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From ‘trial community’ to ‘experimental publics’: how clinical research shapes public participation

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ABSTRACT
In relation to clinical trials, it is far more usual to speak of the community (singular, static) than of publics (multiple, emergent). Rarely defined, the community is commonly taken to be the existing people in a given area, which the trial will engage, mobilise or sensitise to facilitate successful recruitment and retention. Communities are assumed to pre-exist the research, to be timeless, and to be a whole (sometimes consisting of different parts, referred to as stakeholder groups). In this paper, we suggest a conceptual shift from ‘trial community’ to ‘experimental publics’. Using an empirical case study of an HIV prevention trial in Zambia, we draw out the following key points: firstly, publics do not pre-exist research activities but are enacted in concert with them. Secondly, publics are dynamic and transient. And thirdly, experimental publics are situated at the intersection of various forms of inclusion and exclusion, both locally and globally. Our findings emphasise the need to create long-term forms of participation in science, which transcend both the instrumental goals and the individual timelines of specific trials.

Introduction
In relation to clinical trials, it is far more usual to speak of ‘the community’ (singular, static) than of ‘publics’ (multiple, emergent). Rarely defined, the community is commonly taken to be the existing people in a given area from which a trial will recruit individuals to become research subjects. For example, the UNAIDS/WHO guidance on ‘Ethical Considerations in Biomedical HIV Prevention Trials’ is replete with references to ‘the community’, as illustrated in the following extract:

A key means by which to protect participants and the communities from which they come is to ensure that the community in which the research is carried out is meaningfully involved in the design, implementation, monitoring, and dissemination of results of HIV prevention trials, including the involvement of representatives from marginalized communities from which participants are drawn. (UNAIDS & WHO, 2007, p. 11)

Reinforcing the idea of the community as primarily a source of trial participants from which researchers draw, the Microbicides Trials Network notes:

… community is defined as the group of people who are most likely to participate in, be affected by or influence the conduct of the research. The community may include the particular group or population from which study participants are chosen. It may also include the broader geographic community in which the study is conducted … (Microbicides Trial Network [MTN], 2016)
As others have observed, the term has found great popularity in research and policy arenas, but is often deployed uncritically and in a way which dehistoricizes and decontextualizes the people whom public health interventions target (Biruk & Prince, 2008; Zion, 2005).

‘Community’ thus comes to prefix a range of terms associated with scientific outreach, such as ‘community engagement’, ‘community mobilisation’, ‘community sensitisation’ and ‘community advisory board’. Communities are assumed to pre-exist the research, to be timeless, and to be a whole (sometimes consisting of different parts, referred to as stakeholder groups). On the basis of in-depth qualitative research conducted alongside a large transnational HIV prevention trial, we challenge these assumptions about trial communities. We propose instead the notion of publics as a way to describe the emergence of particular groups in relation to medical research. Drawing on theoretical work by Warner (2002), Michael (2009), and Marres and Lezaun (2011), we present an empirical case study to illustrate the emergent and transient nature of experimental publics, as well as their constitutive outsiders.

The paper is organised as follows: firstly, we provide a brief summary of Rose and Miller’s arguments in relation to the problematics of government. Clinical trials, we argue, enact a form of governmentality through their enumerative practices. We then turn to Epstein’s work on the inclusion-and-difference paradigm in medical research, in order to suggest how those who are subject to trials’ governmental practices may be determined on the basis of categorical identity work, implemented through strict inclusion and exclusion criteria. These two features of trials – their selection of particular groups and their governance techniques – together contribute to the formation of particular kinds of publics. To elucidate this, we turn to the extensive literature on publics, drawing specifically on work by Michael (2009). Having outlined these three pillars of our conceptual apparatus – governmentality, the inclusion-and-difference paradigm, and the constitution of publics – we present our empirical case study to illustrate the creation of an experimental public. In so doing, we wish to encourage a re-thinking of ‘the community’ as a potential series of partial, emergent, and temporally contingent publics, which enact and are enacted in relation to the research practices they are presumed to pre-exist.

The politics and publics of trials

In order to think about how trials create publics, we start with Rose and Miller’s (1992) work on the problematics of government, in which they locate modern forms of political power not in the nation state, conceived as a unified and autonomous actor, but in technologies of government. Technologies of government are the mundane mechanisms through which authorities act upon the conduct of those they wish to govern. They include inscription devices, such as forms of notation and calculations; measurement and display techniques, such as surveys and tables; assessments such as tests and examinations; and systems for standardisation and professionalization. Power accrues to those who deploy such technologies, since they enable both the creation of particular kinds of subject and simultaneously render them knowable.

In international health research, projects of various kinds have come to supplement, and in some cases replace, the provision of services by the state (Prince & Marsland, 2013). Within this context, clinical trials can be envisaged as technologies of government, institutionalising the surveillance and objectification of the body and the creation of particular types of subject in those whom they recruit. Regular techniques and procedures involved in the management of trial participants include observation, measurement, examination, notation, and statistical calculations comparing individuals to established population norms. As Rose & Miller point out, such techniques of power are not concerned with constraining citizens so much as “making up” citizens capable of bearing a kind of regulated freedom’ (p. 174). In return for subjecting themselves to rigorous, repetitive and sometimes invasive forms of surveillance, trial participants receive a range of benefits, the most valuable of which may be free access to medical care.

While state provision of medical care is theoretically available to all its citizens, the provision of services within a clinical trial is constrained by the definition of who is eligible to participate as a research subject. The politics of inclusion in medical research has a long history, both in colonial and postcolonial
times (Prince & Marsland, 2013). For the purposes of our analysis of a contemporary HIV prevention trial, we find Epstein's theoretical characterisation of developments in experimental science apt. Analysing developments in the United States in the 1990s and 2000s, he argues that there has been a move to include what are perceived to be under-represented groups in clinical research, based on categorical identities such as sex, race, and sexual orientation. Epstein traces the categorical alignment work done by advocates to superimpose categories of political mobilization and bureaucratic administration onto biomedicine. This uncritical transposition, he argues, has a profound impact on the policies, forms and surveillance systems that prescribe biomedical work practices (Epstein, 2007, p. 278).

Such categorical alignment work can be seen clearly in the case of vaginal microbicides, whose development was heavily influenced by the women's health advocacy movement. In an attempt to reduce the vulnerability of women (particularly in Africa) to HIV infection, advocates mobilised funding and scientific expertise to develop new pharmaceutical products specifically for women. While recognising that the disproportionate burden of HIV in women was rooted largely in society, this movement re-focused the prevention effort on biology. Developing products that women could use autonomously, and therefore covertly in some cases, scientists and advocates focused the testing of new molecules on women, even where they might have a preventive effect on men (Montgomery, 2012). This resulted in the recruitment of tens of thousands of women to vaginal microbicide trials, of which the case presented here is but one.

So far, we have argued that the enumerative practices of clinical trials, which form part of broader apparatuses of non-state power, play a key role in the creation and governance of populations. Drawing on Epstein's work, we have suggested that trials actively differentiate those who are eligible for inclusion in this form of participation from those who are not. We now turn to a third body of scholarship to argue that the result of these practices together leads to the formation of experimental publics.

In his theoretical work on publics, Michael (2009) distinguishes between two broad categories: Publics-in-General and Publics-in-Particular. Publics-in-General ‘can be regarded as an undifferentiated whole that is distinguished from science’ (p. 620). In this respect, it has some commonality with ‘the community’ in relation to which trials define themselves. Publics-in-Particular, by contrast, are associated with specific scientific projects or interests – they ‘emerge with technoscientific issues…can be pinned down spatially…[and] are demarcated in relation to some external event’ (p. 623). The kinds of publics which trials enact possess these characteristics, at least partly by virtue of the fact that they operate within the inclusion-and-difference paradigm in biomedical research.

While there have been various articulations of group constitution in relation to medical research, we find Michael's resonates most strongly with the two features identified above. Michael focuses on the work of enactment, both that others do to bring publics into being, and that publics do themselves to demarcate their boundaries from other publics. In particular, his characterization of publics as ‘partially emergent from processes of rhetorical differentiation and identification’ (p. 618) captures the way in which trials demarcate the boundaries of participation through inclusion and exclusion criteria. Ideas about the enactment and emergence of publics are shared by others who have theorised the social formation of such collectives. For example, in their work on the ‘emergent concerned groups’ of muscular dystrophy, Callon and Rabharisoa observe that group identity ‘is an achievement rather than a starting point…the outcome of real research in which the groups are heavily engaged’ (Callon & Rabeharisoa, 2008, p. 232). Focusing more on the temporal nature of emergence, Warner observes that ‘a public can only act within the temporality of the circulation that gives it existence’ (Warner, 2002, p. 68); and extending this in relation to experimental publics, Marres & Lezaun find that ‘the necessary containment of experimental publics – their attachment to particular artefacts, their dependence on material architectures, the unrepeatability of experimental performances – works to restrict the reach of their political effects’ (Marres & Lezaun, 2011, p. 503).

Drawing on Marres and Lezaun, as well as on Michael, we use the term ‘experimental publics’ to draw attention to the moral and political capacities with which medical research comes to be invested in a particular time and place, and the transient forms of participation it impels.
Case study: vaginal microbicides and the MDP301 trial

[V]aginal microbicides are experimental products designed to prevent HIV infection in women. As a result of strong international advocacy from the women's health movement, they came to prominence in the late 1990s as a 'woman-controlled' technology intended to empower women to protect themselves from infection by their male partners (Heise & Elias, 1995; Stein, 1990). The microbicides research agenda has focused on enrolling women in clinical trials to test products; men have often been represented through a deficit model of masculinity that sees patriarchal structures as a cause of women's oppression and poor health outcomes (see, for example, MacPhail et al., 2009; Woodsong, 2004). Over the past decade and a half, there has been a progressive move to involve men in microbicide trials (e.g. Kilmarx et al., 2008; Montgomery et al., 2015). It is now recognised that engaging male partners will be key to the uptake and success of an eventual product (Lanham et al., 2014; Montgomery et al., 2011).

This paper draws on one of the largest phase III trials of a microbicide candidate conducted to date: MDP301 (McCormack et al., 2010). The trial was conducted between 2005 and 2009 by the Microbicides Development Programme (MDP), a large, not-for-profit, African-European partnership, funded by the UK government through the Department for International Development and the Medical Research Council.

Methods

This paper draws on data collected in Zambia in 2008 for PhD research conducted by the first author. The PhD explored how research into new HIV prevention technologies is produced and how it contributes to the construction, maintenance or deconstruction of gender relations. Drawing on Foucauldian theory, it interrogated the techniques of power through which transnational scientific networks are mobilised to test new products and how these in turn affect scientific practices, knowledges and identities across socio-geographic boundaries (Montgomery, 2010). Although this work took a critical step back from the trial, it was conducted under the auspices of the MDP, for whom both authors worked as social scientists. This paper therefore provides interpretations at once critical of the trial, but also grounded deeply in its implementation.

We conducted 35 in-depth interviews at MDP Zambia: 14 with staff members, six with key stakeholders, and 15 with female trial participants and their partners. We sampled staff purposively across disciplines and levels of seniority; trial participants and stakeholders were selected in consultation with the trial's senior social scientist and Community Liaison Officer. Community stakeholders were selected on the basis of having prior knowledge of or involvement with the trial and included community advisory board (CAB) members, church leaders and NGO staff. We conducted five focus groups: one with CAB members (n = 8), two with female trial participants (n = 16, randomly selected from the trial database according to age) and two with local men (n = 16, likewise split into younger and older groups). The latter were suggested by the chairs of the 10 local Resident Development Committees (RDCs, which form part of local government structures) in the trial catchment area and represented a range of men of different ages and occupations.

All interviews and focus groups were recorded, transcribed, translated where necessary and imported into NVivo. Analysis focused on the production and regulation of identities through discourse, as well as the discursive production of power/knowledge. Key dimensions of the coding included techniques of power and threats to prevailing social hierarchies; the construction of different kinds of knowledge, and their movement, legitimation and denial; networks, participation and group belonging; and the stabilization of the research artefact (e.g. evolving use and user groups for microbicides). Coding, memo-writing and interpretation followed Charmaz’ vision of a reflexive, constructivist grounded theory that digs deep into the empirical while building 'analytic structures that reach up to the hypothetical' (Charmaz, 2006, p. 151). An initial process of detailed line-by-line coding within interviews led to the development of a set of provisional categories, used to code subsequent transcripts in a more focused
manner. This iterative process involved testing the adequacy of categories against the data (constantly turning between codes and data) and then of moving between cases (comparing data to data).

The study was approved in the UK by the London School of Hygiene & Tropical Medicine Ethics Committee and in Zambia by the University of Zambia Biomedical Research Ethics Committee.

**Findings**

**New sites of governmentality**

The clinical trial site in Zambia was one of six research centres involved in MDP301. Located in Mazabuka in Southern Province, MDP Zambia was set up specifically for the purposes of the trial, in an area where clinical trials were largely unheard of. The rationale given for choosing the town was that it was based around a large sugar plantation, Zambia Sugar, which provided a stable population ideal for research. Mobility was much lower than in the capital and the population was well documented, with residential areas already mapped out. Since clinical trials had not previously been conducted in Mazabuka, this type of research was new both to local residents and to the Zambian staff who were recruited to run the project. Discursive accounts produced within the trial construed MDP as a novel and exciting enterprise that was taking science beyond the hospital laboratory and 'into the community'. Community engagement was a keenly emphasised aspect of the trial and the site had a well-staffed, dedicated team of community mobilisers headed by a Community Liaison Officer.

In the early stages of MDP, visits were made by the UK coordinating team to the Zambian site to conduct staff training. A large part of this focused on the protocol and clinical procedures, in order to ensure consistency across the programme. Scientific method demands that multi-site trials be conducted according to strict protocols and standardised procedures. Through lists of inclusion and exclusion criteria, trial protocols draw lines of division delineating who can be considered a research subject and who not. In this trial, the criteria concerned sex and age (women only, over 18), disease status (HIV negative only), geography (within the trial catchment area), sexual behaviour (not having sex more than 14 times a week), and willingness to comply with a range of tasks (undergo genital examinations, receive health education about condoms, have regular pregnancy tests, use study gel as instructed). In practice, this enabled the constant monitoring of women's bodies and behaviours over a 12-month period, whether through expert assessment or self-surveillance.

As such, the trial can be seen as a technology of government, controlling women through the surveillance of their bodies and other techniques such as regulation of their fertility and imposition of conditions on their sexual behaviour. For example, the trial actively monitored and regulated women's sexual behaviour: they were counselled to be on a reliable form of contraception and were required to have a pregnancy test every four weeks; they were required to be sexually active but not to have too much sex, were advised not to insert things into their vagina, not to wash within an hour of sex, and not to have anal sex. Self-regulatory techniques, such as the completion of coital diaries and the requirement to return used and unused gel applicators to the clinic for accounting purposes, aligned women's 'autonomous' choices with the ends of public health government.

For Zambian staff tasked with implementing the protocol, the institution of these practices was not straightforward:

**John**: As I got into the programme, things became more complex, because I had to understand a lot of things from the clinical perspective, which is not my background.

**Interviewer**: What sort of things?

**John**: Things to do with data capturing…the protocol itself, the procedures we were going to follow and the type of women we were going to recruit and why we're recruiting them. And I was now looking at that in terms of what we actually believe in, or the norm of this place.

**Interviewer**: Tell me about that.
John: Basically, before MDP came into place, things to do with HIV testing were really not something that you could talk about openly. And then when I looked at the Case Record Forms for data capture, they were all issues to do with sex and it was more or less like bringing out the bedroom to the open. (John, MDP Zambia community mobiliser)

Breaking the joint taboos of HIV testing and talking about sex were both pre-requisites for inclusion in the MDP trial. However, the institutional incitement to speak about sex and to capture data from women was not met with passive adoption. In the process of trying to ‘engage the community’, the programme ran into several difficulties, these primarily being rumours that the research was Satanic and opposition by men in the community to their wives’ participation.

**Categorical exclusion and its effects**

Rumours that MDP was a Satanist organisation plagued the research from the start and were still circulating at the time of this fieldwork, five years after the site opened. Blood stealing, Satanism and witchcraft are common idioms for expressing discontent about social inequalities across Africa, and are regularly appropriated to express dissatisfaction in relation to medical research (see e.g. Geissler & Pool, 2006). In MDP, the most prevalent rumour was that the trialists took people’s blood and either used it for Satanic rituals or sold it in South Africa or the UK. Respondents linked the rumours to men’s opposition to the programme, with some also suggesting they came from women ineligible to join the study. Common features of the rumours were wealth accumulation, blood, and foreign involvement. The rumours can be seen as a response to the categorical exclusions enacted by the trial protocol, occurring against the backdrop of deep social inequalities on the sugar estate. It is worth elucidating this context below.

When the trial site first opened on the sugar estate in Mazabuka in 2003, it did so as a Voluntary Counselling & Testing (VCT) centre. At this time, Zambia Sugar, on whose premises the MDP site was based, had recently been taken over by the Illovo Group of South Africa. As part of a publicity campaign for MDP, the new manager was the first to go and get tested through VCT. However, male workers at Zambia Sugar reportedly took this as a sign that testing would be compulsory for employees in order to weed out those who were HIV positive from the workforce. As such, they feared for their jobs and shunned the programme. One community mobiliser who had gone door to door speaking to men told us that when they heard that MDP was targeting women, they interpreted this as a strategy to identify them and their HIV status through their wives. At the same time, in April 2003 (a month after the MDP Feasibility study started in Mazabuka), Illovo was implementing changes to its pension scheme and men feared that if they were found HIV positive and lost their jobs, they would not be able to access their pension money. Even in 2008, in focus groups with men, some reported that MDP was Satanist because it was using women as a means to undermine the men:

- **Facilitator:** Did it bother you that MDP is looked at as an organisation for women?
- **Richard:** Yah, it bothered me, because how do you only test women when HIV can also affect a man?
- **Taylor:** And that’s one reason many people associated it with Satanism, because they know that women are weaker vessels [mumbled agreement from the others], it’s very easy to convince them.
- **Other men:** To convince them.
- **Taylor:** When you convince a woman, it will be very easy for her again to convince the husband. So people said, ‘Oh, these people, they know the gimmick. They know that if we enter from a woman, then it will even be easy for the woman to convince the husband.’

Several issues combined at this time to produce anxiety amongst men and hostility towards MDP: the take-over of Zambia Sugar by South African investors and reform of the pension scheme coincided with the arrival of a UK-funded clinical trial recruiting people for VCT on the sugar estate. According to staff members, not only were clinical trials alien to the community, but HIV was highly stigmatised and HIV testing was neither widely available nor widely acceptable. Fear of death, loss of income,
desertion by one’s spouse and community rejection were discursively bound up with knowing one’s HIV status, and since antiretrovirals were not available, there was little incentive to test. At the same time, MDP was drawing what were perceived to be large amounts of blood and was giving women money (reimbursement for their participation) when they came to get tested.

The extraction of precious resources - whether blood from female trial participants or sugar from the labour of their male partners - was linked to the UK. It was well known that the trial was funded by the UK’s Department for International Development; at the same time, Zambia Sugar had been recently acquired by Associated British Foods, later accused of corporate tax avoidance and of making no corporate income tax payments in Zambia at all between 2008 and 2010 (Lewis, 2013). As our analysis starts to show, by focusing on women as a categorical group rather than the social structures and processes that led to their disproportionately high rates of HIV infection, the trial at once created a forum for women’s participation in science, but simultaneously distracted attention from the pathways that led to gendered health inequalities in the first place.

**Trial participation and the creation of an experimental public**

The Satanism rumours can be interpreted as ‘a way of talking that encourages a reassessment of everyday experience to address the workings of power and knowledge and how regimes use them’ (White, 2000, p. 43). Male focus groups were permeated by a discourse of exclusion regarding the trial, and a sense of injustice that they had been side-lined by the researchers:

You find that here, they very much welcome women rather than men and when they are doing these researches of theirs, it’s just between the MDP and the women, but forgetting their husbands.

The fact that MDP was recruiting women only, without actively seeking to involve men in the trial, threatened the governing relationships that existed prior to its arrival. Here, as elsewhere in Zambia, women are brought up to be submissive to their husbands and to follow rather than initiate (Milimo, Munachonga, Mushota, Nyangu, & Ponga, 2004). Women are not generally regarded as autonomous individuals; customary law treats them as dependents, with property and inheritance rights contingent on marriage or family ties. Although legally women’s rights are determined by both customary and statutory law, with the latter prohibiting discrimination against women, in practice, customary law undermines this and provides the dominant discourse through which women’s subordination is secured.

By excluding men from the trial, established power relations between men and women were threatened in a highly visible and public way. The trial channelled knowledge – and therefore power – in a distinctly gendered way, making women the primary receivers of information. Firstly, women attained knowledge of their HIV status, which was a pre-requisite for enrolment. Built around this was pre-and post-test counselling, which educated them about HIV, including modes of transmission and protection. Secondly, they were the recipients of knowledge about the gel, receiving information about its development and testing, detailed instructions on how to keep it, insert it, negotiate its use, document its use, adjust existing practices around it (such as vaginal douching and inserting), plus anticipated benefits and side effects. Thirdly, through ongoing clinic visits, counselling sessions, physical examinations and educational events, they obtained wide-ranging sexual health information and knowledge about their bodies in terms of STIs, pregnancies, and other ailments, which were under regular surveillance.

As a result, women were positioned as agential scientific citizens through their active contribution to the research. They were the ones invested with knowledge of the product, charged with dispensing it, identifying potential side effects and accurately reporting to the trial staff. Because the trialists relied on women to use the gel as instructed outside the direct observation of the study, women were invested with considerable agency, the exercising of which was fundamental to the success of the research. In focus groups, women identified their accumulated knowledge from the trial as distinguishing them from other women who had not taken part in the research:
Interpreter: Is there any difference between you ladies who have been coming to MDP and those who have not been coming?

Janice: We are different.

Elizabeth: Us, we have been enlightened about these diseases and we know how to avoid them since we are taught that 'this disease, I am not supposed to do this and that'. So we are different from those who have not joined the MDP, they don't know anything, they don't care. Here, we are being taught. (FGD participants in the 30+ age group)

In what Michael would describe as an act of 'rhetorical differentiation and identification', women enrolled in the trial distinguished themselves from their non-participating peers, saying that the knowledge they gained not only 'enlightened' them but also liberated them: 'we become free-minded because we know our status, unlike those who do not come here, they are not free'. Another participant pulled together these aspects of enlightening and liberating to suggest that the research awakened women to themselves and to the possibilities in their lives:

Nora: This research is just okay. It will be like, it will be like …. In Nyanja I would say 'Galamukani' (wake up) women.

Interpreter: What does ‘Galamuka’ mean?

Nora: To get smart. It is like you were asleep, then 'hey, wake up!' You see? (Nora, trial participant, 37)

Because women were the ones being given the information on how to use the gel, it was their prerogative to share that knowledge with their partners. In this sense, women acquired power within their relationships; not through withholding knowledge of the gel from their partners, or because they tried to use it regardless of their partners' consent, but precisely because they shared the knowledge and established gel use within their relationships. By virtue of participating in the trial, women became experts in the new prevention technology, an expertise that men could not access directly but only through their partners. The effect of this was not limited to individual relationships, but took on broader significance within the densely populated areas which formed the trial's catchment area. The women, who often came to the trial clinic in groups, spoke of collective empowerment, as in the extract below, where the neighbourhood as a whole is identified as benefitting from the research:

Do you know why I like the trial? I am a mother of two, and every month I am made aware of my status, including whether I am pregnant or not. In the neighbourhood where I come from it has done us a lot of good, people are aware that they should not get pregnant carelessly, because if you become pregnant you will have to stop participating on the programme. (Female FGD participant in the 18–30 age group)

Contests for the prerogative to govern

By recruiting only women to the research, and gaining only the woman's consent to participate, men saw the trial as directly challenging their control over their wives. It is in this context that we should consider the rumours linking MDP to Satanism – as an expression of mistrust towards forms of ownership by outsiders, whether the local means of production, local businesses or indeed women's agency. Exclusion from participation was directly referenced in this regard, as the following focus group extract illustrates:

Now you find that when she comes here (to the trial site), she comes here on her own...me, I don't know what she comes here to do, I don't know who attends to that person, you see. And then she just comes out and gives me orders, 'this is what I will be doing from now onwards'. You see, as men, we don't accept such orders. OK? So, this mistake was made from the word go. Had it been that when they started this programme, if my wife was interested in this programme, it was going to be better for them to say, 'OK, is your husband there?' ‘Yes’ ‘OK, we want him as well, let him also come.'

While some men responded to this exclusion through rumour, others objected in more demonstrative ways, exercising their own authority both through violence and surveillance. Whilst violence against women was said to be common in general, some men reportedly used violence or the threat of violence to control their wives' behaviour, specifically in relation to the research. During the fieldwork, respondents spoke many times about incidents of violence involving men beating their wives and
preventing them from attending the research site. For example, when asked whether there were men who had not allowed their partners to participate in the trial, one trial participant recounted:

They are there, yes. Like I said, that when starting, we started five of us, but the other three were stopped by their partners. One was beaten …she is my neighbour. He beat up the wife and so the wife stopped, just like that, up to now.

In focus groups, some men stated unambiguously that they would beat their wife if she brought study gels home without having informed him first; trial staff likewise confirmed this to be the case:

Interviewer: Have you seen many cases of women whose partners have stopped them coming back (to the study)?

Gertrude: [Affirmative] Mmhmm, we’ve had some. And some beaten, you know, we have had such for sure, we have had … Some, they would come actually beaten; you ask them, they say, ‘No, I fell’. But the friends would say, ‘Actually, this person was beaten’ and so on and so forth. For sure, there is big control.

Another way in which men exercised authority over their wives was through surveillance. While men were not enrolled in the trial, and the power of surveillance rested with the researchers, some men contested this exclusion by re-instating themselves as their wives’ guardians at the trial site. The counsellors and nurses related how some men escorted or followed their wives to the site, and how some wanted to be present during genital examinations. In addition, there were accounts of men completing their wives’ coital diaries for the study, and engaging directly with the researchers about their wives’ sexual behaviour, for example to verify whether they were having extra-marital affairs.

**Participation and the problematics of government**

In December 2009, MDP announced the results of the trial: the microbicide gel was safe, but not effective in preventing HIV transmission (Microbicides Development Programme, 2009). In spite of substantial, long-standing efforts to engage ‘the community’ from the trial’s inception, the reception of this result in Zambia was incendiary. A journalist blogging from Lusaka presented the trial as a ‘botched’ and ‘criminal’ scandal that had directly infected large numbers of poor and illiterate Zambian women who had taken part in it. The story was taken up by the national press and a furore erupted, leading to the temporary suspension of all microbicide trials in the country. Entries in the blog implied that knowledge generated by the trial locally was being withheld from Zambians and information sent outside the country, to the UK:

> The microbicides research trials which begun as far back as 2005 have over the years yielded discouraging results, though little has been made public. According to classified information gathered from the latest outcome, ‘results of the trials have since been submitted by the Medical Research Council of the United Kingdom to the Microbicides Development Programme’ (Kabange, 2010b, emphasis added).

The blog also called for the arrest and punishment of MDP researchers and presented the organisation as a threat both to the nation and to the sovereignty of local leaders:

> A Zambian traditional leader has fumed over reports that a number of his female subjects who underwent a microbicides gel clinical trials have contracted HIV, the virus that cause AIDS [sic] (Kabange, 2010a)

The close of the trial and the ceasing of its practices, which we have characterised as technologies of government, allowed greater space for the articulation of these counter-discourses in relation to medical research. During its lifetime, the trial created a public of female ‘biocitizens’, constituted within the clinical research as informed, represented, agential. Through procedures such as blood testing, genital examinations, and the collection of demographic and sexual behaviour data, women became governable subjects, endowed with freedom and autonomy, as specified in their signed informed consent forms. After the trial, these technologies of government ceased. Although we do not know what happened to the female trial participants once data on them ceased to be collected, the response to the trial post hoc suggests this form of public was a temporary one, ultimately supplanted by locally prevailing forms of political representation.
Discussion

In this paper, we have argued that the bureaucratic and enumerative practices of clinical trials create publics. In the trial in question, this occurred through the institution of technologies of the self such as regular and repeated self-surveillance in relation to sexual behaviour. These technologies rested on the institution of practical modes of governmentality, including sexual behaviour questionnaires, pregnancy tests, genital examinations, in-depth interviews, and coital diaries. These data collection practices built up and shaped a particular form of trial membership, with the notion of women's agency at its heart. Through such activities, a process of 'rhetorical differentiation and identification' occurred, with those enrolled into the trial discursively and practically differentiated from – and subsequently differentiating themselves from – others. We have suggested that these research-enacted groups share characteristics with what Michael (2009) refers to as 'Publics-in–Particular', and what we choose to call 'experimental publics'.

The particular characteristics that have salience for public health research are the following: Firstly, publics do not pre-exist research activities but are enacted in concert with them. Thus, rather than 'going out to the community', 'engaging', 'sensitizing' or 'mobilising' the community, we should instead focus on the way in which research activities produce new kinds of collectives and, in so doing, co-create their constitutive others. Viewed in this way, the epistemic effects of experimentation come into sharp relief, and it becomes possible to think about eligibility beyond endpoint analyses. In other words, the recruitment of particular groups to clinical trials is not simply a scientific question, but has deep social implications relating to citizenship and representation. Rumours linking Satanism to medical research and community outrage over 'botched' trials suggest the need to think more critically about the constitution of biomedical subjects and publics. As others have argued, instrumentalist models of community consultation and public participation may not be adequate (Kelly, Ameh, Majambere, Lindsay, & Pinder, 2010).

Secondly, publics are dynamic and transient. The case presented here demonstrates the impermanence of techniques of government in the context of global health research and the forms of resistance they can produce. Publics are not created once and for all time in a linear fashion, nor is governance of such publics monolithic. The project cycles of trials mean that resources come and go, and with them, the infrastructures and instruments of governmentality. In this context, trialists should not be surprised by what has been cast as the fickleness or ruthlessness of participants who act accordingly, for example by co-enrolling in trials or 'dumping' study product (Karim et al., 2011). Study subjects are not located in the social vacuum which the randomized controlled trial idealizes; they are situated at the intersection of other forms of inclusion and exclusion, both locally and globally – in the labour force, in familial decision-making, in property rights, and so on. These more permanent social structures need to be taken into consideration in the design of research, even where that research is testing a biological 'magic bullet'.

The idea that research produces effects, and that amongst these effects are the very groups the research is designed to study is not new. The productive work of methods has long been articulated in anthropology (Fabian, 1971), and more recently in science and technology studies (Law, 2004). In relation to medical research, a multitude of studies have described the performative effects of interventions, from the construction of new subjectivities (Nguyen, 2010) to how the production of findings under experimental conditions helps shape their implementation in the clinic (Petty & Heimer, 2011); and how trials enact multiple ontologies upon which their results depend (Brives, 2013). Yet these ideas have been slow to take hold in public health. With this paper, we have wished to re-frame 'the community' in simple terms, bringing to the fore that enumerative practices implicate power relations and that these are amplified by the politics of inclusion and exclusion criteria. Further, that such power relations reshape group dynamics in ways that can be deeply felt yet highly transient. Rather than speaking of the static, singular, and enduring 'communities' that researchers assume pre-exist their arrival, we would do better to speak of 'publics' which are dynamic, multiple and transient, and are enacted in relation to research practices.
Conclusion

In this paper, we have suggested a conceptual shift from ‘trial community’ to ‘experimental public’. Some implications of this move are as follows:

1. Researchers should be aware of the generative effects of enumerative practices such as observation, form-filling, and sample-taking. These apparently mundane procedures demarcate who belongs - and who does not – to this form of public participation. Rather than ‘sensitizing the community’, trialists should think instead about how they contribute to the creation of a particular kind of public and its constitutive outsides.

2. Researchers should recognize the moral and political capacities of the research in which they are engaged, rather than assuming these to be part of a separate domain of action. In practice, this means acknowledging and challenging infrastructures of inequality and being cognizant of them when accepting research funding and selecting collaborators.

3. Researchers should seek to create long-term forms of participation in science, which transcend both the instrumental goals and the individual timelines of specific trials.

These things are already happening in some places some of the time. Our concern is to stimulate a change in focus from communities as the passive recipients of research to publics as actively and dynamically co-created with medical research and its findings.

Notes

1. Pseudonyms are used throughout.
2. This is supported by the 2007 Zambia Demographic and Health Survey (ZDHS) which reports that 65% of men questioned in Southern Province said wife beating is justified and 40% of women in Southern Province had ever experienced physical violence. Across the ZDHS, almost eight out of 10 women who experienced physical violence reported their current or former husband/partner as a perpetrator (Central Statistical Office [CSO], Ministry of Health [MOH], Tropical Diseases Research Centre [TDRC], University of Zambia, and Macro International Inc (2009). 
3. A retrospective analysis of data from the MDP301 trial site in Johannesburg found that more than one-third of the 150 female trial participants taking part in a social science sub-study reported intimate partner violence, of which half the cases were related to involvement in the trial (Stadler, Delany-Moretlwe, Palanee, & Rees, 2014).
4. A small sample of men was recruited to take part in interviews and focus groups as part of the social science component of the trial, but did not enrol as ‘trial participants’ as such.

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