP research is anything but failure. It is about attempts to assert some kind of national integrity – an integrity that ultimately is difficult to achieve because a choice must be made between holding on to opportunities for cutting edge research or defending the integrity of an HIV treatment policy. These are choices and not synergistic givens. Even as choices they are highly limited because it is not researchers in Malawi who autonomously determine research agendas, nor is it HIV experts who have the power to establish an ideal national HIV treatment policy for a country hit hard by AIDS. These challenges and structural constraints make the lament over 'drug sacrifice' and 'losing out' within long histories of dispossessions and imperial relations all the more salient.

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Disclosure statement

No potential conflict of interest was reported by the authors.

Notes

1. These included The Centers for Disease Control and Prevention, the National Institutes of Health, and University of California San Francisco, among others.
2. The Gates Foundation provided \$6.5 million for sites in Cameroon, Nigeria, Ghana, Malawi and Cambodia. The National Institutes of Health awarded \$2.1 million to UC San Francisco to conduct a trial in Cambodia. The Center for Disease Control was awarded \$3.5 million to conduct the trial in Botswana, Thailand, and the US.
3. National Science Foundation funding enabled Peterson to hire her former colleague, Chigwedere, who brought Nthete on board (both at the University of Malawi, College of Medicine/ College of Health Sciences). They were instrumental in identifying interviewees and the research strategy. Together we all contributed to conducting interviews, sharing data, generating analysis, and writing this article. Peterson, Folayan, and Chigwedere travelled to international conferences to conduct research. Peterson, Folayan, and Olatubosun Obileye carried out the research in Nigeria. Chigwedere, Nthete, Folayan, Peterson, and Matilda Kunthi carried out research in Malawi. Peterson and Folayan and analyzed the majority of the data. Both the research and the publication received ethical approval from the University of California, Irvine, USA; Obafemi Awolowo University in Ile-Ife, Nigeria; and the National Health Sciences Research Council in Lilongwe, Malawi.
4. The drug industry has been intricately tied to the investment industry since the 1980s, which has demanded short-term gains and high rates of appreciation in return for finance capital. These are demands that are relatively difficult to meet given the risks and long-term need to bring a drug to market (10–15 years). Drug companies survive these demands by merging and acquiring others. It also seeks ways to develop blockbuster drugs – those earning over \$1 billion per year (on all these points, see Cooper 2008; Dumit 2012; Peterson 2014; Sunder Rajan 2012).
5. In addition to HIV prevention research, these institutes conduct a wide range of studies including breast feeding, HIV resistance studies, lymphoma, Kaposi's Sarcoma, mother-to-child HIV transmission, vaccine trials, and microbicide use (Malawi College of Medicine-Johns Hopkins University Research Project (no date).
6. For other examples of semi-permanent and permanent foreign research institutions in Africa, see Fairhead, Leach, and Small (2006) and Reynolds et al. (2012).
7. While we do not have statistics, one ethicist in Malawi and two in Nigeria noted the substantial increase in the number of foreign research protocols seeking permission to conduct clinical trials from the early 2000s.
8. FEMPREP was a multi-center, double-blind, randomized, placebo-controlled effectiveness and safety study. The trial 'assigned 2120 HIV-negative women in Kenya, South Africa, and Tanzania to receive either a combination of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) or placebo once daily. The primary objective was to assess the effectiveness of TDF-FTC in preventing HIV acquisition and to evaluate safety' (Van Damme et al. 2012, 411).
9. VOICE was a Phase 2B, five-arm, double-blinded, placebo-controlled, multi-site, randomized, controlled trial. The trial 'assess(ed) daily treatment with oral tenofovir disoproxil fumarate (TDF), oral tenofovir-emtricitabine (TDF-FTC), or 1% tenofovir (TFV) vaginal gel as pre-exposure prophylaxis against HIV-1 infection in women in South Africa, Uganda, and Zimbabwe' (Marrazzo et al. 2015).
10. At both the Johns Hopkins Blantyre site and the UNC Lilongwe site, these included HTPN 035 (a Vaginal Microbicides gel, which began enrollment in 2005 and concluded in 2008), MTN 015 (a Study of Women following HIV-1 Seroconversion in Microbicide Trials), MTN 019 (a study of Tenofovir gel in pregnancy, which is currently pending approval). Currently at the UNC Lilongwe site, the trial MTN 020 is testing a vaginal ring that contains the non-nucleoside reverse transcriptase inhibitor, Dapivirine. The Network had conducted a microbicide trial in Malawi in the past using non-antiretroviral based compounds called buffergel and PRO2000.
11. At the time, the HIV treatment policy's first line standard regimen is a Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) dose. It also lists three alternatives. The second line (for adults) includes Zidovudine (AZT) + Lamivudine (3TC) + Tenofovir (TDF) + Lopinavir/ Ritonavir (LPV/r). At least up until 2008, there were no alternative formulations to the second line nor was a third line regimen established. See Ministry of Health, Malawi (2008).

12. For example, a Niverapine – an antiretroviral used to prevent mother-to-child HIV transmission – study (Eshleman et al. 2005) in Malawi showed that there was high resistance after a single dose of therapy in contrast to other African countries where there was little or significantly less resistance.
13. See Folayan and Allman (2011) on industrial labor in clinical trials.
14. For colonial institutional relations, see Feierman and Janzen 1992; Hunt 1999; Packard 1989; Vaughan 1991.

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