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Editorial

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In this second part to the special issue 'STS and Global Health: Critique and Complicity', we explore some of the issues at the intersections of STS and Global Health raised in the first editorial (3/2017) through a constructed dialogue between an epidemiologist, an STS scholar and a critical activist. Such tongue-in-cheek dialogues and coffee house conversations offer a rough narrative and a fruitful form to tease out some of the different positions involved in encounter of STS and Global Health (see Hirschauer and Mol, 1995; Woolgar, 1989, 1993 for examples of the use of dialogues and conversations in STS). In the postscript to this special issue, Amit Prasad again picks up and further develops the concerns of integrating postcolonial theory and history into STS analyses of Global Health. Prasad urges to deconstruct the discoursive emplotment of 'otherness' and how the west-centric divide –in latent or manifest form- spreads through representations of medical and scientific practices in places that are regarded as non-West.[1]

Coffee time at the conference: The global health complex in action to tackle antimicrobial resistance

Dr. Epi(demiology), Dr. STS (Science and Technology Studies) and Dr. Activist have been sitting all morning in a dark and airless auditorium listening to speakers address the conference 'Global Solutions to Antimicrobial Resistance (AMR): A Joined-up Approach'. As a dazed stream of delegates shuffles out and into the coffee queue, Dr. Epi feels moved to state the obvious about AMR and in the process, strikes up a conversation with Dr. STS and Dr. Activist who are standing nearby. It quickly becomes apparent that said 'joined-up approach' is easier said than done. Can the three delegates reach a solution to AMR by the time the next Plenary starts?

Dr. Epi: AMR is essentially a problem of misuse of antibiotics, so aside from developing new drug products, can we also develop interventions that

solve the problem of misuse and non-adherence to these drugs? For instance, we could use mobile phones or electronic pill counts to curb the problem of non-adherence. There is already some literature showing that these work.

Dr. STS: We can't simply assume beforehand that the problem lies solely with patients not adhering to their drugs! Global Health rhetoric always blames the patients for not going where the technology is; it's a trap to believe that it is never the technology that is at fault.

Dr. Epi: But how can the drugs be at fault here when so much has been spent on R&D?

Dr. Activist: Antibiotics and other drugs are developed and produced through exploitative research processes, that's the problem! There is active exploitation of communities in the Global South, among vulnerable populations, to produce products for the benefit of people in the West. The pharmaceutical industry is rolling out easy solutions! We can see this in so many of the new vaccines. Look at the strains which are included in things like the Rotavirus and flu vaccinations - the strains of the viruses included in these vaccines on the market are not those affecting most of those in the Global South! They are only designed for the benefit of people in the West.

Dr. STS: It's not only the drugs. Just looking at how they work distracts attention from all the processes involved in producing and enacting antibiotics. It is also the public health systems delivering the drugs, with their protocols, guidelines, diagnostic devices, laboratory equipment, treatment categories and monitoring tools that is at stake. Antibiotics are global health technologies that encompass all these things and they in turn have an impact on whether the drugs work or not.

Dr. Epi: Hmm. [Dr. Epi does not look convinced]. But is that not a problem of health system strengthening? And in addition, can we find other technologies which might help us detect misuse and poor adherence?

Dr. STS: Well, a lot depends on how you define a health system and what you include in that category. My point is that technology needs work to function. And what makes it function are factors and elements that you epidemiologists would subsume under the heading 'health system', but it goes beyond that, it also involves the work that patients need to do to access health centres and adhere to their drugs; the work of suppliers and distributors to ensure drugs are in stock and expiry dates matched; the work of the scientists, companies and donors involved in developing the drugs and deciding on components, dosages, marketing and availability. Assuming that Global Health technologies or interventions exist independently of this labour is naive. It does not do justice to the complexity going on here. And it is one of the reasons why many Global Health interventions fail and potentially why we have the problem of AMR in the first place! Not enough attention has been paid to what it takes to make antibiotics work and consequently research has not focused on these components and resources have not been allocated. One of the great strengths of STS is its ability to embrace complexity instead of arguing that complexity needs to be limited or simplified and to understand all the elements that make the technology, drug, and so on.

Dr. Activist: There is a moral problem underlying your approach to complexity. The Global Health complex and your 'complex' approach doesn't acknowledge that these networks are embedded in extremely steep power gradients. The networks are part of global neo-liberalist forms of capital-production that create extractive structures and systems of oppression. Looking at that complexity without a theoretical framework fails to see this and without addressing them makes you complicit in them. The way I see it is that Global Health projects don't alleviate health problems but instead create and re-create them. They allow rich expatriates to do research in fancy places while on some self-defined moral high ground, allegedly looking after the brown poor.

Dr. Epi: I can see why you would say that, but there are people working on health projects who really want to do the right thing.

Dr. Activist: There is no moral exteriority here – even publicly funded research projects are nested in a neoliberal funding structure. Can you deny the dynamics of race and colonialism at play in Global Health? International collaborations are, in effect, capitalizing on the poverty in those regions. They are silent about how to resolve the structures that cause the health problems that they are trying to tackle.

Dr. STS: But to take that argument to its logical conclusion, you are also making a living out of this…

Dr. Activist: (now seemingly offended): I am here to confront the power imbalances that medical research relies on, to address structural violence, rather than to walk in halls of fame.

Dr. Epi: Listen guys, take it easy, can we put politics and ideology aside for a minute and think about how we can solve this? We have people dying because antibiotics are not working and you guys are busy arguing about complexity. Instead, we could spend a minute to create a theory of change about how we can control all the variables of this, in order to change the use of antibiotics globally and…

Dr. STS: Change? We? Change?

Dr. Epi: Yes, obviously. Well, there is only so much we can do, and something is better than nothing! In the end, implementation is the responsibility of countries themselves. And new technologies such as m-health solutions or rapid tests can overcome dysfunctional infrastructure and weak health systems because they allow surveillance, counseling or testing without relying on transportation, laboratory infrastructure and well-staffed clinics… But the way that you talk is too jargony, no-one can follow that. So can we come back to how we can change practice? We are losing time arguing, when instead we should think about policy transfer and impact. I don't think it's enough that we publish in *Lancet Global Health*, so can we think who our stakeholders are? Does anyone know that WHO advisor for AMR, and national advisors? Can we get an appointment with them to organise a quick policy brief to disseminate our findings? Increasingly, that's the future, because if we wait for these systems to be strengthened then thousands of people will die. We need to act now with these technologies to save lives.

Dr. Activist: Your attitude is creating an artificial state of emergency, built on half-baked ideas and ill-thought through positions, which are rushed out onto the world's poor and also costs lives. Nobody wants people to die, but this 'something is better than nothing' attitude creates so many problems. Why can't you accept that the 'something' that you speak about is contingent on all sorts of things, including politics and money, and often has very little to do with the best interest of the sick and dying? Many Ministries of Health are so donor-dependent in dealing with their infectious diseases problems, that they are limited in what they can spend their funds on. And it is often those items that can be counted - like drugs - that are being pushed by the big funders. So, it is the global community of scientists, donors, regulators, drug companies and policymakers that has a considerable influence here! We need to pay much more attention to the critical role of politics in Global Health.

Dr. Epi: But measuring is a good thing! We need evidence-based policies! We don't want to go back to the days when the WHO made policies based purely on expert opinion. We need to know what works, do cost-effectiveness analyses and systematic reviews of the evidence and when there is no data we can model it. Maybe we need more implementation research to address the problems you outlined with 'making antibiotics work'. You social scientists should do that!

Dr Activist: Well, I think that many social scientists will take objection to what you're suggesting here. Social scientists do more than listen and talk and social science methods do not exist solely to research how best to implement your research findings! Besides, there's lots of data that already exists in the social science literature about why people might not take a full course of any medication, including all the work that has been done charting the social lives of medicines. So when you say 'data', I think what you really mean is *numerical* data. I think that what lies at the heart of this is that qualitative data are not taken seriously as providing evidence unless they're collected specifically for each and every research project wanting to implement its particular findings. Well, if you want to talk about a waste of resources we can start with this point… Anyway, coming back to the drug/adherence intervention development processes: the current Global Health intervention designs and products are not relevant to those in the Global South because they fail to understand the local context. Southern partners are excluded from the design process and Northern partners have all the say. As I said before, these are historically-based structural processes that have not changed much from colonial times!

Dr. STS: Clearly technologies also embody assumptions about the users, norms, values, and logics of the places that they are designed in and for. We saw this with the latest Ebola outbreak. Tracking mobile cell phones was supposed to be the answer to all the problems and they were supposed to be used as a means of keeping track of people and the epidemic as it unfolded. Yet we now know that many people in the Global South have a different relationship to their phones to those in the Global North, where one person owns one phone and that phone is closely tied to their personal identity. In West Africa, it is common to have more than one phone with multiple sim cards. So depending on who is involved and consulted, design and implementation choices differ.

Dr Epi: OK, point taken, community engagement is needed in order to cope with AMR. I would suggest that we reach out to patients and members of the public and ask them.

Dr. Activist: Community engagement does not exist to mop up your poorly thought-through projects. Besides, are there any community members at this conference?

Dr. Epi: Ahem… the organisers should probably have invited patient representatives and clinicians.

Dr. Activist: Even if they had, I've been to those kinds of meetings and - no offence intended - but they are nearly always with nursing mothers and the elderly unless they're with 'hard to reach' groups, in which case you get these expert participants there to make a living out of their identity. Very little proper consultation takes place with a wide range of people, including working professionals. Honestly, I've heard scientists working in areas with close to 300,000 people talking about a handful of people as community engagement representatives without saying how those people were selected! Why that handful and not another?! When quizzed they always say things like "these reps were chosen by the community", so creating a circular problem around what a community *is*, such that it can select these handful of reps! So-called participatory research is also exploitative if people in the Global South are taken advantage of as tokens for community engagement activities. As such, it is yet another neoliberal gesture that by-passes the state in favor of philantrocapitalist Global Health actors. Unless it is activist, citizen science, and led by communities on their own terms, it remains exploitative. Because how can communities in the Global South take part in these processes? The rules have already been set by the Westerners and are not easy to comply with if funding or capacity is scarce. Also, certain forms of scientific knowledge count more than others, but require research infrastructure, funding and access to journals.

Dr. Epi: This is why research capacity building is so important! And it is a very clear policy recommendation: build local research capacity to deal with the AMR threat.

Dr. Activist: Well I think, that before we go any further it's important for you to know that many people prefer to use the concept of capacity *strengthening* as it suggests that there is already some capacity there, whereas as *building* gives the impression that there is nothing there to begin with. Anyway, yes, capacity strengthening is important, but the form it takes is just as important. If you're going to provide training to healthcare staff to use a specific piece of technology which helps them to detect the active pharmaceutical ingredients in each batch of antibiotics they receive then it's possible to argue that this is capacity strengthening. But is it the most effective use of resources, and are transferable skills being developed here?

Dr. STS: Communities of patients and healthcare workers are not the only users of AMR technology or interventions that matter here. I feel like I'm repeating myself. Donors, distributors, technicians, scientists, policymakers, guideline makers, regulators, and so on also matter. You need to think about your non-users as well, like the private doctors, who in many countries are treating the majority of patients when they first seek care. Besides, why is it always the capacity of those in the Global South that needs strengthening? Surely, in the interests of symmetry we should also be talking about strengthening the capacity of the scientists and those in the Global North to appreciate how technologies and drugs work in the real-world.

Dr. Epi: You really like to make things more complicated! How should we practically involve all these people in our research projects? Who should pay for this? Where should they meet?

Which countries, regions and social strata should they be from? They will never be representative of all users! And what if they do not reach consensus? I understand that we need to incorporate the preferences and values of patients and clinicians into guideline development processes and ideally also get some feedback from them in the development of new drugs and interventions. Social scientists should do more studies on preferences and values that we can use in global guidelines and decision making processes, and we could make an argument for generating more funding for those kinds of studies alongside trials. But beyond this, shouldn't we leave technical design decisions to the technical experts and subject the outcomes to proper scientific evaluation? We can then optimise roll-out with implementation research studies after the technologies have been designed.

Dr. Activist: Not only are such ideas based on a top-down notion of expertise (most likely also white, male and middle class), and a hierarchy of knowledge, they are also based on ideas about diffusing technologies and interventions that rely on a techno-cultural construction of the 'West versus the Rest'. To subvert these structures would take a lot.

Dr. STS: Hold on, social science research produces proper scientific evidence! It's just not handled as such by the Global Health community, which is obsessed with trials and systematic reviews! Have you ever tried to publish a social science piece in the *Lancet Global Health*? I mean 3,500 words! Besides, all scientific practice is localized and situated and so is enacting technologies. It's essential for the Global Health community to recognise this, since its mission is to develop technologies that work across different places.

Dr. Epi: Ok, ok, I'm starting to be convinced by your arguments that there's more than one way of thinking about AMR. But what does this mean in plain English and practically-speaking? How would you intervene to save people's lives?

Dr. STS: We cannot establish a norm as to what types of technologies (whether fluid, locally or participatory designed, or not) travel well from one place to another - this is always a question of how the different elements that enable the technology to function interact. And then different actors might define the success of a technology or intervention differently. There are just no magic bullets. While all practices are situated there are also stabilizing and standardizing elements across situations and time. STS scholars have also argued we shouldn't take Global Health technology for granted, but should problematize it in terms of how the local and the global relate to and are reconfigured by each other. How do different actors talk about the local and the global and how are these discourses tied into specific practices? Answering these questions requires more than qualitative interviews as off-shoots of scientific projects; we would need detailed ethnographies of Global Health technologies and interventions across local and global sites over longer periods of time.

Dr. Activist: On this we agree. If someone could point me to a bigger oxymoron than the phrase 'rapid ethnography' I would be most grateful. What we're talking about here really needs detailed, theoretically informed ethnographies!

Dr. Epi: So your proposal is to include more and more varied ethnography? Are you not running the risk of producing a new knowledge hierarchy? Should everybody just listen and follow ethnographers' interpretations and advice, instead of the RCTs and systematic reviews by epidemiologists? What you Dr. STS seemed to say earlier would suggest something else, more like broad, interactive interventions that would place those involved with development, evaluation and implementation of Global Health technology, ethnographers and local knowledge on the same footing in seeking to improve antibiotics treatment adherence and prescription across the local health practices and related actors. This could be a viable strategy for creating something long-lasting and truly inter-disciplinary. What do you think?

The three delegates finally reach the end of the coffee queue, just as the call for the next Plenary is announced. Dr. Epi stumbles into her friend Dr. Health Economist and before she leaves she turns to Dr. STS and Dr. Activist: "Just think about it, we could start something together, we could apply funding to do just that". Though hesitant at start, Dr. STS and Dr. Activist see the potential of collaboration for changing Global Health from inside, and the intellectual challenges this would bring. Dr. Activist feels vindicated; he takes a cup

of Cafédirect Fairtrade Columbian coffee and returns to his seat on the edge of the auditorium. Dr. STS looks at the available options on the table; she can't decide between Café direct Fairtrade Columbian coffee and Twinnings English Breakfast tea. Within herself, she is worried that her position could become more exploited, and that her sure footing is potentially lost for good.

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Notes

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Knowing Pandemics: An Investigation into the Enactment of Pandemic Influenza Preparedness in Urban Environments

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Abstract

How does microbial emergence become a local area of medical, political, and technological intervention in cities such as London or Frankfurt? Through a multi-sited ethnography of urban health authorities, hospitals, blue light services, and epidemiologists, this article examines the achievement of pandemic order in times of crisis. Its specific focus is on pandemic influenza preparedness. By tracing the complex spatiotemporal, technological, and administrative dimensions required for the articulation of a local pandemic threat, this paper will look at how public health experts know about the arrival of an influenza pandemic, how sociotechnical networks are assembled in the decision-making process, and how single cases of illness are drawn into spaces of pandemic potential. Integrating concepts from science and technology studies and critical global health, the article highlights how disease emergence entails hard work and administrative, technological, political, and biomedical skills in order to be made present and tangible. In consequence, it will be argued that local pandemic preparedness does not result from a linear adaption of internationally circulating standards, but from rather precarious modes and modalities of ordering.

Keywords: influenza preparedness, emergency planning, global health

Introduction

This paper is about the enactment of influenza preparedness in the cities of London and Frankfurt. Specifically, it offers insights into how seemingly global microbial circulation processes are entangled with emerging practices of risk management and urban governance through complex sociotechnical networks, thereby initiating specific pandemic orderings that determine what can be seen, known, or said within the social context of emergency planning (see Hempel, 2011: 9).

To discuss how local spaces of pandemic potential emerge, the paper combines insights from critical global health scholarship and the literature on technologies of biosecurity, risk, and infectious disease surveillance. It employs the concepts of preparedness and enactment (see Mol, 2002). First, the preparedness: what does preparedness mean in a global health context? Second, the enactment: how are pandemics enacted?

Pandemics, by definition, are considered global events (Last, 2001: 179), believed to impact human health, and economic and political wellbeing on a global scale. They are problematised in the context of global health discourses. Anthropologist Andrew Lakoff (2010: 59) reminds us that "different projects of global health imply starkly different understandings of the most salient threats facing global populations, of the relevant groups whose health should be protected, and of the appropriate justification for health interventions that transgress national sovereignty". Thus, nowadays, the management of pandemic crises is believed to overwhelm the capacity of national public health systems. Current modes of global health security, as Lakoff (2010) argues, rely on compliance from national governments in establishing preparedness measures tailored to potentially catastrophic pandemic threats. However, pandemic preparedness is not only a high priority political rationale, it also assembles medical and security measures, providing a framework to be implemented in local, national, and international preparedness plans.

Pandemic preparedness is often described as a source of friction between the numerous voices, interests and policies in the area of global health (see Wallace, 2009): economic concerns arise around the disruption of financial flows, the imposition of travel bans, and the impact of factory farming on viral emergence. Political debates problematise different modes of knowledge production, big data, and biosecurity issues. Controversies develop surrounding the efficiency of pharmaceutical intervention. Among the many voices evolving in the area of global health, the World Health Organization (WHO) has certainly played a key role. Shortly after the emergence of SARS and highly pathogenic avian flu viruses in 2005, the WHO cautioned against the security threats posed by microbes with pandemic potential. In the World Health Report 2007, WHO Director-General Margaret Chan stated:

> These threats [of infectious disease emergence and antimicrobial resistances, MW] have become a much larger menace in a world characterized by high mobility, economic interdependence and electronic interconnectedness. Traditional defences at national borders cannot protect against the invasion of a disease or vector. […] Shocks to health reverberate as shocks to economies and business continuity in areas well beyond the affected site. Vulnerability is universal. (WHO, 2007: 2)

In a 2015 interview with Science magazine on the lessons learnt from the 2014 Ebola outbreak in West Africa, Chan reflects on international outbreak response measures:

> Countries that are affected by an outbreak should be transparent and report their diseases. Countries that are not directly affected should not impose trade or travel measures over and above what is recommended by WHO. This is part of the International Health Regulations [IHR], an international treaty with the good intention of building a collective defense system against a common threat. But the implementation of the IHR is very poor; there is a lot of disincentive. Why should I report? The minute I report, you impose a trade ban and travel ban on me. That is why we need to review the IHR and change them to provide incentive instead of disincentive. […] We can encourage countries by telling them: "We will help you out but not just to contain the outbreak." After the outbreak is done, we will do a gap analysis, together with the government, and bring in supporters, donors, to help them build a health system that is better capable of detecting an outbreak. (Science, 2015)

As vulnerability is portrayed as universal, pandemic preparedness has become a *global* enterprise. Nowadays, international global health experts agree that there is a need for international and transdisciplinary cooperation to successfully combat, contain, and monitor emerging pathogens. As determined by the IHR 2005 outbreak management has altered priorities, away from containment measures at entry points such as airports and seaports, towards rapid response at the source of an outbreak. Now, all countries are encouraged to meet a set of "core capacity requirements […] in order to detect, assess, notify and report the events covered by IHR" (WHO, 2013). Although the WHO has no legal means of ensuring compliance, the report assures that compliance is in countries' best interest as through the proper detection, assessment, notification, and reporting of outbreak events the

country in question is supposed to be capable of containing the outbreak and reducing its disruptive impact (while this is also believed to maintain the country's "good standing in the eyes of the international community", WHO, 2007: XV)[1].

From a global health perspective, then, pandemic preparedness might be understood as a – necessary – response to microbial messiness[2]. Yet, on the other hand critics rightfully claim that microbial 'emergence' is neither a natural phenomenon, nor a mere consequence of a growing interconnectedness: pathogens do not suddenly 'emerge' somewhere, for example in the backyards of Southeast Asian poultry farmers. Rather disease emergence depends on enacting specific analytic and sociotechnical frameworks: classifications of emerging infectious diseases are contingent on certain conditions (Farmer, 1996; Grisotti and Ávila-Pires, 2010): to be classified as emergent, a pathogen needs to be linked to a specific disease (for example bird flu), to a vulnerable population (for example young children), to surveillance systems (for example the Global Influenza Surveillance and Response System), and to a territory (for example the UK). In order to fulfil their function as classificatory categories, categories need to be "discrete, measurable and definable" (Abeysinghe, 2013: 922; Bowker and Star, 1999). Also, emerging microbial agents depend on political and normative frameworks to be articulated, problematised and transformed into microbial risks that can be known, managed, calculated, or visualised (Collier and Lakoff, 2008: 9–12; Barker et al., 2013). As such, pandemics and politics are closely entangled, as a pandemic is "not an event out there, but a decision to be taken" (Guggenheim, 2014: 9). This article aims to contribute to this discussion by scrutinising how exactly these decisions are made in the face of microbial and scientific uncertainty, and how global health knowledge on emerging pathogens is enacted, contested, and circulated. Engagement with knowledge and uncertainty from an STS-informed perspective helps question the dichotomy between an object to be known (the pandemic) and the knowing subject (public health experts; see Mol, 2002). It also helps to de-naturalise the event-like character of a pandemic (see Guggenheim, 2014) and essentialist assumptions about disease emergence. In her critical account on the WHO alert phases, global health scholar Sudeepa Abeysinghe (2013) shows how the reality of the 2009 H1N1 pandemic failed to match the classificatory categories as employed by the WHO, stressing the discrepancies between the rarity, variability and flexibility of pandemics on the one hand, and the stability, risk-based and formalised nature of classifications on the other hand.

From a social science perspective, influenza preparedness is a modality of future-oriented emergency or resilience planning. Preparedness relies on actors, and it relies on the anticipation of risks. Following geographers Peter Adey and Ben Anderson (2012), preparedness can be understood as an apparatus of security, building on a series of devices, practices, discourses, technologies, and standards: "Preparedness does not obey a single logic of performance. Underpinning preparedness […] are rationalities and logics of security performed through techniques of risk management" (Adey and Anderson, 2012: 101). In a related notion, Anderson (2010) argues that anticipation does not seek to eliminate uncertainty, but to invoke a potential future. This future is subject to governance approaches. As such, the concept of preparedness is closely related to other concepts in the world of emergency planning: resilience, contingency planning, anticipatory action, and risk management. In her empirical work on influenza preparedness in Israel, anthropologist Limor Samimian-Darash (2013) argues that preparedness as a set of technologies is distinct from these other approaches in so far as it mobilises a *potential uncertainty* in which several possibilities might emerge simultaneously: "Potential uncertainty is like a question no answer can suppress or saturate. In this sense, potential uncertainty is not equivalent to the unknown future but is linked to the intermediate space between what has occurred and what is about to occur" (Samimian-Darash, 2013: 3). Here, preparedness relies on uncertainty to govern a future that cannot be cut down to calculable forms (see also Abeysinghe, 2014). Preparedness, seen from this perspective, is distinct from other scientific practices (such as risk management) that depend on the eradication of uncertainty in order to establish *facts* (Fleck, 1980).

As a political concept and rationale, preparedness has attracted much scholarly attention, and numerous publications have displayed its close relationship with biosecurity issues (Collier and Lakoff, 2008), addressed the politics inscribed into security technologies (Ellis, 2014) or analysed preparedness in connection with disaster management programmes in more general terms (Tironi et al., 2014). By combining historical accounts of previous pandemics with insights into experimental microbiological research, anthropologist Carlo Caduff (2015: 177) sketches how public health discourses cumulate in a pandemic prophecy, articulating a "total threat, affecting everyone". Geographical research has been particularly productive in stressing the tensions between "fixity and movement, territory and circulation, centralised control as well as redistributions of responsibilities" underlying current approaches of preparedness and precautionary action (Hinchliffe and Ward, 2014: 137; see also Donaldson, 2008; Enticott et al., 2012). Policy transfer studies have illustrated how political ideas wander into scientific contexts where they seem to offer 'technological' answers to specific problems (Walt et al., 2004), and they have questioned the assumption that health policies are integrated 'rationally' into decision-making processes, meaning to construct uniformities across time and space (Timmermans and Berg, 1997).

However, little is known about how global ideas of prevention and influenza preparedness are achieved and *practised* locally through networks consisting of a range of diverse actors – which brings us back to the second point made at the beginning of the article: enactments. Preparedness as a practice has a time and a place. It is something that people do. Working at the intersection of global health policies and the sociotechnical preparedness apparatus, I am particularly interested in this *doing* of preparedness, in the actors involved with it, and in the specific forms of cooperation and translation they are creating. This paper looks at how information is gathered, managed, circulated, and consumed. Consequently, other preparedness practices, such as the stockpiling of antivirals, or the mobilisation of economic resources, will receive less analytical attention.

As urban environments are commonly portrayed as being more prone to infectious disease outbreaks than other areas (due, among others, to high population density, global connectivity, and often poor sanitary conditions; see Alirol et al., 2011), they seem to be a good starting point for research on pandemic preparedness. The boundaries and 'borderlands' (Hinchliffe et al., 2012) of cities are often perceived as potentially fragile and in permanent need of maintenance, stressing cities' crucial role in responding to global health challenges. This article is about the enactment of pandemic influenza preparedness in London and Frankfurt. Being two of the most important international mobility hubs, these cities have implemented a thorough (though different) planning framework. Both accepted their assumed vulnerability as mobility hubs, important business locations, and tourist destinations. Both assemble a broad range of things, people, technologies, biological matter, and information to make their city resilient and prepared. Also, both cities are embedded in very different social structures and different political frameworks.

Through a multi-sited ethnography of urban health authorities, hospitals, emergency services, and epidemiologists in Frankfurt and London, this article examines how pandemic preparedness measures are enacted in these two urban environments. It looks at what Adey and Anderson (2012) call the *life* of an apparatus of security, so instead of arguing about the need for preparedness, or analysing its strategic goals, this article focuses on how to understand the sociomaterial contingencies of pandemic preparedness. Obviously, a pandemic does not merely happen – there is no single objective and reliable parameter that determines the arrival of a pandemic virus in geographically confined areas. Although the influenza virus engages in manifold relationships with other organisms, it is invisible to the human eye. Flu symptoms are similar to symptoms caused for example by pneumonia, a common cold, or other infections. The progress of the disease may differ from previous epidemics. Patients with flu-like symptoms do not undergo routinised virological screening. When taken together, *knowing* that a city is struck by pandemic flu constitutes a complex sociotechnical process. It can never be

pure knowledge. If we do not presume pandemic influenza to be "an event out there" (Guggenheim, 2014: 9), and if we take seriously Theresa MacPhail's (2010: 59) postulation that "scientific authority persists not despite uncertainty, but *because* of it", the question as to how experts *know* about the arrival of flu becomes more pressing. With Annemarie Mol (2010) I believe that the term 'co-ordination' is helpful here

> … since it does not evoke a single, overarching and coherent order in which everything fits just fine and friction-free like the bits and pieces of a mosaic or the components of a watch. Instead, the term co-ordination suggests continuing effort. Tensions live on and gaps must be bridged, hence the need for 'co-ordination'. Coordinating efforts may take many forms. […] Even keeping potentially competing versions of reality (or modes of ordering, or logics) out of each others' way – by distributing them over different sites – may be glossed as a form of co-ordination. It helps, after all, to avoid confrontation and, along with that, chaos. (Mol, 2010: 264).

In this sense, microbial messiness has to be transformed into a pandemic order. What follows looks at how this order is achieved.

The paper will do so by considering, first, the spatiotemporal framework that translates microbial emergence into a pandemic. Against this backdrop, it will be discussed – in a second step – how individual cases of illness are fed into surveillance systems and thereby achieve visibility. Third and finally, the last subchapter deals with the question of how individual concerns result in the local raising of alarm. In short, how are we to understand the material contingencies of pandemic preparedness?

Methods

The article is based upon a four-year multi-sited ethnography of pandemic preparedness as it is practised in the cities of Frankfurt and London (from October 2011 to September 2015). The study design includes comparative elements, although it is not conceptualised as a comparison of two distinct settings along abstract and, presumably, universal categories. Comparability, however, is not an intrinsic quality of ethnographic settings. Comparability has to be achieved (see Sørensen, 2010). I established comparability by defining the concept of influenza preparedness as a quality common to all research settings. Local and national health authorities and the lab were chosen as research settings. I then searched for common patterns and differences which organised how preparedness is practised, achieved, contested, or modified in the different field sites. The ethnographic approach therefore builds upon conceptual and spatial movements between the field sites.

As preparedness is difficult to localise, the pandemic influenza response plans of both cities provided the starting point for the research. The focus of the study was on *urban* preparedness. By approaching the numerous individuals and institutions who contributed to the document, I tried to unravel the complex sociotechnical relationships underlying these plans. From there on, I followed experts in settings as distinct as a virology lab, a warehouse, or the underbelly of a hospital, and tried to understand how they enact preparedness – socially, professionally, and materially – in their respective institutions. Being employed as an anthropologist at a German university, I was willingly invited to perform observations in multiple settings in Germany. Things in London were much more complicated. Invitations to participate in emergency exercises were withdrawn; interviews cancelled or postponed; many emails left unanswered. In consequence, I was thrown back on interviews and occasional observations as the main means of investigation in the UK.

The study combines 67 qualitative expert interviews, participant observations, and document analysis as its main methods. It has been conducted with the help of the project's research assistant Kevin Hall. Experts were approached from local, regional, national, and international health authorities. Experts include people – mostly medical doctors or former military members, but also a small number of nurses, microbiologists, and journalists – working within urban health authorities, the media, blue light services, hospitals, airports, public transport organisations, and other institutions commonly referred to as 'critical infrastructures' (as defined by the European Commission, 2008)[3]. These experts ful-

fil the functions of emergency planner, pandemic flu lead, business, security or resilience manager, director, scientist, or coordinator. Consequently, most occupied leading positions. Participant observations, with a duration varying from one day to three weeks, were conducted in a virology lab, during a vaccination programme, at medical congresses, at team meetings, and on four emergency exercises. The research team worked its way through an extensive amount of pandemic plans, guidelines, and medical publications. Some empirical work was performed as a team – including myself and Kevin Hall – while other parts were based on a division of labour between the two of us.

The interview transcripts and field notes were coded, organised and analysed using f4 and ATLAS.ti software. Eight categories were identified (see Glaser and Strauss, 2008): emergence (1), measures taken (2), achieving preparedness through local networks (3), management of information (4), self-assessment (5), historical and institutional background (6), planning assumptions (7), and risk (8). This article is based on research findings summarised under the categories 'achieving preparedness through local networks' and 'flows of information'. For each of them, a number of first order categories were assigned. 'Achieving preparedness through local networks' included the categories of local needs, different roles, how things work within the network, conflicts and how to solve them, networking, raising the alarm. 'Flows of information' was categorised into planning assumptions, filtering information, information infrastructures, and friction.

As the empirical data collected throughout these four years are complex and manifold, this article does not claim to present an exhaustive overview over the whole project. Instead, it focuses on those interviews and observations concerned with the translation of abstract global threats into local risks to be known, assessed, enacted and integrated into pandemic planning measures. Its main focus is on London, with the case of Frankfurt being used at the end of each paragraph to illustrate briefly how preparedness is practiced differently (or similarly) in Germany.

Pandemic preparedness in London and Frankfurt: facts and frameworks

In the UK, the anticipation of future threats runs under the rubric of preparedness and resilience, both of which aim to secure cities against terrorist attacks, power failure, and 'natural events' such as flooding, stormy weather, heat waves, or the emergence of infectious diseases. Preparedness is embedded in a larger framework of generic planning approaches. This is how the Greater London Authority (GLA) explains why London needs to be prepared:

> London is generally a very safe place – however there are a number of hazards and threats that could impact the city, and the people and businesses based there. […] In the London Resilience Partnership, we want to make sure that if a major emergency does affect the capital, we are ready to respond and work together to help minimise any impacts. […] When we talk about a 'major emergency', we use the definition given in the Civil Contingencies Act (2004), which is:
>
> - an event or situation which threatens serious damage to human welfare;
> - an event or situation which threatens serious damage to the environment; or
> - war or terrorism which threatens serious damage to security
>
> Our Strategy defines resilience as: the ability to detect, prevent and if necessary to withstand, handle and recover from disruptive challenges. (GLA, 2015)

In London, preparedness is located in collaborative arrangements representing the functional elements of the city (ranging, among others, from blue light services to water, media, transport, and power). These are organised within the London Resilience Partnership, consisting of about 170 widely heterogeneous organisations, and the London Resilience Team, reflecting a legal requirement as implemented in the Civil Contingencies Act of 2004. The members of the multi-agency partnership meet regularly, even in the absence of acute crises. While some are dedicated influenza specialists, others are trained as emergency planners or business continuity managers and,

therefore, coordinate the response to different incidents, not just pandemic influenza. The planning framework is determined by the London Resilience Pandemic Influenza Response Plan in its sixth version (GLA, 2014), and complemented by specific plans for Public Health England and the NHS. In the UK, the decision about the respective response phase is taken nationally and communicated to the local authorities, who might then decide on which response measures to spur into action at a regional or local level.

Until 2011, the UK had adapted the linear scheme of escalating phases as depicted by the WHO (a more linear approach was mirrored by the earlier UK National Framework of 2007). The deviation from this concept is often described as one of the most important 'lessons learnt' through swine flu:

> Although the World Health Organization (WHO) is responsible for identifying and declaring influenza pandemics, the UK was well into the first wave of infection when WHO declared a pandemic in 2009. The use of WHO phases to trigger different stages of the local response were considered confusing and inflexible and it was decided to develop a more flexible approach, not driven by the WHO phases and determined nationally was needed for the UK. (PHE, 2014: 12)

Underlying this statement is the belief that pandemic realities might not be congruent with preceding planning assumptions. Additionally, pandemic planning in London in its current form does not represent the final stage of a linear adaption or transfer process. Rather, my fieldwork coincided with the reformation of the UK healthcare system, which impacts on the work and routines of local emergency planners: agencies and institutions disappeared, merged, were newly established or renamed, responsibilities shifted, as did trusted colleagues. At that time, institutional routines, essential to the articulation of pandemic preparedness, had not yet been settled. In addition, some of the current plans came under revision, while other agencies – such as Public Health England – started to develop new plans.

In Germany, pandemic planning is embedded in a different planning tradition that draws upon the rationales of infection control ('Infektionsschutz') and civil protection ('Bevölkerungsschutz'). German constitutional law determines that the federation is responsible for defence against threats such as fires, flooding or war-related hazards. The origins of preparedness planning in Frankfurt can be traced back to the mid 1990s, when Ebola outbreaks in Africa caused concerns among local public health experts, triggered by the city's close proximity to the international airport. One hospital in particular sought guidance from the federal public health agency on how to handle patients with Ebola who might enter the hospital's A&E department. A task group for epidemic disease control ('Arbeitsgruppe Seuchenschutz') was established. Around 1999, when the WHO published their first pandemic preparedness plan, the task group proceeded to develop a first scheme for the management of pandemics in Germany (Fock et al., 2000, 1999).

Only shortly thereafter, some of the members of the *Arbeitsgruppe* started to expand their planning assumptions, and to adapt them to the local needs as articulated by public health and emergency planning experts in Frankfurt, resulting in the first local preparedness plan in 2008. Pandemic planning in Frankfurt, however, is not part of a generic planning approach, but constitutes a distinct area of intervention, lying within the centralised responsibility of the local health authority ('Amt für Gesundheit'). Consequently, the local task forces and work groups preparing for infectious disease outbreaks in Frankfurt are led by the local health authority. They also meet regularly, but they do not constitute a multi-agency partnership, and they do not plan for other incidents, such as power failure. Here, the legal framework of planning is settled by the 'Katastrophenschutz-Dienstvorschrift DV 100' and attributes the operative and tactical leadership of disaster management to the Amt für Gesundheit (Stadtgesundheitsamt Frankfurt am Main, 2008: 7). It is the Amt für Gesundheit, together with the mayor, who acts autonomously in declaring that a pandemic has arrived in the city.

Both cities are among the most import global business locations. In the UK, financial services are categorized as essential services and assigned the same importance as food, water, transport, energy, health, and telecommunications. They are represented in the local resilience forums (Civil Contingencies Secretariat, 2013: 34). Although planning in Frankfurt obeys a different institutional logic,

local emergency experts frequently stressed the importance of the Frankfurt trade fair: pandemics endanger the circulation of financial flows. Nevertheless, the financial sector is largely absent from our material. It is not an intentional absence. Rather, we had difficulties in accessing the inner circle of emergency planners within the financial sector and the pharmaceutical industry in both countries[4]. While resilience planning is supposed to obey the rationale of transparency, some parts of the planning seem to be more transparent than others. However, it is necessary to remember that when disease threats are articulated, many other subjects, interests, and policies are present on the scene. What follows in this article considers those very aspects of pandemic preparedness that cannot be reduced to the conceptual guidelines found in pandemic preparedness plans.

Results

Translating microbial emergence into a pandemic event: spatiotemporal dimensions

This subsection starts with a brief consideration of the spatiotemporal dimensions of an influenza pandemic. How does the planning framework articulate the emergence of not just any, but a *pandemic* virus?

As described above, pandemics are considered global events. The development of a pandemic has been objectified into six phases, each mirrored by the escalating response scheme of pandemic preparedness (see WHO, 2015; ECDC, 2015). The pandemic's temporal dynamic manifests itself in the specific chronology ascribed to the development of the event: it escalates. The pandemic phases are each characterised by the boundary-breaching mobility of the virus a) to cross the species border by mutating from an animal virus into a human-animal virus, and b) to spread from 'community-level outbreaks' to other regions. By obeying a spatial logic of regions, as geographer Stephanie Lavau (2014: 8) describes, virological surveillance "produces a well-bound virus that moves from body to body, and place to place. The threat […] is one of incursion, of moving into places and bodies it should not, such as disease-free zones or poultry". The movement of pandemic viruses is portrayed here as a movement from disease-free communities into those already infected with the flu: it is depicted as expansive and reflexive of the virus' natural properties. Community-level outbreaks in no less than two countries in one WHO region equal phase five, while phase six is defined by further community-level outbreaks in at least one other country in another WHO region. Boundaries here are geographical borders that constitute territories and institutional responsibilities[5].

Table 1. WHO pandemic phases (derived and modified from WHO, 2015).

Phases	Description
One	No animal influenza virus circulating among animals has been reported to cause infection in humans.
Two	An animal influenza virus circulating in domesticated or wild animals is known to have caused infection in humans and is therefore considered a specific potential pandemic threat.
Three	An animal or human-animal influenza reassortant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.
Four	Human-to-human transmission of an animal or human-animal influenza reassortant virus able to sustain community-level outbreaks has been verified.
Five	The same identified virus has caused sustained community level outbreaks in two or more countries in one WHO region.
Six	In addition to the criteria defined in Phase Five, the same virus has caused sustained community level outbreaks in at least one other country in another WHO region.

While the WHO definition of pandemic phases aims to set a global framework for the understanding of and response to pandemic dynamics, not all countries are eager to adopt this framework – the declaration of a pandemic and its respective phases still lies within the responsibility of the WHO on a global scale. In the UK, a (post swine flu) national decision was taken to adopt a planning framework that is not driven by the WHO phases, but determined nationally. Public Health England (PHE) describes the UK response phases as follows:

> The UK approach uses a series of phases: detection, assessment, treatment, escalation and recovery (DATER). It also incorporates indicators for moving from one phase to another. […] The phases are not numbered as they are not linear, may not follow in strict order, and it is possible to move back and forth or jump phases. There will also be variation in the status of different parts of the country reflecting local attack rates, circumstances and resources. (PHE, 2014: 12).

The approach has been made flexible and detached from international frameworks, strengthening national decision-making processes. Similarly, the influenza pandemic preparedness plan in Frankfurt has been adapted to local needs, rather than simply mirroring the WHO phases. In its current version, the pandemic phases, as declared by the WHO, have to be evaluated on the basis of whether cases are occurring locally ("intern: in FFM/Deutschland"), or abroad ("extern: im Ausland"; Amt für Gesundheit, 2012: 11). Depending on the cases' geographical locations, a different set of response measures will be spurred into action. But other than in London, decision-making processes have strong local and federal links and weaker national ties. Although the spatiotemporal framework developed by the WHO is essential to make meaningful statements about pandemic viruses in both settings, the global declaration of a pandemic is not enough to activate the full range of local response measures in London or Frankfurt: technological dimensions are of equal importance.

Translating infection into data: technological dimensions

As described above, microbial mobility is contingent on classificatory schemes, assembling scale, temporal dynamics, and microbial mutability, in order to be translated into pandemic events that *matter*, to borrow Caduff's (2015) expression. Against the backdrop of a pandemic, singular cases of illness and symptoms are drawn into local spaces of pandemic potential through diagnostic algorithms, syndromic surveillance, and diagnostic laboratory tools. Viruses are invisible to the human eye, travel within the bodies of their host organism, and might be present without causing any symptoms. The vast majority of viruses pass undetected. Therefore, it is by no means clear how and when an emerging pathogen arrives in a country such as the UK or Germany. It is also unclear how emergency planning experts know about this arrival. Although the simple answer might be "surveillance systems tell them", there is more to this than meets the eye. Science and technology studies have taught us that knowing is a practice (Law and Mol, 2002). To *know* that a pandemic virus has crossed national borders and arrived in a country, several actors, conditions, and events have to be in place: the 'detection' of the virus depends on devices and actors.

As the mobility of viruses is closely linked to the mobility of their human or animal host, influenza surveillance practices target the host population – not the virus itself. The following examples are derived from the London field sites and illustrate the assembling of the sociotechnical means necessary to make infections tangible and manageable.

First, a virus needs to meet the body of a human host. This host might be a receptionist living in Uxbridge and commuting to Central London. During her ride on the underground Piccadilly Line, someone sneezes right beside her. The sneezing releases droplets, containing mucus, flu viruses, and other microbes. One virus finds its way into her nose. Ventilation introduces it into her lung where the virus attaches to her respiratory epithelia. The receptionist is now a potential host. Virus particles bind to receptors on the host's cells. The receptionist's body then releases IgA antibodies and produces mucoproteins, but her immune

response is unable to fight the viral invader successfully[6]. As the virus finally releases its RNA into the host's cytoplasm, viral replication is initiated. Within hours, the host's respiratory epithelial cells produce a large number of virions, soon infecting neighbouring cells (see Behrens and Stoll, 2006: 92–100). Two days later, the receptionist falls ill from the flu. She feels unwell and develops a fever. Soon, her feeling unwell will be integrated into syndromic surveillance systems as she adopts her patient role, calls in sick at work and goes to the local acute service to seek medical advice. At the admission, medical staff make a syndromic diagnosis at presentation, perhaps supported by laboratory diagnostics, as an infection control expert at a local hospital explains:

> In the low season we would try specifically to make a virological diagnosis. So respiratory specimens and then laboratory diagnostics, specifically looking for flu. We try to keep that going for as long as we can in times of laboratory pressures. But if there were a major outbreak with very, very large patient throughput, then we would shift to a syndromic algorithm rather than laboratory confirmation. (Infection control manager, 2013)

Such a virological diagnosis represents a non-sentinel sampling. From this doctor's explanation it becomes clear that each influenza phase enacts a distinct kind of knowledge. There might be things and practices "integral to" this process of knowledge making, but not "integrated within" it (Hinchliffe and Lavau, 2013: 262). In times of pressure, a diagnostic algorithm comes into play. It is provided by the Health Protection Agency (now Public Health England) and includes questions about severity and duration of symptoms. If the patient feels "non-specifically unwell", she might challenge the hospital's triage and isolation plans:

> [In-hospital transmission] was very... It was difficult to track. […] I guess the one thing it really highlighted though was the problem of... picking patients after admission. So it was very easy picking them up if they came in to admission with respiratory symptoms. The ones that... proved a problem were the ones that came in non-specifically unwell... and then became an obvious respiratory case after they got to the wards. (Infection control manager, 2013)

Here it is described how different forms of symptoms are distributed across different hospital sites, multiplying the receptionist's flu-ridden body. Ideally, the patient's symptoms such as 'coughing' are translated into standardised syndromes: the receptionist has now become a 'respiratory case'. Different sites are bridged. The data will be fed into a computer system used to triage hospital patients and to monitor the local disease situation. If laboratory pressures are low, nose and throat swabs of the respiratory case will be taken, put into a small transparent plastic tube, labelled, packaged, and sent to the lab. Local surveillance systems include not only the data-based monitoring of respiratory activity through the hospital, but also networked connections to other agencies:

> We have our hospital data from our own laboratory. So we do viral diagnostics. And we can see when we are starting to get an increase in activity. Within our own in-patients. But also we've got close links with the Southeast London Health Protection. So we look at their weekly data. And also there is an NHS London network that provides weekly flu data. (Infection control manager, 2013)

The infection control manager describes how different forms of knowledge are drawn together: virological data, syndromic surveillance, and case numbers, resulting in what has been termed 'observational knowledge' (Hinchliffe and Lavau, 2013: 272). Surveillance practices bridge the gaps between different areas and technologies of expertise, such as the virological laboratory, clinic, or public health authority, that is, they facilitate the circulation of information (Waldby, 1996). Here is how a virologist at the National Institute for Medical Research explains how this process takes place in the UK's national context:

> General Practitioners [would be] doing two things. One: noting the level of influenza on the clinical signs, and a subset of these collecting samples to be given to the national influenza centre for virus isolation and preliminary characterisation. […] Those then are initially assessed by the national influenza centre. […] They also will have cases in which for example people are particularly ill. And this would be non-sentinel surveillance in which people are, at the national influenza centres,

> are asked to characterise the viruses from these people that are particularly ill with influenza. And those will be also considered because we need to bear in mind that we, if the virus... if there is a nasty virus out there, it may not be picked up so readily by surveillance. But it might be picked up by non-... by the sentinel surveillance, might be by a non-sentinel sample. So the samples come as a mixture of surveillance, sentinel sampling and non-sentinel sampling. (Virologist, 2012)

He pictures a gap between routinised attention and 'nasty' viruses. Surveillance practices make productive use of this gap. In the lab, virologists, technicians, and machines isolate and characterize the viruses found in the swab, they perform plaque-assays or follow PCR protocols and use specific kits developed by the biotechnological industry. Yet, not every circulating virus will be picked up easily by the national surveillance systems, nor does an increase in positive results necessarily originate in an increased rate of viral emergence, as surveillance technologies and viruses intra-act:

> You could have a large city somewhere else without surveillance and you wouldn't pick anything up because nobody was looking for it! So you also have to have good surveillance. And that's what Germany and the UK do! So you pick it up! Because you're good at it. (Virologist, 2012)

Here, the material contingencies of virological surveillance are stressed: success is entangled with its sociotechnical surroundings. In this process, viral isolates are compared to other viral isolates that have been described previously. Does the pattern relate to any known pattern? Or doesn't it?[7] Virological surveillance initiates a meaningful – pathological – connection between coughing patients at A&E and a mathematical entry into a computer database. Surveillance data depict patients as either sick from the flu or healthy, thereby obscuring divergent bodily practices and expressions by translating them into something that is easily comprehensible by public health officials (French, 2009: 110).

Additionally, sentinel surveillance schemes are in place. They are supposed to pick up 'nasty' viruses:

> Consultant: [Most GPs] wouldn't normally take samples from people, if they made a clinical diagnosis of flu or influenza. But certain of our GP practices commit to taking samples from anybody who has flu-like symptoms. And those samples are sent on a weekly basis to the reference laboratories […] The first test says: is this influenza? Yes or no? And usually it's influenza A and that's what previous pandemics have all been. And then they would go on to say: is this H1N1, H3N2, [one] of the viruses that we know cause seasonal flu? And if […] they weren't able to characterise any of the known flu viruses, they would then go on to say, well, this must be a new one that we've picked up. And they would develop the tests. Because they do have the other antigens. So they would be able to then test for a range of H1, H and N antigens. And say: oh look, this is H7N3, or whatever it might be. And then they'd be able to describe that to us. And then […] they can quite rapidly roll out a new test among all of the public health laboratories around England. So within about two weeks of detecting a new virus they can get the testing kit out to… […] So that we could then detect that virus, wherever it was coming in from.
>
> [MW]: […] Would one single [sample of a] viral strain, which has never been described before, would [it] be enough to alarm you?
>
> Consultant: Well, you might need more than one sample. […] But if we were through that detection mechanism, you know, if a new strain were to emerge here […] twenty people in the first week would have it. And some of them would be picked up through that scheme. […] If we detected one new virus, we probably wouldn't put out a major alert. But if over two weeks we had seen six or eight people with exactly the same new strain being picked up through that mechanism, then I think we would declare the early stages of a new pandemic (Consultant, 2013).

Sentinel surveillance, as this consultant describes, mobilises virological knowledge. Data on previous pandemics merge with current antigen concentrations. Again, thresholds are difficult to establish. How many isolates of a new strain are necessary to cause concern? Digital humanities scholar Lindsay Thomas (2014: 298) reminds us that the harnessing of data is always incomplete. By assembling fictional futures and models, the pandemic-to-be

is normalised and integrated into the routines and practises of local agencies. The information on whether pandemic viruses have been 'detected' or not is forwarded through global, national, and regional surveillance networks (such as the European Influenza Surveillance Network, the Global Influenza Programme, or Winter Health Watch), but it also travels through other channels and traverses numerous scientific and non-scientific domains, endorsing prevailing assumptions and stories (Burri and Dumit, 2008: 305), as the third subsection will show.

Local agencies have also implemented additional monitoring arrangements to anticipate possible influenza outbreaks. As a means of syndromic surveillance, staff (and sometimes school) absences are monitored and reported. As a member of the fire brigade explains, monitoring goes beyond a mere statistical analysis – it has "interpretative powers as well" (Emergency planning team, 2013). In order to release these powers, software systems had to be adapted to translate staff absences into codes signifying 'flu' or 'bad cold'. I learnt that a significant amount of money or time had to be invested into the adaptation of these systems. Thus, a blending of different surveillance practices (sentinel sampling, non-sentinel sampling, syndromic algorithms) generates data supposed to 'mirror' or even anticipate the pandemic situation.

Epidemic conditions, sociologist Martin French (2009) claims, "make desirable those discursive techniques which seem to admit clear, concise communication. Perhaps no discursive technique claims more clarity than mathematical expression" (French, 2009: 111). A mathematical foundation makes it easier for knowledge of outbreak events to be transmitted from one area of expertise (such as virology) to another (such as emergency planning) without distortion. Mathematical expressions are common to the different fields of expertise involved in pandemic planning. Accordingly, risk assessment based on these mathematical foundations is commonly depicted as rational, logical, and objective decision-making. STS scholarship on the pursuit of scientific objectivity, however, reminds us that numbers such as those derived from surveillance technologies are never mere representations of nature, but that they are 'materialized relations' (Verran, 2010), powerful devices (Porter, 1995), and socially performative (Bauer, 2013). As such, numbers play a key role in the enactment of risk reasoning: they bridge the gaps between distinct areas of expertise and intervention (such as computer science, population health, or urban governance) and generate powerful new linkages, thereby rendering microbial emergence governable by risk. Accordingly, it is only through systematic technological attention that individual bodily expressions such as sneezing are translated into numerical data to be visualized, communicated, and acted upon[8].

Similar linkages are evoked in Frankfurt where the local health authority plays a key role within this process:

> We are always monitoring the disease situation in Frankfurt. […] So, we get the numbers. […] So, every single case is shown on the map. Spatially distributed. […] And […] in case of a pandemic, if we say… it's a pandemic situation, not depending on any specific kind of pathogen, or if we are threatened by a pandemic situation. Then we'll be provided with the numbers of people calling in sick from the workforce – not their names of course, just the number of people who called in sick and stayed at home. We get these numbers from the university hospital. […] The fire brigade will be doing the same thing. So we'll have an overview of what the sickness absence rate looks like. And if it's up to 10, 15 per cent, then I'll start to get concerned. And will talk to the mayor or the health delegate, and we'll think about activating response measures.[9] (Infection control manager, 2012, translation: MW)

So numbers are monitored on a regular basis. These numbers do not reflect microbial emergence, nor are they identical with the number of influenza infections, but they establish meaningful – pathological – connections between local Frankfurt residents calling in sick, on the one hand, and the global pandemic situation on the other. They constitute a "productive alliance of knowledge forms and practices" (Hinchliffe and Lavau, 2013: 259). Pandemic planning in Frankfurt is embedded in a considerably smaller institutional context (consisting of the local health authority, the fire brigade, local hospitals, the police, and the airport). Similar to London, diagnostic algorithms will be put in place in times of

pressure. Different to London, the management, not so much the gathering, of data was emphasised as an important area of intervention. Emergency planners invest much time and effort in the construction and modification of 'reliable' modelling software, and strive to determine thresholds, boundaries, and detectors to signify the arrival of an event (the 'Meltzer Modell' has gained some local popularity). Again, this is supposed to render microbial uncertainty governable through risk assessment.

But, even if surveillance systems signal the presence of a virus with a genetic makeup deemed as unusual or risky, a further step needs to be taken to activate response measures: someone has to raise the alarm.

Translating uncertainty into alarm: administrative dimensions

As discussed above, technologies of medical surveillance (algorithms, protocols, kits, swabs etc.) produce cases and data. In what follows, it will be looked at how these cases and data are subject to pandemic ordering attempts. The last step of the translation process encompasses the administrative dimension where pandemics are rendered governable by local emergency planners, resilience managers, and health experts. To become a truly local threat and to activate the local response plans, the alarm has to be raised.

> There is not just one parameter that says: if this happens, we do x, y and z. It's a lot of different things. […] So there are all these different parameters that you have to look at in terms of making a decision […] It is not one set of parameters – you have to consider *a number* of them. And at the end of the day there is no formula. It's your judgement based on what you know about people – or what you don't know about people. And the disease and what's happening within the community. (Pandemic flu expert, 2012)

As this expert stresses, there is "not one set of parameters" signifying the arrival of pandemic flu: knowledge is contested and multiple. The monitoring of microbial mobility and case numbers does not necessarily result in easy decisions. Rather, monitoring produces another set of data that must be transformed into information which needs to be mobilised to reach its target audience (public health officials, the workforce, or the broader public). Different data bases and information systems have to be linked. They "kind of talk to each other", as a member of the health protection team explained – although, as she added with amusement, "sometimes [they] don't talk to each other as well as they should be" (Health protection team, 2013).

Pandemics are often discussed as circulatory processes, or as a crisis of circulation (wherein 'good' circulations have to be facilitated, and 'bad' circulations have to be minimised, see Elbe, 2009: 73). Among the many things mobilised during a pandemic – such as vaccines, fears, alcohol gels, experts, or standards – most experts we interviewed highlighted the central importance of communication: information has to be mobilised in the management of infectious disease outbreaks. This requires efforts, and it requires time. Numbers and concerns need to be communicated; reliable and trustworthy information has to be separated from less reliable and less trustworthy information. Sometimes, not only quality but also quantity of information poses a problem: preparedness produces "too much information". Implicit here are assumptions about which knowledge might count as 'correct' and 'helpful', and which knowledge is rejected or ignored as irrelevant or wrong. Generally, reliable knowledge is attributed to national and international health authorities (with NHS, PHE, WHO, and CDC being the most important ones) and has been validated through lab confirmation. In practice, the mobilisation of trustworthy knowledge requires effort:

> …we have something called the London local authority coordination centre […]. That's actually a conduit for all 30 local authorities. We *take* information to them, we *put* it into a single format, and we give it to those people who need to have it. (Emergency planning team, 2013)

A manager within the London Resilience Team says:

> As far as flu is concerned, [the sub regional resilience forum functions as] a forum for the passage of information and sharing of information. (Emergency manager, 2013)

Both of these statements mirror policy positions, and both stress the necessity to circulate knowledge. Information handed down by public health authorities must be filtered according to the specific needs of the workforce, or any other target group. Filtering is meant to maintain the boundaries between 'good' (that is, trustworthy) and 'bad' (that is, misleading) communication. However, information seems to be vulnerable since it cannot be contained or controlled (as aptly illustrated by SARS in China). Information released by public health authorities competes with other kinds of information that are already out there in the world. During the 2009 pandemic, for example, the German vaccination campaigns were challenged by controversial debates around the risks and benefits of the two different available vaccines, one containing an adjuvant (*Pandemrix*) intended for the broader public, and the other without an adjuvant (*Celvapan*) intended for certain population groups, including the troops and government employees. While government officials and health authorities promoted the campaign, other sources of information (blogs, medical experts, the media, or circulating rumours) displayed Pandemrix' side effects and spread fears of a two-class health system. These informations competed for attention, and – seen from a public health perspective – endangered the successful implementation of the vaccination campaign. 'Good' and, therefore, trustworthy information, as emergency experts claim, is characterised by a reliable and independent source, and by a choice of words that are unambiguous and clear:

> The importance of good communication was a... was a key. […] The importance of having, you know, one voice, one set of figures. […] So that we didn't have someone saying there were 200 cases and someone said 150. It was... It was about trying to ensure that there was a consistency of message that people felt they could rely… (Pandemic flu expert, 2012)

'Good' communication, according to this expert, ensures that health authorities do not produce multiple, or inconsistent pronouncements. Facilitating the circulation of 'good' and trustworthy information is key to decision-making processes. It is useful to note here, that raising the alarm entails *collective* decision-making processes. These processes are articulated with technologies, data, plans, and rationalities: preparedness is achieved through local networks. Parts of these complex structures are manifested in the London Resilience Partnership, but the network extends well beyond the surface of centrally set structures, incorporating friends and colleagues from other agencies and countries (some of whom might have worked in the same lab or met during a conference), as well as manifold sources of information, ranging from daily newspapers to newsletters, blogs, or rumours. Some agencies have employed dedicated 'risk specialists' whose task it is to check websites, read the news, and meet up with other members of the local partnership. A bulletin summarising the weekly events is sent out every Friday by London Resilience, and a monthly NHS influenza newsletter circulates. This is how an expert within NHS England explains how she learns about emerging viruses and makes decisions:

> A colleague from the Health Protection Agency said something is going on, can't really talk to you about it yet, but keep an eye out! Then I picked up through the ProMED digests […] They collect all sorts of news reports of human, animal, and plant diseases. And so those reports are coming through that... So I was observing that... emailed a couple of people to ask what was going on. And there is a patient in a hospital in London, so we know about that through our medical director and our other routes in this organisation. So because... the patient is in a NHS trust in London, we know about it that way. So what I was doing yesterday – apart from everything else I was doing – was trying to understand what we knew about the virus, […] how bad might it be, what's the particular situation. (Flu expert, 2012)

Similarly, an emergency manager within the London Resilience Team describes:

> There is a process to monitor... London on a day-to-day... not on a day-to-day basis, really on a week-to-week basis which is done by London Resilience Team. Public Health England have real time monitoring of disease which they report on a regular basis. We include that in our reports. As soon as we notice a change in the sort of... out of the norm as it where, so for example last week they were reporting a fair number of chest infections.

> But within seasonal standards. Seasonal norms. As soon as there is a change from that there'll be a discussion between us, Public Health England, to assess what measures are now needed to respond. So that could be at the most simple level: exchange information, have a teleconference. Is this sudden impact really big, we need to call the most senior people in now for a meeting, to start identify the strategy. (Emergency manager, 2013)

Obviously, as these quotes illustrate, there are numerous enactments of the pandemic. Different (and possibly competitive) versions of the outbreak have to be measured and compared. In the above quoted examples, a broad range of sources and practices come into play: a chat with colleagues from another agency, maps displaying case numbers, a formalised newsletter, email correspondence, local reporting structures, real time monitoring, standards, statistics, and a teleconference. This kind of networked information management comes as a blending of routinised (and centrally set) reporting structures and more informal channels. It might raise concern, but it is not sufficient to raise the alarm.

Thus, these illustrations seem to indicate that order within complex disease ecologies is only partly achieved through centrally set regulations and laws. Neither is it an individual and autonomous decision of the flu manager in charge (this would also conflict with the command and control structure underlying the centrally set reporting structure in the UK). Rather, order in these extra-ordinary situations is achieved through networked efforts and sociotechnical assemblages. It is the result of co-ordination efforts, as described by Mol (2010).

The situation is fraught with tension: colleagues doubting the severity of the pandemic, disputes about how to head a meeting, media reports displaying the risks of flu vaccines, or members of the workforce refusing to come to work. Tensions such as these have to be bridged, and while not all interviewees agreed upon the measures taken during the 2009 pandemic, they all were eager to stress that the network worked efficiently [9].

The technologies used to perceive, communicate and finally to manage outbreak situations – to achieve coordination – are pretty mundane: telephones, newsletters, PowerPoint software, laptops, and computers. Much of the work being performed by emergency planners does not differ significantly from the work performed by a social scientist. To a large extent, pandemic preparedness is about reading, analysing numbers, looking for information, making phone calls, evaluating information, or meeting with colleagues. Flu experts and emergency planners make phone calls to discuss laboratory findings with colleagues working in Colindale, Berlin or Geneva. They subscribe to weekly newsletters, displaying epidemiological and virological data and reporting on flu activity across Europe. They look at the colourful maps that represent the circulation of influenza viruses and that either offer a global perspective, or a form of representation categorised by country, area, or territory. They initiate teleconferences with their local resilience team, and book meeting rooms and time slots. They analyse numbers to contextualise the epidemiological data provided by transnational health organisations. They read case stories in the newspaper and the social media. They order and stockpile alcohol gel. They meet with the mayor's office to discuss the situation. Is the city at risk? Or is there no reason for concern? The information they assemble is heterogeneous, sometimes contradictory, and reflects the manifold interests of local authorities and organisations. Pandemic preparedness' most important setting is the office[10].

Yet it is noteworthy that pandemic preparedness itself does not aim to impact on the outbreak: it does not seek to stop the pandemic from happening. Rather, its underlying rationale is anticipation, or response. Risks, at this level of the translation process, are discussed as emerging from overplanning, the circulation of 'bad' information, or a declining interest in the imperative of emergency planning (ironically described as 'pandemic fatigue') – they seem to endanger not only the effectiveness of the planning procedure, but also compliance and support from the broader public (see Wolf, 2016).

Similar to London, the management of information in Frankfurt is believed to be key to successful preparedness. Accordingly, 'good' information has to be brought into circulation to make informed decisions. The process is enacted in a comparable way as a networked information management and blends different layers of communication, as this doctor at at local hospital explains:

> ProMED is the most important source. Reading it is part of my morning routine, like having a coffee. […] Then of course the Robert-Koch-Institute. ECDC is included in ProMED…. Well, and personal contacts play an important role. […] We are in touch with nearly 25 EU-member states […] If something is up there, we will be informed through a mailing list. […] But it is not officially legislated, this kind of communication. […] And if you read something and realise 'oh, this happens near Guiseppe', then you would probably write Guiseppe and ask about it (Infection control manager, 2013, translation: MW)

The action undertaken here does not distinguish between 'official' and other sources of information – both might generate concern. As in London, centrally and federally set reporting structures exist in a parallel reality to larger informal networks of friends and colleagues. Interestingly, it is through these very networks that pandemic preparedness exceeds and expands across national boundaries. The decision to raise the alarm, however, is a centralised decision.

Conclusion

This brings us back to the introduction. The article started with the question of how emergency experts know about the arrival of pandemic flu in a given territorial context, and they were found to *know* in different ways.

First, the spatiotemporal framework as set by the WHO establishes criteria to understand the characteristics of a pandemic and to coordinate response measures. Within this framework, pandemic viruses emerge as *novel* bio-agents possessing a different genetic make-up and the ability to master the interspecies barrier. This framework requires the novel virus to spread across national borders and the WHO regions. Acting as a *truth claim*, it develops policies of an escalating and boundary-breaching outbreak dynamics and translates microbial emergence into a pandemic event that can be known and acted upon.

Second, individual cases of illness are translated into data. Here, globally circulating viruses need to be 'detected' by local surveillance systems, assembling patients, sneezing, GPs, blood, hospitals and databases into mathematical techniques that bridge the gap between different areas of expertise. Virologists, public health experts, politicians, and emergency planners are enabled to act upon numerical risk assessments, likelihoods, and case numbers. Here, knowledge is of a statistical nature and derived from numbers displaying likelihood and impact of a pandemic event.

To activate local response measures, a third step has to be taken: concerns need to be translated into alarm. Decision-making processes have proven to be collective enterprises rather than individual and autonomous – it is mostly through networked information management that local experts contextualise surveillance data and informal sources of information. As coordination attempts, networked information management practices aim to manage the circulation of information to, as Mol (2010: 264) claims, keep potentially competing versions of reality out of each other's way. Within this administrative framework, knowing is closely related to reaching consensus and distinguishing between 'reliable' and 'less reliable' information.

When taken together, knowing pandemics in London and Frankfurt shows differences as well as similarities. In both cities, knowledge on pandemics is discussed as governing (through) networks. Both cities enact different layers of centrally set and informal reporting and communication structures and both cities struggle to link different sets of data and to "make information systems talk". But both cities have found slightly different answers to this quest. In comparison, the local networks show different underlying dynamics. In London, the network dynamic can be described as *volatile*. It results from a large number of heterogeneous institutions and plans, as well as from the restructuring of the health care system. Consequently, many agencies tried to resuscitate the network through personal acquaintances and connections. "Making friends with other agencies" was described as a common and effective strategy to take care of networks.

Frankfurt, in contrast, shows an *expansive* network dynamic: local emergency planners stressed a need for integrative, centralised, and coherent governance structures. They have implemented tools (such as a software system to monitor patient allocation from a centralised perspective)

to expand their planning approach to other local and regional agencies. Here, to take care of networks might be translated into standardisation and centralisation.

Two conclusions can be derived. First, the above-described examples might illustrate that the concept of disease emergence cannot be reduced to 'naturally' circulating viruses to be detected by international surveillance systems. It can never be *pure* knowledge. Rather, the emergence of influenza viruses within territorially defined regions is only enacted through a set of meaningful relations that enable certain ways of preparedness and response to be articulated (and others to be silenced): it requires hard work and administrative, technological, political and biomedical skills to make a pandemic present and tangible, and it seems doubtful that pandemics constitute sudden events or natural disasters. Displaying the facticity of pandemic knowledge and its epistemological foundation, however, does not mean that this knowledge is false, nor does it deny the reality of people suffering from, or dying of, the flu.

The second thing to be concluded is the observation that local preparedness does not result from a linear adaptation of global health standards, nor does it constitute the movement of policies from the global level to the local – if policy transfer is defined as the intentional, spatiotemporal, and significant movement of "something related to policy from one place to another" (Bissell et al., 2011: 1141). By applying a perspective informed by ontological politics (Mol, 2002), pandemic preparedness seems to alter when viral emergence is moving through global health classification schemes, individual bodies, algorithms, labs, and meeting rooms. Consequently, as studies on implementation and standardization have illustrated (Walt et al., 2004; Aarts et al., 2004), it seems doubtful that the introduction of global health policies results in predictable local outcomes. Global health, seen from this perspective, cannot be reduced to either a medical or an institutional framework, but it is simultaneously social and technological, scientific and political, volatile and expansive – and it relies on uncertainty to govern potential outbreak situations. Uncertainty here is at the same time descriptive about the world (in that it conjures a need for preparedness) as well as performative in the world (in that it reifies an apparatus of security).

When taken together, *knowing* that a nation or a city is struck by pandemic flu constitutes a complex sociotechnical process that transforms microbial messiness – global in scale – into local scale pandemic orders. Pandemic orders are achieved through pandemic ordering practices, a re-arrangement of what can be seen, known, or said within the social context of emergency planning. Pandemic ordering practices do not obey a single logic, and goals of intervention may vary: seen from a business continuity perspective, some measures might contradict the rationales of infection control. Vice versa, infection control measures might endanger business continuity. The head of agency A might have a different opinion from the head of agency B. Many kinds of information compete for attention. People suffering from fever and sneezing might decide to consult a doctor, or they might decide to stay at home. Planning measures might fail. All of which puts pandemic preparedness in a different light. It may well be about centrally set structures, but it is also about the efforts of ordering within different contexts. Pandemic preparedness, seen from a STS perspective, bridges spatial, technological and administrative gaps between globally circulating viruses and local areas of intervention, thereby enacting global health as a matter of local concern and political intervention.

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Endnotes

1 Critical approaches claim that international infectious disease management technologies and the securitisation paradigm mainly meet the needs of Western states, rather than addressing truly global concerns (Davies, 2008; Fidler, 2003).

2 In this paper, the term 'microbe' will be used to refer to both viruses and bacteria. Within the biological sciences, it is currently acknowledged that viruses possess both characteristics: those that support the assumption that viruses are 'dead' biochemical entities, and those that are attributed to the world of living organisms. Thus, viruses transgress traditional binary definitions of living organisms or dead matter (Villarreal and Witzany, 2010).

3 In both research settings, we did not succeed in contacting the police, the stock market, the pharmaceutical industry responsible for the manufacturing of vaccines, or internet exchange services (DE-CIX in Frankfurt counts as the world's leading internet exchange point).

4 The pharmaceutical industry is a powerful voice within global health security: in the UK, for instance, national stockpiles of Tamiflu and Relenza were established to be used as prophylaxis and to treat suspected cases (GLA, 2012). It is estimated that the UK government spent £500m on antiviral drugs (Goldacre, 2014). In 2014, a report published by the Cochran Collaboration reviewed, among others, the efficacy of Tamiflu and found no solid evidence that the drug would reduce the risk of flu-related complications and hospital admissions.

5 The world has been divided into six WHO regions: Africa, the Americas, South-East Asia, Europe, the East Mediterranean and the Western Pacific.

6 While the presence of the virus does not necessarily result in infection, infection in turn does not necessarily result in illness.

7 What lab staff finally sees there, of course, depends on the specific diagnostic tools and procedures as specified by virological protocols: while some aim to identify neuraminidase subtypes, others search for antibodies or rely on haemagglutination inhibition testing (WHO, 2011). In the UK, real-time PCR is used for sentinel virological surveillance.

8 Lyle Fearnley reminds us that if surveillance systems depend on categorical lists of pre-defined diseases, they will fail to detect microbes with uncertain biological make-ups (Fearnley, 2006, 5).

9 To give some examples of the many forms of coordinating efforts undertaken by interview partners: staff members with inadequate hand hygiene had to undergo specific health education routines, 'misinformation' about the risks and benefits of vaccination was met through the release of 'reliable' information, and mistrust was expressed and discussed in informal chats with colleagues rather than through official reporting structures.

10 Of course, many other spaces are included in the crafting of preparedness, such as virological labs, hospitals, pharmacies and public restrooms.

Clinical Trials and the Drive to Material Standardisation: 'Extending the Rails' or Reinventing the Wheel?

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Abstract

There have long been calls from within both industry and academic groups to reduce the bureaucratisation of clinical trials and make them more 'sensible', with the focus on approvals and guidelines. Here, I focus on the mundane environments of a multi-centre clinical trial to ask how 'sensible' it is to standardise trials at the level of material objects. Drawing on ethnographic data collected in the UK, South Africa and Vietnam, I present three vignettes of material standardisation. While acknowledging some positive effects, I argue that standardising in this way may be antithetical to sustainable and relevant clinical research. Three dimensions of this are discussed: 1) the external validity of evidence from pragmatic trials 2) the gap between experimentation and implementation and 3) long-term site capacity to conduct research. Drawing on the literature on 'situated standardisation', the paper concludes by suggesting a greater acknowledgement of the need for trials not only to be 'sensible' but also 'situated'.

Keywords: clinical trials, standardisation, materiality

Introduction

The lure of standardisation exerts a firm grip on clinical research. Over the twentieth century, increasing moves have been made to modernise, standardise and thereby cement medicine's status as 'science'. These have included the organisation and regulation of pharmaceutical drug trials and the rapid ascent of the evidence-based medicine movement (see Epstein, 2007). As the poster child of evidence based medicine, the randomised controlled trial (RCT) relies on standardisation to make experiments consistent, transparent and comparable. Various kinds of standard are at work, and here Timmermans and Epstein's (2010) sub-types are useful: terminological standards work to stabilise meaning across different sites and times and enable individual elements to be aggregated into larger wholes; procedural standards delineate how processes are to be performed; and design standards 'set structural specifications: they define the properties and features of tools and products' (Timmermans and Epstein, 2010: 72). Such standards ensure the uniformity and mutual compatibility of sociotechnical systems (see also Timmermanns and Berg, 2003) and have become a defining feature of the way in which evidence is produced in clinical trials.

In multicentre clinical trials, as in other domains of social life, standards mean that people and things can be coordinated in a consistent and measurable way that would otherwise be almost impossible to achieve. Standard Operating Procedures (SOPs), Working Practice Documents, technical manuals and protocols, to name but a few of the everyday tools of clinical research, allow communication between different (potentially incompatible) systems, and enable movement, calculation, precision, universality and objectivity across sites. However, standards, being the result of social work (Bowker and Star, 1999; Lampland and Star, 2009) and requiring collective labour, negotiation and buy-in from multiple stakeholders (Berg, 1997; Fujimura, 1992; Jordan and Lynch, 1998), are not politically neutral. As Timmermans and Epstein (2010: 74) aptly put it, their "objectivity, universality, and optimality are hard won victories that can be heavily contested by third parties lobbing accusations of bias and politicization".

In relation to clinical trials, then, it is important to ask whose benefits are served by particular standards, and in the case of conflicting standards, whose should prevail. While the standardisation of clinical guidelines has been well analysed in this respect (Cambrosio et al., 2006; Castel, 2009; Knaapen, 2013; Knaapen et al., 2010), a feature of multi-centre clinical trials that has been relatively neglected is the standardisation of material settings. Perhaps because of their mundanity these have received little or no attention in the clinical trials literature and limited analysis in social studies of science.

A notable exception is Petty and Heimer's (2011) analysis of how HIV clinical research shapes clinics not only at the point that research findings are implemented, but through the very process of conducting such research in the first place. Petty and Heimer argue that clinical trials transform medical practice in the places where they are conducted by modifying the material environment, reorganising bureaucratic relations and increasing the valorisation of research. Clinics that *conduct* research, they argue, are in a better position to *implement* the results of research because they have been re-made in ways that smooth the transition of practice. They draw on Latour's (1983) image of scientific facts being like trains that that do not work off their rails to characterise this phenomenon as "'extend[ing] the rails' that allow scientific research results to be driven into the clinic" (Petty and Heimer, 2011: 357).

Like Petty and Heimer (2011), I am interested in global public health trials, which tend to fall at the 'pragmatic' end of the explanatory-pragmatic continuum (Thorpe et al., 2009). That is, they seek to determine the effects of an intervention under *usual* rather than *ideal* conditions. With the emphasis on usual conditions, the assumption might be that standardisation of the experimental environment across sites is minimal or even absent. However, trial sponsors often invest in site infrastructure and provide standardised consumables (such as diagnostic tests, laboratory reagents, and stationary) as part of scientific 'capacity building'. It is this material standardisation with which the current paper is concerned. In contrast to Petty and Heimer's (2011) conclusion that the standardisation of research environments leads to the more ready adoption of new research findings in medical practice, I start from the more sceptical position that the proliferation of standards in research sites may have negative as well as positive effects. This position is informed by ten years working on medical research projects and frequently hearing sites referred to as vessels through which clinical trial traffic can be routed. As trials from a range of sectors, sponsors and disease areas proliferate at 'good' sites, how 'sensible' does trial-specific standardisation become, and what are its effects?

For a number of years there have been calls for an end to the bureaucratisation of clinical trials (Groves, 2009; Shurlock, 2013). This is evident in the re-writing of the European Commission's guidelines on the conduct of clinical trials, the Sensible Guidelines Group (SGG) and the US Clinical Trials Transformation Initiative. At the heart of these initiatives is a belief that over-regulation has brought the development and testing of new pharmaceuticals to its knees and is delaying the introduction of potentially life-saving drugs to patients around the world. A 2008 special issue of *Clinical Trials* brought together papers written by members of the SGG which focused on a range of aspects of such over-regu-

lation, including the restrictive interpretation of privacy laws and its negative impact on the use of personal health information in trials (Armitage et al., 2008); excessive and inefficient on-site monitoring (Baigent et al., 2008); obstacles to conducting trials with vulnerable patient populations (Cook et al., 2008); and overuse of and overly complex adjudication of clinical events (Granger et al., 2008).

An overarching critique made by the movement towards sensible clinical trials is the inefficiency of a 'one-size-fits-all' approach to conducting and regulating medical research. Proponents question how appropriate, relevant and representative the regulatory guidelines for the conduct of RCTs are (Yusuf et al., 2008). The International Committee of Harmonisation's guidelines to Good Clinical Practice (ICH-GCP) have come under particular fire, in particular their uncritical application to all kinds of clinical research study in all kinds of differently-resourced settings (Lang et al., 2011). Rather than taking the guidelines as a set of principles by which to conduct ethical trials and report accurate and reliable data, study sponsors have instead "appl[ied] the guidelines as a single standard" (Lang et al., 2011: 1555).

The movement towards sensible clinical trials provides an interesting starting point for considering standardisation in clinical research, by virtue of the fact that it provides a ready-made critique from within the orbit of the pharmaceutical industry itself. However, the SGG, it should be noted, sits in a field dominated by a powerful pro-pharmaceutical industry lobby, which has sought to de-regulate trials as part of more systematic neoliberal attempts to make pharmaceutical regulation less restrictive. As Abraham, Davis and others argue, this has produced toxic results for public health (Martin et al., 2006; Davis and Abraham, 2013; Light and Lexchin, 2012). Moving the focus to trial practices themselves, the literature on the political economy of clinical trials could not be clearer about the links between pharmaceutical neoliberalisation and the enrolment of vulnerable populations into potentially exploitative regimes of commercial experimentation (Fisher, 2009; Petryna, 2009; Sunder Rajan, 2007).

In this paper, I examine the material standardisation of trials and – as a way to contribute both to debates in STS and in Global Health – ask the question, "how sensible are clinical trials?" In adopting this terminology, I am clearly not condoning the deregulation of clinical research, or celebrating a more permissive approach to pharmaceutical experimentation; instead, my aim is to challenge what is done in the name of good science, where this indexes both the rigour of the experiment and its moral claims to build capacity. I use the term 'sensible' heuristically to frame the analysis of a publicly-funded academic-run trial into anti-Tuberculosis drugs, an area in which so-called market failure has led to the need for new regimens to be tested outside the industry model (Cousins, 2016; Frick, 2016). Within this context of sparse investment and infrastructural poverty, the question as to how 'sensible' each step in the clinical testing process was was never far away. By bringing a classic STS concern (standardisation) to bear on the topic of global health trials, I aim to craft an analysis that – in line with the aims of this special issue – speaks critically but constructively to both fields.

The paper proceeds as follows. Firstly, the ethnographic study of a specific multi-centre trial is presented. Thereafter, I go on to present three vignettes about material standardisation: diagnostic devices, drugs and samples. The vignettes are analysed to show the social effects of standardisation for the sites taking part in the trial. In the ensuing discussion, I argue that while material standardisation can have positive effects, it may also contribute to conditions which are antithetical to sustainable and relevant clinical research. I discuss three dimensions of this, namely 1) the external validity of evidence from pragmatic trials 2) the gap between experimentation and implementation on which a new policy's success can depend and 3) long-term site capacity to conduct research. Drawing on the literature on 'situated standardisation' (Zuiderent-Jerak, 2007; Engel and Zeiss, 2014), I conclude by suggesting a greater acknowledgement of the need for trials not only to be 'sensible' but also 'situated'.

Methods

From May 2012, for a period of 12 months, an ethnographic study was undertaken to understand

the processes of governance, exchange, sharing, value-creation and appropriation in a transnational biomedical research project. The study was designed to investigate how different partners in a multi-sited trial conceptualise and attribute meaning to collaboration; how the division of labour is organised; how exchange practices, such as sharing, giving, and transferring shape the trial network; and how transactions occur, e.g. in relation to collaboration, training, recruiting participants, sharing information and materials. In order to do this, I conducted twelve months' observation of a publicly-funded RCT investigating new treatment options for multi-drug resistant tuberculosis (MDR-TB), basing myself at the trial's UK coordinating site, and attending over 30 team meetings and teleconferences. I accompanied UK staff on site initiation visits to two clinical sites in South Africa and Vietnam (each lasting two to four days), as well as visiting these sites independently to observe the scientific and administrative practices of the trial (5 weeks in total). I conducted a total of 34 interviews with staff working on the trial across coordinating and clinical sites, including principal investigators, trial sponsor, trial managers, statisticians, clinicians, nurses, pharmacists, and monitors.

During the observation, fieldnotes were taken and these were typed up on a daily basis. Interviews were digitally recorded, transcribed, and translated where necessary. All data were imported into NVivo software for qualitative data analysis. Coding, memo-writing and interpretation followed the principles of constructivist grounded theory (Charmaz, 2006). An initial process of detailed line by line coding within interviews and fieldnotes 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).

Ethics approval was obtained in the UK by the University of Oxford Central University Research Ethics Committee; in South Africa and Vietnam by the relevant local institutional review boards; and in addition by the International Union Against Tuberculosis and Lung Disease Ethics Advisory Group. For institutional observation, written informed consent was obtained at each site from the principal investigator, and verbal consent from staff. All staff gave written informed consent prior to being interviewed.

Study settings

The three sites which formed part of this multi-site ethnography consisted of a publicly funded UK clinical trials unit, a government-run TB referral hospital in South Africa and a government-run tertiary hospital in Vietnam. In South Africa, the TB hospital encompassed, within the hospital grounds, a research unit separately funded and staffed by research grants, but recruiting patients from the general hospital population. A clear demarcation between research and care was noted by research staff, with some antagonism reportedly created by the different sources of funding, which manifested itself in different nursing duties, work uniforms, prestige, and so on. By contrast, in Vietnam, research was conducted by government-funded staff and was seen to be an integral part of the career trajectory for those who wanted to progress. Research was valued by hospital management and, while creating more work for staff, was also seen as a conduit to changes in patient management based on the latest evidence. The sites in question were just three of a larger number of sites taking part in this multicentre trial across Europe, Africa and Asia. They were selected for the ethnographic study in consultation with the trial management group, trial steering committee and the principal investigators of the sites themselves. The trial and its sites are not named in this paper in order to preserve anonymity.

Findings

Standardising 'usual conditions'

> There's a quick examination of little sealable clear plastic bags that the study drugs will be dispensed in; also of how to print off labels for said bags. The pharmacist shows us how she prints off labels and cuts them to size with a ruler and a craft knife. The visitors say that in this trial, she will be able to dispense with this time-consuming task, because they will provide a special printer and labels that are the right size. The pharmacist looks nonplussed;

> I can see she already has two printers in her small office, a HP and a Cannon. Adding a third printer for the study, the Zebra printer, seems almost comical. – Extract from fieldnotes, site visit to the hospital pharmacy, Vietnam

Within the scientific community, the trial was regarded foremost as a pragmatic, rather than an explanatory trial. The trial in question asked, "does this intervention work under usual conditions?" and did so in a number of different settings in order for the results to be seen to be widely (globally) applicable and therefore to form the basis for a World Health Organisation (WHO) recommendation for MDR-TB treatment. According to the protocol, the trial explicitly adopted a practical, programme-based design to make sure that if successful, the results would be generalisable to routine programme settings.

The distinction between explanatory and pragmatic is important here because it indicates an intention on the part of trialists to either create and control an 'ideal' environment for the experiment or to refrain from intervening in the experimental setting and let events take their course. However, what became clear during the ethnography – and is illustrated by the fieldnote extract above – is that even at the pragmatic end of the spectrum, considerable effort goes into procuring materials for trials, from pharmaceuticals to medical equipment to stationary. In the trial in question, a multitude of objects were shipped to the clinics in order to ensure material standardisation. Such objects included ziploc bags, drugs in the intervention arm, electrocardiograph (ECG) machines, label printers, printed CRFs and logs for recording everything from the temperature in the drug store to sample chain of custody.

The trial also standardised the way in which data was collected, not only in terms of the physical forms just mentioned, but also in the structure of questionnaires, the phrasing of questions, the units of measurement and so on. The questions assumed a single reality in multiple settings that could be apprehended by asking the same question the same way in different places and at different times. A variety of texts instructed those implementing the trial in how it was to be achieved, and, additionally, regulated this. A prime example was the protocol; others included SOPs and Working Practice Documents. These texts were strictly controlled: their circulation was limited and any changes had to be made through a centralised and audited process. 'Version control' was observed, to ensure old versions of the text were not in use. In some cases, an electronic infrastructure was in place both to govern and to provide an audit trail of changes to texts. This is part of a much larger regulatory framework mandated by the Medicines and Healthcare products Regulatory Agency (MHRA) which oversees the activities of clinical trials units in the UK.

Below, I present three examples of material standardisation at work.

Diagnostic devices

Electrocardiography literally involves the inscription of the electrical activity of the heart. It is used as a diagnostic device to measure abnormal heart rhythms, be this during regular patient care or specifically for research purposes. As part of safety monitoring, ECGs were used in the trial to monitor patients' heart activity and reduce the risk of adverse events related to one of the study drugs. Additionally, ECG data were being collected to assess the impact of study drugs on QT (the QT interval is the time from the start of the Q wave to the end of the T wave and represents the time taken for ventricular depolarisation and repolarisation), for which there was little existing data. ECG machines were purchased centrally and shipped out to trial clinics. The shipping process entailed many delays and significant labour from the coordinating team to ensure safe and timely delivery. Indeed, much time was devoted to discussing the ECG machines in team meetings and teleconferences. The clinics could not start enrolling patients into the trial until they had received the ECG machines, been trained in their use, and got them set-up and working. This put all involved under a certain amount of pressure, since budgets were being spent employing staff for the trial, and these budgets had to last until the trial was completed.

ECG was one means through which the trial participants' bodies were translated into data; the beating heart 'travelled' from the trial clinics to the UK and back again through a circuit, coordi-

nated not by a clinician, but by a data manager. During a presentation at one trial site, the UK data manager elaborated on how this circuit worked: the ECG machine – a MAC800 – is shipped from London, via the trial sponsor in Paris, to Johannesburg. A doctor or nurse at the site uses the ECG machine to take readings from the patient's heart. The MAC800 comes with software which enables the medical staff who conduct the procedure to save the output as a PDF and email it to the data manager at the coordinating site in the UK. The coordinating site then passes the data on to an independent cardiologist at a UK university, who has offered his expertise to the trial. He interprets the readings and can make recommendations on changing the patient's treatment, if necessary. So it is that a beating heart in South Africa is transformed and travels all the way to the UK.

Why was it, I asked a clinical investigator in the UK, that the ECG machines needed to be shipped around the world; weren't such things available locally?

> The ECG machine, now that was a standardisation issue and that was, well …a) they wouldn't have them anyway and we wanted the reports to be the same on each, and set them up so that they could get the same information out and that was standardised. Plus that it was set up for them and they didn't have to each figure out how to get out the necessary information on whatever system they happened to have bought.

She went on:

> R: [The independent cardiologist] advised on our approach to the monitoring of these patients and how we approach that in the protocol. So he advised us on that, not just individual cases. He advised us on what sort of ECG machines and what sort of holters we needed.
> I: The MAC800?
> R: He didn't ask for it that specifically, but you know, we said how difficult it would be, because we're going to all these places that aren't used to doing, haven't done ECGs for years and he said, "Oh you just get one of these machines that, you know, that print out the answer for you".

The ECG was thus very much a part of the evidence-making apparatus of the trial. It was of central importance that the readings be standardised across different settings, and it was seen as desirable that the machines simply 'give the answer' rather than requiring extensive staff training. The schedule for conducting ECGs was also standardised in the protocol; to avoid confusion in the data, sites were asked not to conduct ECGs unless scheduled.

While the ECG machine has potential as a knowledge tool in clinical practice generally, this potential was foreclosed by the way it was configured in the research. In the hospital in Vietnam, I was told that the ECG machine was the only one available on the ward, but that it could only be used for trial participants because the software was programmed to require a study number. If a patient who was not enrolled in the trial needed an ECG, the staff had to borrow a machine from the emergency resuscitation department:

> For the ECG machine, it's required that we have patient information; it's like a key. If the machine doesn't get that information, there's no key and it can't measure. Some doctors ask me to measure their patients and I say that if there's no trial code, the machine won't work. Therefore it can't measure, so we've never used it to measure non-trial patients.

Therefore, whilst the UK investigators aimed to help the site clinicians by simplifying the technology, in practice, this meant that site staff were effectively locked-out of the machine, unable to adapt its use to their local requirements. The ECG machine delimited the experimental context; it only worked on and for certain people who had codes (study number, user code) and whose relationship with the machine and with each other was directed to the experimental goal. This was likewise reflected by staff in South Africa, as the following extract illustrates:

> I: Do you still do the ECGs [in spite of the fact that government staff provide routine care]?
> R: Yes. Because ours is a different ECG. It has to be saved onto a disk and it must be emailed to our [trial] data team. So that's also a procedure on its own.

While staff at both sites were excited to receive new, high-tech equipment, because the machine was standardised across trial sites, it was difficult for them to incorporate its use into their routine care setting. In some cases, this disrupted established relationships between local staff working on the trial and their colleagues.

Drugs

> When you deal with a clinical trial, the minimum you can do for the benefit of patients entering the trial – you ensure the quality of the medicines, but also there is even a research objective, where you need to ensure that there will be a repeatability of the results of what you are assessing in terms of regimen for the drugs provided to South African sites, for Vietnamese sites…If you've got different qualities, what kind of assessment will you make in the end? It will be completely unhomogenous. Which is not at all what you look for in a clinical study. – Coordinating site staff member

The trial was testing a new regimen of existing drugs which had been approved, licensed for various indications, and were already on the market. The novelty lay in putting them together in a particular combination of dosages and schedules. Patients randomised to the intervention arm received this new regimen, while patients randomised to the control arm received the locally-used WHO-approved MDR-TB regimen. Neither patients nor clinicians were blinded to treatment allocation, but laboratory staff, who produced results on patient outcome measures, were.

The drugs for the trial regimen were standardised. They were purchased through the Global Drug Facility for TB, a WHO-housed procurement mechanism that ensures a single quality standard. The drugs for the *control* regimen were not standardised between the different trial sites, since each country has its own National TB Control Programme with its own protocols and procurement channels. The procurement of standardised drugs across the trial was one of the biggest challenges the trialists faced, since it involved estimating timelines for drug dispensation and expiry, obtaining import permits and VAT exemptions, negotiating delays in customs, acquiring and monitoring suitable storage facilities, etc. In fact, since the drugs the trial was testing were all already licensed, they were available in-country, but because the quality could not be assured, the decision was taken to import them.

As the staff member quoted above notes, standardising the drugs in the trial does two things: it ensures the patient receives a quality product and it allows a comparison to be made across different settings as to the effectiveness of the new regimen. The trialists seek pharmaceutical homogeneity in order to conduct a rigorous scientific experiment; in effect, their aim is to ensure that the drugs in the different countries are all the same.

The drugs procured for the intervention arm in the trial were not treated the same way as the drugs in the control arm (the WHO approved in-country regimen). The imported drugs had to be stored separately from other drugs, and the hospital pharmacies had to create special spaces for this. A raft of paperwork was associated with dispensation, swallowing, return and destruction. Logs had to be completed for accounting purposes (prescription register, receipt log, packing log, return log, destruction log…); drugs had to be dispensed into individual daily and weekly plastic bags (to ensure consistency and correct dosing); and any un-swallowed drugs had to be returned to the pharmacy (to enable audit and prevent circulation on the black market). It was not just the drugs themselves that became differentiated in this way; the people handling them also acted and were acted upon differently: patients were marked out as different by receiving their pills in individual bags rather than straight off the dispensing trolley; nurses had to handle returns differently, keeping all un-swallowed tablets in their bags and sequestering them for accounting purposes; pharmacists and coordinators had to destroy drugs, which normally would be reintroduced into circulation.

The destruction of drugs was a contentious issue, which was not well understood by all staff, as the following conversation with the pharmacist at one site illustrates:

> I: In terms of the destruction of drugs, can you tell me how that works?
> R: For us, for this trial, it's mostly been patient returns, and obviously once a drug is expired, it will also go onto the destruction. So when the patient

> brings back returns it's written into the destruction log and placed into a green bin, as dedicated for destruction, so when that reaches a certain level, we'll get authorisation from [the UK trial manager] and it will be uplifted and an outside company takes it off for destruction and then they'll give us a destruction certificate.
> I: And why do you have to seek permission to get the drugs destroyed?
> R: I don't know [laughs]. It's written in the log there! "Permission granted" – I don't know why!

In a more reflective moment, a coordinator of the National TB Control Programme in one country told me, "I know it's research, but I still cannot understand why we have to destroy drugs… The problem here is that the drugs for today are exactly the same as the drugs for tomorrow…why don't we reuse them? If the dosages are different then I'm fine with not using the drugs again, but they are all the same, so why do we throw them away?" While the drugs looked the same to this doctor, who was concerned with treating patients as an end in itself, to the trialists – who were concerned with treating patients as a means to answer a scientific question – they were not. Today's dose may have been the same as tomorrow's dose chemically, but it was not in evidential terms. In order to capture knowledge of how well the drugs are working, it is important to the trialists to know how many of the dispensed drugs have been taken. Since it seems feasible that the trial implementers could simply write down the number of un-swallowed drugs before re-dispensing them, one is led to ask what the sequestering and destruction of drugs in the trial achieved.

The procurement pharmacist told me there were two reasons. The first was to make sure that none of the un-swallowed drugs made their way onto the black market, where their use could not be controlled:

> [In] all these countries, withdrawal of expired medicine is very poorly controlled…so it's very tempting to do some black market just with whatever, even the expired drugs, because a lot of people don't know that expired drugs could do harm or could not be efficient, so they will find customers for it …So just to make sure that bringing extra drugs in these countries, at least we are responsible for how they're going to be destroyed, just to make sure they're not going to nourish any dirty system.

The second was to satisfy regulatory audit, in which the sponsor could be asked to back up the trial result with evidence from pharmacy accounting logs:

> I used to be a Good Clinical Practice auditor and… there is a very easy way to find out whether a company or an entity – a sponsor which has organised a clinical trial and is announcing outcomes on 350 patients – to make sure that really 350 patients have been treated. There is a very easy way to do it: "OK, give me all your files with how many drugs were provided, how many were dispensed, and which were destroyed." And if the balance doesn't match…Mmhmh! And often people, when they want to cheat, actually it's very difficult to really set up false drug dispensary forms.

The first reason the pharmacist gives concerns the physical status of the drug as chemical; the second, its status as evidence. In the former, the sponsor is imagined as a responsible actor in the local economy of pharmaceutical dispensing: trial drugs must not enter the informal marketplace and must therefore be destroyed. In the latter, it is portrayed as a responsible actor in the global economy of evidence-making: the destruction of trial drugs makes accounting practices add up. The practice of destroying drugs rests on a belief that records from actual drug destruction can be differentiated from faked records. It is very difficult to cheat, the pharmacist says. This belief privileges empiricism by implying that data derived from direct observation can be identified as true over made-up data. The obvious truth of the data lies in its correspondence to real events. Therefore, in order to achieve convincing evidentiary ends, the drugs must actually be destroyed.

While this position may be sensible from a drug regulatory perspective, from the perspective of some of the people working in the clinics, it was incomprehensible. Local staff understood that they must operate according to global standards, written into guidelines they had been given, but did not necessarily understand the reasons for the guidelines. In the resource-limited settings of this trial, where there were insufficient drugs to treat

patients, the idea of 'throwing away' good drugs was seen by some to be uneconomical, wasteful and morally wrong. This was compounded by the fact that achieving drug destruction according to global standards significantly increased the burden of work for public sector staff, who already had a heavy workload.

Laboratory results

As part of the national TB management protocol in South Africa, patients must provide sputum samples to be sent to the National Health Laboratory Service (NHLS). Samples take several weeks to be cultured and results are returned to the ward to inform patient management. At the same time, however, patients enrolled in the trial had to provide a second sample, which was sent to a specialist research laboratory, where the same information was extracted, but based on a set of laboratory procedures that were standardised for all the trial sites to follow. This information was also returned to the ward, usually more quickly than the NHLS results, and was stored in the patient's file. Following GCP, results did not contain patients' names but only study numbers.

A staff member described the tension that this standardised procedure produced in the hospital:

> We have to send our bloods through an accredited laboratory and our sputum specimens through an accredited laboratory. *So we have to have a parallel process*…To be a research-accredited lab, you need certain standards, I don't even know what they are…Sponsors want standardisation across all the sites, so therefore they select specific laboratories to do the work. And they accredit them. Now one of the ways that this has posed a challenge is that our bloods and our sputum specimens don't have patients' names on them; they've got study numbers and ID numbers. And for example we had a patient with a low potassium and we spoke to the doctor, but she was concerned that this piece of paper didn't refer to this patient because it didn't have the patient's name on. (emphasis added)

In spite of the pragmatic nature of the trial, and the attempt to produce evidence under usual programme conditions, it is clear that in relation to various parts of the care cycle, 'parallel processes' are instituted in order to standardise. In relation to laboratory tests, the knock-on effect was felt acutely at the patient-provider interface, as the following quote illustrates:

> Well I know from the nurses that there's sometimes some antagonism because obviously two doctors trying to manage a patient can cause problems, and especially since our results come from a different lab and their results come from NHLS labs … so the ward staff are then a little bit reluctant to react on results where it doesn't actually have the patient's name on it. They want their own results to come through.

As this example illustrates, when research is introduced into a routine care setting, different sets of standards may clash. Standardisation for care and research do not necessarily map onto each other; new forms of standardisation (such as the processing of lab results) can be interpreted as a de-valuing of existing practice and a critique of current standards. This can cause resentment among care staff, with a potential knock-on effect for patients and subsequently for recruitment and retention in the trial. Various examples of this were given by trial staff, perhaps one of the most notable being the delay to patients' discharge from hospital following a negative smear result:

> We've had a couple of occasions when our smears come back as negative on a Thursday and the patient wants to go home for the weekend, but the hospital smear is not back. So now the patients say, "But study smear's negative, why can't I go home?" Or we get a culture result that comes back negative, theirs is still pending, and it can be a two week difference, which …for our patients it's very significant.

Extending the rails or reinventing the wheel?

Because things aren't standard across different settings, trials tend to standardise. But because things aren't standard across different trials, standards proliferate. The coordinating staff frequently had to negotiate the practicalities of standardising across multiple settings, being well aware of the scientific and regulatory requirements placed on clinical trials, but equally cognizant of the very real effects for clinical sites of any attempt to standardise practice. This was vocalised as a desire not to

'reinvent the wheel' where local guidelines and practices could be accommodated within the protocol, but equally as a responsibility to maintain control over unchecked heterogeneity.

For clinical sites, exposure to standardisation through multicentre trial participation can be positive, in that a range of new skills and commodities can be acquired by working with different collaborators on different experiments. At both clinical sites, staff spoke highly of the benefits of participating in international research projects, including the trial in question. Reported benefits spanned the levels of the institution, patients and staff. At the institutional level, multicentre trials could lead to reputational gains, by virtue of being associated with well-known international partners. At the patient level, benefits related to early access to new treatment standards. And at the staff level, interviewees spoke of acquiring greater knowledge and skills and being able to work to international standards. For example:

> If we sign African investigators on and train them how to do research in [this trial] and then they go on and write investigator-initiated studies because of the experience they had in [this trial], that's capacity building. You know GCP training and all that kind of stuff.

> I think that the international research is helpful not only for patients but for staff also. We learn so much when we run this study. Because for international research, we have to have many standards and these are international standards and in Vietnam we have not so much experience. But step by step, by studies, we learn and hope we can reach the international standards.

However, working on multicentre trials was also said to have negative effects, such as staff being overwhelmed by the continual need to learn and implement new processes; duplication of systems and equipment that was not needed (see the printer example at the start); and fractures in the transferability of research findings to the standard of care once a given research study yields results. Criticising the duplication of work needed between the databases of the National TB Programme and the trial, one staff member commented:

> This study goes its own way, different forms and documents and templates, it does create a burden for staff. If [this trial] is successful and later on it still requires procedures like that, I don't think they can follow it.

Another at a different site alluded to frustrations with parallel processes and the lack of agency site staff had in relation to their everyday working practices:

> Well we did try at the beginning of the study to ask [the UK trial manager] to give us a log so that we could amend it so that it would be in line with our working practices and we don't change too much of our SOPs and things like that. Because it's new also, it would be difficult to remember what you have to do. So they were reluctant to send us the format in which we could change it. They said they would only send it to us in pdf format and then they'd ask us "what is the change that you need and give us an explanation as to why we need to change it".

These examples show the tensions between standardisation and localisation that must continually be negotiated by all parties in an international multicentre trial. The material artefacts mentioned in this paper (diagnostic medical equipment, databases, drugs, printers, stationary, sputum specimens, and test results) necessitate a raft of novel practices, and it is often these practices – rather than the artefacts *per se* – which result in the intangible gains touted for transnational research, i.e. capacity building, reputation, etc. As currently conceived, the two cannot be separated. The challenge for global health trials is to acknowledge the value in local specificity and rather than seeking to efface it, work with it to produce science that is both rigorous and situated.

Discussion

How 'sensible' is standardisation? In this paper, I have provided three examples of material standardisation in a multicentre clinical trial which trouble an easy answer to this question. On the one hand, clear rationales exist for such standardisation on ethical, regulatory and scientific grounds. On the other hand, efforts to make things the same across diverse care environments, even

down to the level of how drug labels are printed, potentially create conditions which are antithetical to sustainable and relevant clinical research, including 1) the external validity of evidence from pragmatic trials 2) the gap between experimentation and implementation on which a new policy's success can depend and 3) long-term site capacity to conduct research. I address each of these in turn below.

The first dimension of the sensibleness of standardisation concerns the extent to which the experimental environment reflects usual conditions. As each new trial imports (self-) standardised diagnostic equipment, drugs, stationary, and software, clinical sites become repositories of both material worth and evidentiary values. When a trial ends, the result is extracted, while these ordinary yet un-usual objects remain behind. As each trial requires and produces its own uniformity, and as the traffic in trials increases (particularly in 'good' sites), so the 'representative care setting' is re-invented again and again. This leads to questions about what the site is ultimately representative of, and how far the evidence produced within it can easily be adopted or transferred to other places. In contrast to Petty and Heimer's work suggesting that a clinic's ability to conduct research positively influences its ability to implement research findings by 'extending the rails', I have argued that the lack of a stable organisational environment can have adverse effects in this respect, leading to the continual reinvention of the wheel. While Petty and Heimer (2011) acknowledge that the extent and permanency of standardised practices in clinical research settings can vary, they nonetheless emphasise the positive association they engender between research and implementation. I agree with them that "conducting research is likely to have its most lasting effects when the network of ties and the infrastructure built and reconfigured in the course of doing a research project are later appropriated by subsequent research projects and care programs" (Petty and Heimer, 2011: 357), but based on over a decade of observation, this is not commonly the case.

Entangled with this first dimension is the second, which concerns the bifurcating effect that material standardisation can have on the relationship between research and care. As the empirical examples in this paper illustrate, standards change the worlds upon which they are imposed, reconfiguring relationships between colleagues and between medical staff and patients. While such changes can be positive, arguably driving up professionalisation and introducing the latest standards into clinics, they can also result in a 'double standard', where existing local practices co-exist alongside the new and 'universal', but are devalued. The privileging of external solutions over what is available locally can have unanticipated effects, as numerous studies of technology transfer have shown (see e.g. Müller-Rockstroh, 2012).

What's more, whereas extensive labour is required by trial managers to circulate standardised materials during the course of an experiment, this labour (and the artefacts involved) is usually omitted from scientific accounts of the results. It is troubling that where the aim of a trial is to usher in a new 'standard of care' (as was the case with the trial described in this paper), the standard of care is imagined in pharmaceutical terms rather than as the sum of social and material relations which have brought the result about. Marks' (1997) observation that "even the simplest RCT is the product of a negotiated social order, replete with decisions…and with unexamined assumptions" could only be more pertinent had he added 'mundane artefacts' to the list. While pragmatic trials are designed to generate 'real world evidence' for clinical decision-making in a valid way (Zuidgeest et al., 2017), what the real world is made of is a question needing more granular and transparent treatment.

The third dimension concerns the temporality of standardisation and related to this, the sustainability of 'capacity building' when this is used as a proxy. What is the relationship between standardisation and sustainability in clinical research? It would be logical to assume that once a site is up and running with its GCP and its SOPs, it would be set up to run all future trials, or at least future trials of a similar nature. However, this is not necessarily the case, because each new trial that comes along still purchases and ships in new equipment, new forms, and a variety of other 'new' standards embodied in everyday objects. But what would

happen if these objects were not shipped out and the experiment was done using what was already available locally? If we applied this thought experiment to the real experiment discussed in this paper, the pharmacist would continue to use the printer she has and cut out drug labels according to her own method. The coordinating team would accept that the pharmacy already has systems in place and not ship reams of new logs to be completed in addition to those that are being completed already. ECG machines would be purchased locally and made available for staff to use according to local needs. The results would not be standard, but the information would be there nonetheless.

When things aren't standardised, the adjustment, the interpretation, the making things fit together, has to happen on the part of a trial's coordinating team as well as on the part of the sites. What is privileged is not uniformity but variability, availability, suitability, sustainability. Such an approach would require a greater recognition of the situatedness of trial results, that is, an express appreciation that the local is inherent to aggregated clinical evidence. Zuiderent-Jerak (2007), and subsequently Engel and Zeiss (2014), building on Timmermans and Berg's (1997) notion of 'local universalities', have thus referred to the need for 'situated standardisation' in the development of clinical guidelines: "Situated standardisation means that standards are practised in a situated manner, by assessing what the role of the guideline is in a particular service delivery situation and then adapting it respectively" (Engel and Zeiss, 2014: 205). As elaborated by Engel and Zeiss (2014) in relation to MDR-TB guidelines, this allows for local innovation within the confines of control, such as healthcare staff 'going beyond' what is officially sanctioned by the guidelines. Within the context of a clinical trial, this kind of local adaptation may well result in a so-called 'protocol deviation'.

Is there a place for 'situated standardisation' in multicentre trials? Some would argue that it already exists, and indeed recent methodological developments, namely so-called adaptive trial designs, suggest that there is a growing acceptance of adaptation over rigid standardisation (Montgomery, 2017). It is not only in biostatistics and trial methodology that such developments are occurring; in the critical medical humanities, Savransky and Rosengarten (2016) recently offered a different take on the ontology of health and disease, regarding such processes as always situated achievements:

> [W]hile RCTs locate mechanisms through the abstraction of discrete, isolated entities and variables from their 'confounding' environments, the practice of situating, by contrast, does not allow such clear-cut distinctions. Rather, both an object and its situation are entangled, spatially and temporally, to one another such that both become co-determined through their specific, reciprocal transactions and exchanges. (Savransky and Rosengarten, 2016: 170)

While their proposition provokes a series of questions about how to produce evidence of effect that can be generalised across settings and situations, it remains – as they themselves acknowledge – 'a fiction' (Savransky and Rosengarten, 2016: 171). As I have shown in this paper, there is an element of fiction to the 'real world' settings of the pragmatic trial, but that does not mean we should discount such evidence out of hand. Rather, what is needed are critical analyses of how the gap between evidence and implementation is forged, and a dialogue between the biomedical sciences and the critical social sciences as to better ways forward.

Conclusion

In this paper, I have sought to move beyond the dualism of critique and complicity which frames this special issue, by highlighting the ambiguity of standards in practice in the context of a global health trial. Sociological studies of standard-setting emphasise that standards and standardisation are not inherently good or bad, and demonstrate the ways in which standards can be made to work in local situations (Timmermans and Epstein, 2010). That is, standards tend not to be rigidly adopted in practice, but are most successful when they incorporate a degree of – but not too much – flexibility (Lampland and Star, 2009; Engel and Zeiss, 2014). The drive towards 'sensible' clinical trials, which has to date focused

on standardisation in the regulatory realm, would benefit from a broader appraisal of the forms of social control which suffuse the experimental process. The introduction of standards into the material environment transforms the existing social order, or 'social software', of clinical trial sites. We therefore need more thoughtful consideration of how the proliferation of standards accompanying increasing levels of clinical trial traffic in some places not only erases what is 'representative' about these places but also troubles what is meant by 'capacity building'. I have suggested in this paper that a productive way forwards is to propagate an appreciation of the fact that clinical trials need not only to be 'sensible' but also 'situated'.

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Imaginings of Empowerment and the Biomedical Production of Bodies: the Story of Nonoxynol-9

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Abstract

In this paper, I will explore the development of vaginal microbicides (female-initiated HIV prevention methods designed as gels, films, sponges and rings women can insert vaginally before having sex to protect themselves against HIV infection) as a women's health intervention that entangles feminist ideals of empowerment with biomedical enterprise. The field of vaginal microbicide development pays heed to both the specific biological vulnerabilities of 'the female body' that are understood to make women more susceptible to HIV infection as well as the social gendered power relations that leave women at a higher risk of HIV within the power dynamics of their sexual relationships. I am particularly interested in the ambiguity that emerges between the effects of a biomedical search for facticity through clinical trial testing and advocacy promises of empowerment, which I will explore through analysing the clinical trials of Nonoxynol-9 microbicide candidates in the early 1990s – a microbicide candidate that was continuously linked to vaginal ulceration and consequently a potential increase in receptivity to HIV. Through an interrogation of clinical trial reports, advocacy documents and a social science study in which the women trial participants articulated Nonoxynol-9 as their "protector", I argue that the story of Nonoxynol-9 shows an intrinsic ambiguity between the field's feminist promise of empowerment and the effects of the biomedical search for an effective microbicide candidate. Drawing on the work of Karen Barad, I argue that agential realism is able to provide a robust analytical framework to interrogate the political and ethical effects of this ambiguity that the field's own discourse of empowerment does not sufficiently provide.

Keywords: HIV, vaginal microbicides, agential realism, global health, new materialism

Introduction

In this paper, I explore a women's health intervention that entangles feminist ideals with biomedical enterprise – the development of vaginal microbicides (female-initiated HIV prevention methods designed as gels, films, sponges and rings women can insert vaginally before having sex to protect themselves against HIV infection). In particular, I am interested in the relations and discrepancies between feminist ideals of women's empowerment and the effects of biomedical process that become apparent through clinical trial testing of microbicide candidates. At present, microbicides are being tested in clinical trials and have been since the early 1990s with mixed and at times

controversial results. Since the early 1990s eight microbicide candidates have made it to trial: Nonoxynol-9, SAVVY, Cellulose Sulphate, Carraguard, PRO 2000, Buffergel and Tenofovir gel. Currently, the new candidate with the most promise is the vaginal ring, which proved safe and effective in recent clinical trials and is currently undergoing open-label studies (Baeten 2016: 2; MTN, 2016).

The advocacy campaign for microbicides has been voiced as an explicitly feminist campaign, largely fuelled by an understanding of gender dynamics that speaks in terms of women's empowerment and aims to transform gender and sexual power relations. According to the Global Campaign for Microbicides (GCM), the largest microbicide global advocacy body, the microbicide would offer women a way to empower themselves in the context of their sexual lives, where other forms of protection, such as a condom, may not be available to them or may be problematic. The field of vaginal microbicide development pays heed to both the specific biological vulnerabilities of 'the female body' that are understood to make women more susceptible to HIV infection as well as the gendered relations that leave women at a higher risk of HIV within the power dynamics of their sexual relationships. The development of microbicide's engagement with the female body, gender dynamics, ideals of empowerment and the HIV virus places the field at a fascinating juncture, at the intersections of nature and culture, sex and gender, material real and utopic future – junctures that correspond with the aims of many STS approaches, including the work of 'feminist new materialisms'.

In this paper, I engage Karen Barad's (1998, 2003, 2007) performative onto-epistemology of agential realism and provide a reading of the development of microbicides which foregrounds the clinical trial as an apparatus of bodily production, i.e. a socio-scientific milieu constitutive of the bodies put on trial. I understand Barad's theoretical work to resonate with the aims of microbicide development as Barad both engages science and technology while paying attention to the sexual politics of scientific development. As such, Barad's work is situated on the cusp of STS and its predominant focus on the scientific production of human/nonhuman hybridity, and feminist and queer theory that foregrounds the performativity of sex(uality) and gender (Barad, 1998, 2012, 2015). As such, Barad not only celebrates human-nonhuman hybridization, but also pays heed to the processes through which the human comes into being and the potential dehumanisation such constructions might entail – "*the more or less "human", the inhuman, the humanly unthinkable*" (Butler, 1993: 8). Consequently, agential realism is not only a fruitful method for a critical analysis of science and technology, but also a theoretical engagement that lends itself to political aims of embodied resistance to gendered and sexualised power structures. Such a theoretical focus resonates with the key issue at stake in this paper – the materialisation of empowerment ideals.

In this paper, I will look at the first microbicide candidate that made it to trial, which is also the most controversial to date, Nonoxynol-9. I will analyse the Nonoxynol-9 trials as a case study that very clearly epitomises the discrepancy between the effects of a biomedical search for facticity through clinical trial testing and advocacy promises of empowerment. However, this case study is not intended to represent the entirety of the field of microbicides and several decades of candidate testing.

The argument set out in this paper is situated in a more encompassing textual research project based on a collected archive of the development of microbicides from the early 1990s until the end of the GCM in 2012 (see Van der Zaag, forthcoming). This archive consists of a collection of advocacy documents, clinical trial reports and social science studies predominantly collected through keyword searches in the PubMed database and the GCM website. This collection of texts allows me to investigate the different articulations of the development of Nonoxynol-9 and the manner in which different aims, ideals and materialities were put into discourse.

It is no coincidence that I place clinical trial reports together with social science studies and advocacy documents. I aim to show the complexity of the field of vaginal microbicides, the different meanings and materialisations that have been construed by the wide variety of actors that comprise this field – both human and nonhuman. As such, I engage in a mode of critique that shows

the frictions and relations between multiple actors in their aim to develop a technology to protect women against HIV infection while furthering ideals of women's empowerment. Indeed, I am focused on the differences and similarities between women's health advocacy documents, biomedical clinical trial reports and social science studies to show the differences in how the microbicide is articulated to intervene into women's bodies and socio-sexual lives, paying particular attention to the gendered vocabularies utilised. My approach to these articulations insists that they do not merely represent the problematic the field engages in. Rather, the multiple articulations that make up this field are constructive, they constitute what is at stake within the field of microbicide development, the microbicide as a technology and the women implicated in its intervention. I question, what happens to feminist ideals of empowerment when they materialise through biomedical process?

Women's empowerment as a vehicle of inclusion

According to UNAIDS statistics, worldwide there are around 37 million people living with HIV (UNAIDS, 2016: 1), of which women and girls make up more than half (UNAIDS, 2016: 8). Globally, the number of women living with HIV has been on the rise since the early 1990s. This increase is shown to be more prominent in some parts of the world than others, such as in Sub-Saharan Africa (UNAIDS, 2016: 8). Moreover, the UNAIDS 2010 report states that in Sub-Saharan Africa young women are eight times more likely to be HIV positive than men their age (UNAIDS, 2010: 10). This increasing feminisation of the HIV epidemic constitutes the need for and has been the backdrop to the development of vaginal microbicides.

The development of microbicides commenced in the early 1990s when women were only just becoming visible as a group at risk of HIV. During this time, the concept of 'empowerment' functioned as a vehicle for women's inclusion into global HIV prevention discourse (WHO, 1990, 1992, 1993, 1994, 1995). Within global health discourse women at risk of HIV were articulated as subject to a lack of power in their gendered lives and this distribution of power was understood to fuel their vulnerability to HIV infection. Subsequently, 'empowerment' was understood as alleviating this particular vulnerability, brought about either through behavioural change or biomedical intervention. However, although the need for female initiated HIV prevention was recognised in early 1990s global health discourse, most attention was given to women's socio-economic empowerment initiatives and condom logistics. This is the point where the development of vaginal microbicides critically set its own direction, as it took up biomedicine as a way to transform women's vulnerability to HIV infection and expand an understanding of women's empowerment towards biomedical intervention into the female body.

From its initial conceptualisation, the vaginal microbicide has been understood as an explicitly sexual technology potentially transformative of both gender dynamics and HIV susceptibility, as the epidemiologist Zena Stein argued in 1990:

> At present, the sole physical barrier promoted for the prevention of sexual transmission of human immunodeficiency virus (HIV) infection from men to women is the condom. With condoms, active male cooperation is crucial. The proposition of this paper is that the empowerment of women is crucial for the HIV transmission to women. It follows that prophylaxis must include procedures that rely on the woman and are under her control (Stein, 1990: 460).

Stein put female controlled prophylaxes forward as devices that might very well be less efficacious than a condom, but more effective as they are tailored to meet women's specific needs. As female-controlled prophylaxes were aimed at protecting women's bodies against HIV and simultaneously further women's empowerment, Stein articulated an intimate relation between social dimensions of power and scientific interventions into the female body. The promise of vaginal microbicides entangles the biological susceptibility to the HIV virus with the transformation of socio-sexual power relations. As Catherine Montgomery writes, "[t]he fusing of women's biological vulnerability to HIV with their social vulnerability to infection seamlessly led to the medicalisation of powerlessness

and the search for a medical solution to it" (Montgomery, 2012: 928).

The idea of a vaginal microbicide as a female-initiated HIV prevention method was soon taken up by Lori Heise (Elias and Heise, 1994), the former director of the GCM. The GCM remained the prime advocacy body in microbicide development before it disbanded in 2012. This campaign was officially launched at the twelfth AIDS Conference in Geneva in 1998 (GCM, 2009a). Although the GCM's headquarters were based in the U.S., they described themselves as a – "broad-based, international coalition of organisations working to accelerate access to new HIV prevention options" (GCM, 2012a). Their main goal was "to focus world attention on the critical need for new HIV prevention options, especially for women" (GCM, 2007a, 2010c). The Campaign represented women's need for a microbicide, how a microbicide will intervene in women's lives and, importantly, how the microbicide will function as an empowering technology. What is significant of the GCM is that they both engaged with an understanding of women's vulnerability to HIV as a social problematic as well as the specific vulnerability of the female body, thereby simultaneously engaging the social and the biological without reinstating a sex/gender, nature/culture dichotomy. This entanglement of physical and social aspects of HIV infection becomes visible in their articulation of women's risk, an articulation of vulnerability that is consistently repeated throughout their campaign discourse. They claim that the biological factors that contribute to women's risk of HIV consists of the following:

> Biological factors contributing to women's risk of HIV:
>
> -Women are more likely than men to contract HIV at a single exposure.
> -The cervix is a site of particular vulnerability.
> -Younger women are at even greater risk, since the cervix is physiologically less mature and therefore more vulnerable to infection.
> -Women with asymptomatic STIs may not seek treatment, which can result in serious long-term consequences such as infertility, pelvic inflammatory disease, ectopic pregnancy, infant mortality, and cervical cancer.
>
> Social and economic inequities also contribute to women's risk:
>
> -The vast majority of women with HIV were infected during heterosexual sex – many by their husbands or boyfriends.
> -Women may influence but do not control the sexual and/or drug-using behaviour of their male partners.
> -Violence, coercion, and economic dependency in many women's relationships make it difficult to "negotiate" condom use or to leave a partnership that puts them at risk.
> -In many societies, women and girls are discouraged from learning about their bodies and about sex in general.
> -Often, women are socialised to leave sexual decision-making to men.
> -Gender-based social norms often encourage men to seek multiple partners, while women bare the shame and stigma of disease.
> -Growing economic inequality and eroding social support have driven many women into commercial sex work to support their families (GCM, 2009b).

For the GCM, a vaginal microbicide promises to provide women with a HIV prevention method that would protect their bodies against HIV which women would be able to incorporate into their socio-sexual lives. The specific aim of the GCM was to provide women with a tool they could control and that would answer to women's different needs. Importantly, the GCM worked in close collaboration with biomedical efforts of microbicide development and its large-scale roll out of trials, to ensure that the trials themselves would be spaces of empowerment and that women's vulnerability would not be increased through biomedical process (GCM, 2007b). However, I argue, it is in this meeting of feminist ideals and politics and biomedical enterprise where problems arise, particularly in terms of women's vulnerability to HIV infection within clinical trials.

The clinical trials

Women's vulnerability to HIV, physically, socially, sexually and economically, is a key controversy within the microbicide Randomised Controlled Trials (RCTs) and the field of microbicide development is very much aware of these complexities. To address these, a symposium was organised in

1997 in Washington D.C. which highlighted key concerns and ethical deliberations that are still in effect in the field. This symposium was convened by WHAM (Women's Health Advocates on Microbicides, the main advocacy body preceding the GCM) and the Population Council (the initial biomedical collaborator in the microbicide field), to discuss ethical and practical dilemmas of microbicide testing. It brought together 55 experts in clinical, biological and social science and activists, biomedical ethicists from 15 countries in Africa, Asia, Latin America, Europe, and the U.S. The symposium took place when the concept of a topical microbicide was just taking shape, when boundaries between science and women's health activism were starting to become less rigid and the first Nonoxynol-9 based candidates were entering human clinical trials. Importantly, as the below excerpt of the symposium report indicates, the symposium situated the clinical trial as embedded and active in power dynamics.

> Although women need and deserve a technology they control, microbicide research should not be allowed to deflect attention from the underlying power inequities that put women at risk.
> Microbicide research must be seen as part of an overall program of STI/HIV prevention that includes efforts to empower women and to improve the detection and management of STIs among women, especially in resource poor settings. (Heise et al., 1998: VII).

What the clinical trial was understood to do, entailed more than testing for mere efficacy. Rather the efficacy of the microbicide candidate became intimately related with power dynamics. This is a manner of understanding biomedical engagement that remained with the GCM throughout its later advocacy efforts (GCM, 2010a). However, through the manner in which power is understood and the authority ascribed to biomedical knowledge seeking practices, the clinical testing of microbicides is almost instantly separated from these more encompassing relations and power dynamics. This has remained intrinsic to, and one of the key complexities in, the development of vaginal microbicides. Although the clinical trial is put forward as an active component in women's gendered power dynamics and protection against the HIV virus, it is simultaneously understood as 'the gold standard' of microbicide testing (Heise et al., 1998: 10; see also Rosengarten and Michael, 2013).

The RCT as the gold standard for microbicide testing is directly related to the demands of regulatory institutions (the United States Food and Drug Administration being the most prominent) by which the candidate needs to be approved before it can be produced for large scale distribution, should the candidate prove efficacious. Although the FDA does not explicitly articulate the RCT as the gold standard for the testing of new drugs, their guidelines are interpreted as such that the field endeavours to answer to their requirements through the RCT (AVAC, 2015; GCM, 2015; FDA, 2015; see also Will, 2007). The manner in which this tension between the RCT as an empowering space and the RCT as the gold standard of microbicide testing plays out is through women's (vulnerability to) HIV infection. On the one hand every effort is taken to decrease HIV infections within the clinical trial, specifically by providing STI testing, promoting the use of condoms and providing safe sex counselling. However, the manner in which data is sourced means that, despite the trial's preventative measures, women's HIV infection is anticipated.

The efficacy clinical trials are only conducted on HIV negative women. The data of these trials is readable through women's seroconversions (to HIV infections) as the number of HIV infections in the placebo arm shows how efficacious the microbicide candidate in the product arm is. "The higher the incidence of HIV in the host community, the smaller the number of participants necessary to detect a difference between a microbicide and a placebo. As incidence declines, the number of women necessary to detect an effect rises rapidly, making trials among low-incidence populations extremely cumbersome and expensive" (Heise et al., 1998: 18). The RCTs need to be conducted on populations with a high prevalence of HIV infections in order to gather enough data for statistically significant analysis, which for the phase III trials (human trials testing efficacy) would mean a multi-site population. If the data is not statistically significant the measured efficacy of a microbicide candidate could have been due to chance.

In other words, statistical significance provides 'objective' data concerning the effect of the microbicide candidate on the HIV virus within the female body. Statistical significance remains *the* core method for the success of a clinical trial in biomedical terms, as its success is understood as providing proof of the efficacy of the microbicide candidate, which is called 'proof of concept'.

Because of the need for statistical significance to show the efficacy of the microbicide candidate, the population the microbicide is tested on is selected according to HIV incidence (the number of HIV infections across the potential trial population) and women's specific risk of HIV infection within their sexual relations (as opposed to for instance drug injection). These criteria are aimed at ensuring that the trialists know whether seroconversions occurred during vaginal sex and therefore, consequently, the measure of protection is due to the efficacy of the microbicide. This need of HIV infection leads trialists to enrol groups of women into the RCT who are highly vulnerable to HIV infection in specific ways. In particular, female sex workers and women who have difficulty negotiating condom use. In other words, precisely those women who are understood to be in need of a microbicide, because of what advocates indicate as, their socio-sexual vulnerability, are desirable participants of the RCT because their specific vulnerability will make the RCT more likely to produce a statistically significant result. "This reality helps ensure that despite the best efforts of trial sponsors to actively promote condom use in both trial groups, there will be some women who are unable to do so (making it easier to evaluate a potential microbicide)" (Heise et al., 1998: IX).

Although biomedical development is inherent to the advocacy promise of empowerment, the manner in which women's vulnerability to HIV infection is anticipated in light of the trial's success is not easily reconcilable with the advocacy efforts to diminish this vulnerability through centralising women's needs, protection and empowerment. There is a clear discrepancy between the advocacy promise of women's empowerment and the biomedical development of microbicides that hinges on women's HIV infections within the trial. However, although ideals and materialities stand in ambiguous relation, they are not mutually exclusive. Thus, in order to explicate what is at stake in the development of microbicides, I concur with Jungar and Oinas' statement that "[a]nalyses of potentially helpful interventions into the epidemic as a discursive-material reality become crucial" (Jungar and Oinas, 2010: 179). Textual analysis of the development of microbicides allows me to bring biomedical articulations of the female body, microbicide candidates and virus, social science articulations of women's experience and advocacy ideals of women's empowerment within the same performative frame. In doing so, I am interested in how differences, such as the aforementioned ambiguity, are negotiated and how such negotiations come to bear on the microbicides potential user and thus the empowerment a microbicide is able to promise. As such, my work resonates with Nelly Oudshoorn's research into clinical trials where "…the development phase of a technology becomes an intriguing location for understanding the co-construction of users and technologies" (Oudshoorn, 2003a: 213; see also Oudshoorn, 2003b).

Furthermore, this study makes a significant contribution to social science in HIV and in particular social science studies of the development of vaginal microbicides which engage the experiences of trial participants (for instance the work of Saethre and Stadler, 2010, 2011), but often leave the workings of a trial unexamined (Will, 2007: 85) and present their findings as representative of women's experience. In critical contrast, and aided by my textual point of entry into the microbicide field, I do not claim direct access to women trial participants' experience. Although my own work is in conversation with these studies, what I am interested in is the ways in which these experiences and voices come to be articulated through social science and as such become part of the apparatus of bodily production of microbicide development. Such a performative scope is in line with an emerging body of HIV research that explicitly foregrounds the materialities of HIV, bodies and prevention technologies and biomedicine's constitutive role herein (see for instance Rosengarten, 2009; Race, 2009; Montgomery, 2012; McKnight and Van der Zaag, 2015). That is to say, I am interested in how bodies come to

matter in microbicide development as a material-discursive performative process that includes the articulations of materiality, experiences and ideals.

Agential realism

Karen Barad's work is embedded within so-called feminist new materialism, currently gaining rapid momentum within feminist theory. In correspondence with STS agendas, these new materialisms are concerned with the breakdown of the dichotomous oppositions between biology and society, nature and culture, human and nonhuman and are characterised by paying significant attention to nonhuman actors, especially within the scientifically focused strands of this multifarious body of work. Here, a wide array of theoretical interventions and trajectories is encompassed, including engagements with matter's literacy (Kirby, 1997, 2011), engagements with sexual difference and its futurity (Grosz, 2005, 2011; Braidotti, 2011a), the constitutive role of the sciences (Haraway, 1997; Barad, 2007) and more ecological investigations (Haraway, 2016; Alaimo, 2010). Many feminist new materialisms, including the work of Barad, are pitched against the so-called cultural turn and its focus on cultural processes of signification and identity in the theorisation of sex(uality) (Hemmings, 2011). In particular, Judith Butler's notion of materiality is often invoked as failing to engage with the materiality of the body (Cheah, 1996; Kerin, 1999; Kirby, 1999, 2011; Fraser, 2002; Barad, 1998, 2003, 2007).

What is at stake here are the various materialities these theories engage with and thus the multiplicity of materiality that ensues. Sari Irni (2013) has coined this 'the politics of materiality' which constitutes a certain disciplinary hierarchy of value where engagements with the natural sciences (or 'capital S science' (Willy, 2016: 4)) are understood to be the primary site where materiality is to be found[1]. Attention to such politics of materiality is often articulated through the conceptualisation of this relatively nascent field of theory. Should we speak of new materialisms (Coole and Frost, 2010), material feminisms (Alaimo and Hekman, 2008), neo-materialism (Braidotti, 2000)? These questions are not so much attempts to canonise the field, as they are questions of politics phrased through scholarly genealogical trajectories. Here, it is important to state that these materialisms are not necessarily new, but rather are enabled by a wide range of past feminist theories on materiality including Simone de Beauvoir's (1997[1949]) engagement with biology, Shulamith Firestone's (1970) feminist revolution through technology, Emily Martin's (1989) discourse analysis of the reproductive system, Sandra Harding (1986, 1991) postcolonial critique of science and of course, Donna Haraway's (1976, 1978) critique of the distinction between nature and culture. In other words, and to speak with Sara Ahmed (2008), new materialisms can often be seen to enact a 'founding gesture' - a certain neglect of past feminist theory on materiality, articulated through a 'return to matter' (Hemmings, 2011), that comes to substantiate the 'new' of this multifarious body of work. However, such a gesture has direct methodological and political implications problematic for new materialism as a feminist project. Barad has a complex position within these feminist critiques. On the one hand, she repeats the same founding gesture by setting her theory up against Butler's performative notion of materiality and thus enacting a 'return to matter'. On the other hand, her agential realism explicitly allows for theorisations of sex(uality) and dehumanisation, even if Barad rarely engages such materialities herself.

Karen Barad's approach (1998, 2003, 2007, 2012, 2015) is both deeply embedded in Haraway's socialist feminist theory (historical materialism) as well as Judith Butler's performative materialism (even if in critical relation). Such embeddedness makes clear that Barad's agential realism is indeed materialist, but not necessarily new. Furthermore, the multifarious genealogy of Barad's agential realism, already illuminates that she engages, or at least opens up a theoretical space to engage, a multiplicity of materiality. What I am particularly interested in is Barad's interest in non/human hybridization and science, while a methodological and political emphasis on lived reality (Haraway) and the performativity of sex/gender and (de) humanisation (Butler) remain at stake. Therefore, I utilise Barad's agential realism, not because of the specific science (quantum physics) she engages. Rather, I am interested in the manner in which

Barad engages science as a field of operations through which bodies come to matter. Thus, I would coin Barad's approach, as well as my own, neomaterialist in an effort to both articulate its trajectory through historical and performative materialisms, while paying heed to the contemporaneity of the current feminist materialist debates.

Karen Barad takes Judith Butler's notion of materiality and performativity (Butler, 1993) and its concern with processes of (de)humanisation and rearticulates this theory to account for scientific practice. Karen Barad's point of departure (1998, 2003, 2007, 2012, 2015) is the practices constitutive of the "human" and "nonhuman", these entities do not pre-exist the material-discursive apparatuses through which they come into being (Fraser, 2002: 617). Indeed, who gets to count as human within human/nonhuman hybridizations is contingent on the specific apparatuses through which these entities are constructed. Barad understands scientific practice as performative, the objects and bodies under scientific investigation, their very ontology, is an effect of performative practice. However, agency, for Barad, is not a human prerogative, rather, she develops a performative account of materialisation that is open to intra-action with nonhuman entities, thereby paving the way for an analysis of embodiment that is indiscrete in matters of bodily contours and postanthropocentric in its consistency. In this understanding of performativity, Barad (2007) emphasizes intra-action as opposed to interaction as there are no pre-existing entities to interact with one another. It is within *phenomena* that bodies and objects come to be, through the performative onto-epistemology of intra-action. As such, within scientific development there are no pre-existing bodies, subjects and technologies for scientific knowledge-seeking practices to discover and describe, rather, it is through performative practices that these entities emerge, in intra-action with one another. As an important consequence, especially in light of an analysis of the field of microbicide development, the boundaries between bodies, apparatuses of scientific development and technology evaporate: "...bodies are material-discursive phenomena that materialize in intra-action with (and, by definition, are indissociable from) the particular apparatuses of bodily production through which they come to matter (in both senses of the word)" (Barad, 2007: 209).

Within an onto-epistemology of agential realism (scientific) apparatuses have a central place. Because boundaries between the component entities of the phenomenon are determined through the apparatus, they do not pre-exist. Out of a context of indeterminacy, apparatuses construct the components of/within a phenomenon (such as for instance HIV, microbicide and woman) by temporarily determining them as such. According to Barad (1998, 2007), an apparatus is not purely scientific, but a more complex and encompassing setup consisting of myriad systems of meaning and materialisation. Reading the RCT as an apparatus of bodily production allows me to 'open the RCT up' as not only a scientific space of facticity and objectivity (Epstein, 1996; Michael and Rosengarten, 2013; Latour, 1993; Will, 2007), but rather as a complex site where facts, ideals, bodies, virus, microbicide candidates, sexual practices materialise and become meaningful in intimate, co-constitutive, relation - intra-action. Thus, to get ahead of my argument, reading the RCT as an apparatus of bodily production allows me to interrogate the field's ideals of empowerment and the effects of biomedical knowledge-seeking practices (here vaginal ulceration specifically) not as a mutually exclusive contradiction, but as an ambiguous relation constitutive of the woman/microbicide phenomenon on trial.

The story of Nonoxynol-9

Nonoxynol-9 based spermicides were the first agents to be considered for microbicide development. Their testing commenced in the late 1980s as spermicides that might protect against HIV (see Kreiss, 1992) even before the concept of a 'microbicide' was articulated. Nonoxynol-9 was understood to be a promising candidate by both the advocacy and biomedical field because at the level of in vitro research Nonoxynol-9 showed to be potentially efficacious against several STDs and HIV. Furthermore, since Nonoxynol-9 based spermicides were already being manufactured, they were viewed as a potential microbicide that

would be relatively cheap and easy to produce (Roddy et al., 1998; Cook et al., 1998). Specifically, Nonoxynol-9 was a detergent that functioned by breaking down cell membranes. However, it raised concerns that it did not only break down cell membranes of the virus, but also of vaginal skin and the cervix. Eventually, Nonoxynol-9 based microbicides were shown to increase women's susceptibility to HIV infection due to causing vaginal ulceration.

Nonoxynol-9 had been the active ingredient in spermicides since the 1950s and was approved for distribution before the FDA demanded any rigorous clinical trial testing. As a result, Nonoxynol-9 based spermicides were already available for use, but no one knew exactly how efficacious these spermicides were and, importantly, how safe they were. Advocates understood the uncertainty of Nonoxynol-9's safety and efficacy against STDs including HIV to be exasperated by public rumours that Nonoxynol-9 would be effective against HIV infection. Consequently, women and gay men were already using Nonoxynol-9 lubricated condoms for extra protection and Nonoxynol-9 sexual lubricants (in addition to its use as a spermicide). As a knock on effect, manufacturers put Nonoxynol-9 on condoms and in lubricants to tailor to the needs of those using Nonoxynol-9 based lubricants (Heise et al., 1998: 10).

The context in which microbicides containing Nonoxynol-9 entered the human clinical trials during the late 1980s and were trialled for over 10 years, was marked by a high variety of candidates, trial designs and Nonoxynol-9 formulations. Different trial designs were used, not all of the trials were randomised controlled clinical trials, the amount of Nonoxynol-9 differed from compound to compound (as much as from 50 mg to 1000 mg) and the suppositories differed, as some tested rings, some foams, some films etc. (Martin et al., 1997; Van Damme et al., 2002; Forbes and Heise, 2000). Furthermore, the data produced by the safety trials as well as the efficacy trials was conflictual and is still incredibly difficult to compare. Some small scale observational studies reported promising results and called for more studies in large scale randomised controlled trials to validate their findings (for instance Zekeng, 1993). Other studies suggested the heightened risk increase of genital ulcers (for instance Niruthisard, 1991; Kreiss ,1992). Uncertainty within the scientific and advocacy field emerged around these safety issues, the association with vaginal ulcers and, importantly, the association of vaginal ulcers and HIV infection. This uncertainty provoked a dedication in the field for more and more research, despite Nonoxynol-9's potential side-effects.

The safety trials

The development of Nonoxynol-9 based microbicide candidates had continuously been marked by a worrying safety profile, in particular a concern for its association with vaginal ulcers, which could facilitate HIV virus in semen to enter a woman's body. Consequently, the use of Nonoxynol-9 based compounds would in fact increase women's susceptibility to HIV infection instead of providing protection and inflict harm on the women participating in the trials. A good example of this is the safety study of Niruthisard et al., published in 1991. In a context of uncertainty about the safety of Nonoxynol-9, its possible future, rumours about its effect on the HIV virus and the fact that people were already using it as an HIV preventative gel, this study sought to determine facts about Nonoxynol-9's safety. The study was supported in part by Family Health International and the U.S. Agency for International Development, although (as the report states) the study does not necessarily reflect FHI and AID policy (Niruthisard et al., 1991: 176). The Niruthisard safety study was a small scale observational study conducted on a small number of women at low risk of infection recruited from a family-planning clinic in Bangkok, Thailand. The women participants were asked to insert the compound once per hour, for four consecutive hours daily for a period of two weeks. This study showed that Nonoxynol-9 had harmful effects, as the report states:

> Six of the women or 43% (...) had physical findings that included disruption of the epithelium and/or bleeding. None of the women receiving placebo had abnormal physical findings. The break in the epithelium on the cervical squamous epithelium of four women appeared to be the result of a thin layer of cells sloughing; in some cases the

> layer of cells could be seen still partially attached. The epithelial sloughing appeared on the cervix in the area adjacent to the fornices and was not over the transformation zone. One woman had a severe reaction on the cervix that appeared similar to the strawberry cervix seen with trichomonas infection, but it was more severe and was bleeding and edematous. (...) One woman had physical findings that included bleeding and sloughing of the vaginal mucosa, which also occurred in the fornices. All of the symptoms and findings of the women resolved within 1 week of stopping N-9 use. None of the symptomatic reports were considered severe enough by the women to cause them to stop using the suppositories (Niruthisard, 1991: 177).

The damage this statement describes appears to be severe, involving the skin lining women's vaginas and cervix shedding (sloughing) in certain places and bleeding. A 'strawberry cervix' refers to a cervix that is damaged as such that is has a punctuated appearance, making it look like the skin of a strawberry. This strawberry cervix was oedematous, meaning it was swollen with fluid retention and shown to be bleeding. However, as the report articulates, none of these side-effects were considered severe enough by the women participants themselves to stop using the compounds. This trial report raises questions about the particular local context within which such adverse events are experienced and given meaning by women trial participants - experiences and meanings that might very well differ from biomedical protocol and bioethical considerations (Crane, 2010; Kingori, 2013). Why did the women in this study not think these side effects were severe enough? To what extent did the clinical trial context itself impact on this articulation? Did the trial participants and scientists share the same understanding of what constituted a severe side effect? However, what the wider context of this consideration was, is absent from the clinical trial report. It is not the woman within a wider context or her socio-economic situation, her sexual relation(s) and her body that is on trial here. Rather, this social, sexual and material context is reduced to only one fragment: the vagina/cervix and in particular Nonoxynol-9's effects upon it.

I argue that the clinical trial report is a powerful writing technology (Haraway, 1997: 26) that articulates the objective truth, here, of a scientific object and the body on trial. This articulation enacts an agential cut that separates women's vaginas from the body they are a part of, from the sexual relations in which they act and the economic currency they have (which becomes especially relevant in relation to the efficacy trials below). Barad (Barad, 2007: 148) writes that "apparatuses are the material conditions of possibility and impossibility of mattering; they enact what matters and what is excluded from mattering". In particular, an agential cut necessarily implies particular material-discursive exclusions that remain intimately related to the phenomenon produced by the apparatus, as what Barad has coined an exteriority-within – an effort to pay attention to the productive effects of exclusion inspired by Butler's constitutive outside. As such, the particular agential cut under analysis here does not produce a mere objective truth about the effect on Nonoxynol-9 on the female body, here the vagina and cervix specifically. Rather this agential cut constructs and fragments women's bodies within the story of Nonoxynol-9 as vaginas whose meaning is tied to their degree of ulceration, and in the same move excludes the wider social and material context through which these bodies emerge.

In contrast to the biomedical articulations of their investment in the development of vaginal microbicides, I argue that the scientific objectification of Nonoxynol-9's effect on the vagina/cervix does not merely construe facticity, but constitutes a specific manner in which women's bodies are made to matter in this particular biomedical enterprise. In other words, the entity of trial is not 'the female body' assumed to pre-exist biomedical knowledge seeking practices. Rather, this entity emerges *through* these practices, here, in an arguably problematic way. Furthermore, this entity emerges here as a human/nonhuman hybrid, a microbicide/woman relationality that brings to mind the feminist critiques on STS and in particular Actor Network Theory (ANT) spearheaded by Bruno Latour (see for instance 1993, 2004) for its lack of engagement questions pertaining to the social and cultural processes

inherent to scientific practice through which 'the human' is differentially constituted (see for instance, Star, 1991; Haraway, 1997; Van der Ploeg, 2004; Braidotti, 2013). These feminist scholars critique STS and ANT for its focus on human/nonhuman mingling, to the neglect on social and cultural processes through which the human comes to matter within human/nonhuman hybridisation. Indeed, the woman/microbicide entities at stake here are not hybrids to celebrate. What is particularly problematic is the fragmentation through which the human is offered up in relation to the microbicide candidate: the vagina/cervix that is separated from the body that it is a part of, and the socio-materiality this body exists in, especially with regard to sexual relations and gender dynamics. The manner in which women's bodies are made to matter here hinges on the exclusion of their wider socio-material relationality.

It is tempting to provide a reading of the development of Nonoxynol-9 based microbicides as a critique against science, that foregrounds the manner in which women's bodies are objectified through biomedical endeavours and technological development - a mode of critique characteristic of the versatile field of feminist science studies (Harding, 1986, 1991; Fox Keller and Longino 1996[1982]; Martin, 1989, 1996) and which has a particularly rich history in the feminist critiques of reproduction science (for a generous overview see Thompson, 2005). Such a critique would also resonate with arguments against large scale outsourcing of drug trials and the profit making machine of Big Pharma that Petryna (2009) engages in her writings on the exploitation of bodies for profit. However, such a critique against science is also not able to fully articulate what is at stake here, as it would discard the feminist inhabitation of biomedicine that characterises the field of microbicide development and thus the effort inherent in the testing of Nonoxynol-9. Furthermore, the development of vaginal microbicides has a history of struggling for funding and has mostly been funded by the public sector and philanthropic organisations (Weber et al., 2005), thus as an enterprise it is not so much part of the exploitation of bodies for pharmaceutical profit that Petryna describes.

Within a context of high HIV prevalence, constrained access to healthcare and a wider socio-economic environment that drives women's risk of HIV infection, the development Nonoxynol-9 based microbicides can be considered both ethical and unethical, politically desirable and problematic. This complexity resonates with the ethical and political ambiguity that Johanna Crane (2010) highlights in her critical reading of what constitutes 'ethical science' with regards to RCT testing of HIV treatment and prevention within resource poor settings. As she writes, "the debate is not merely about what is 'right' and 'wrong', but also about how science travels, and about how to forge useful and humane scientific knowledge across terrains of difference and inequality" (Crane, 2010: 861). What agential realism provides is an analytical framework in which this ambiguity (Montgomery, 2015) becomes visible, as apparent ethical and political contradictions do not rule one another out, but rather depend on one another in and for the woman/microbicide phenomenon.

The human efficacy trials

Between 1992 and 2002 three efficacy trials were conducted. These tested the effect of Nonoxynol-9 on women's vaginal cells as well as its effect of dismantling the HIV virus. The first was a study by Kreiss testing a vaginal sponge containing Nonoxynol-9. This trial was conducted amongst 138 female sex workers in Nairobi, between January 1987 and June 1990 (Kreiss, 1992: 479). The trial showed a significant increase in vaginal ulcers in the Nonoxynol-9 arm of the trial and was prematurely halted following the recommendations of the Data Safety and Monitoring Committee in July 1990 (Kreiss, 1992: 479). The report continues to warn that

> [i]t is possible that prolonged and intensive exposure to nonoxynol 9 results in compromising the vaginal and vulvar epithelial integrity (...). Alternatively, nonoxynol 9 sponge use may directly cause genital ulceration as a result of chemical toxicity or mechanical irritation. Reactivation of genital herpes simplex virus infection is another possibility that was not excluded. These findings are of particular concern because genital ulceration in women and men has been implicated as an important risk factor for HIV infection in both

> American and African populations (Kreiss, 1992: 481).

In 1998, the results of another efficacy trial were published, this time testing a vaginal film containing Nonoxynol-9 on just over 1000 female sex workers in Cameroon (see Roddy et al., 1998). In line with the Kreiss study, this efficacy trial again showed an increase in vaginal ulceration. However, the trial did not show that vaginal ulcers in turn increased women's susceptibility to HIV infection. Regardless of its findings that the product increased vaginal ulceration the trial report ends with a call for more research (Roddy et al., 1998: 509). Finally, in 2002, the Van Damme UNAIDS sponsored research on the vaginal gel COL-1492, also called Advantage-S, resulted in significantly more women's seroconversion in the active arm than in the placebo arm of the trial and associated Nonoxynol-9 with an increase in vaginal lesions and ulcers (although based on a safety trial that showed no harm (van Damme et al., 2002: 975)). In other words, this study showed that frequent use of Nonoxynol-9 based vaginal gel increased, rather than decreased, women's vulnerability to HIV infection.

This Phase III trial was conducted between September 1996 and June 2000. The population included female sex workers in South Africa, Thailand, Benin and Côte d'Ivoire. Across the sites 892 sex workers were enrolled, 104 women became infected with HIV during the trial, 59 of whom in the Nonoxynol-9 arm. The higher prevalence of HIV infection in the product arm was possibly due to the vaginal ulcers and lesions most likely resulting from the use of Nonoxynol-9. The level of vaginal ulcers increased with the frequency of use. As the report states:

> Our results show that nonoxynol-9 increased risk of HIV-1 infection compared with placebo. Risk was especially high in women who used the study drug gel more than 3.5 times per day and who also had a high incidence of lesions with epithelial disruption. This finding suggests that nonoxynol-9 has an adverse effect on vaginal integrity when used frequently, thus increasing women's susceptibility to HIV-1 infection. At low frequency use, nonoxynol-9 had no effect, either positive or negative, on HIV-1 infection (van Damme, 2002: 975).

After the Van Damme trial showed a higher amount of HIV infections in the Nonoxynol-9 arm of the trial, the World Health Organization released a statement in 2002 that Nonoxynol-9 is ineffective against HIV and might increase women's vulnerability to HIV infection. "Spermicides containing nonoxynol-9 do not protect against HIV infection and may even increase the risk of HIV infection in women using these products frequently" (WHO, 2002, 1). This statement marked the end of the development of Nonoxynol-9 based microbicides after over 10 years of testing.

It is important to note that the Van Damme trial also showed that women's vulnerability to HIV infection increased with sexual activity and that Nonoxynol-9's effect was therefore related to how women used the microbicide candidate. After the Van Damme trial finished, a social research study was conducted that supports this suggestion. This research was conducted at one of the sites of the Van Damme trial, amongst a group of HIV negative sex workers who worked at truck stops in Durban, South Africa. The primary aim of this study was to show the manner in which these women understood the gel's (placebo or Nonoxynol-9) effectiveness. This research articulates women's belief and hope that they were using the Nonoxynol-9 gel instead of placebo and that the gel was effective, regardless of understanding the RCT's aims and protocol. The study explains:

> The gel took on added significance as a protective device in light of the fact that many women reported that some of their clients and partners did not want to use condoms. Some women were concerned about the condom's effectiveness and viewed the gel as providing better protection. Others believed that in the case of condom breakage, the gel would protect them: "Even if [the condom] bursts, we don't have any problems. We have our protector."
>
> At trial baseline, only 17% of the women reported that they were protected by condoms in more than 50% of the sex acts they engaged in. One woman told her clients who refused to use condoms that she was using the gel; she indicated that these men felt protected by the gel.

> Belief in the gel's efficacy was further reinforced by the economic pressures on the women and their concerns about losing clients:
>
> "You try to force a person to use a condom but when you see this person really doesn't want to use it and is going to the next person who will sleep with him without a condom, and the money he has a lot, you just think that you have your gel, and you take the money" (Mantell et al., 2006: 1075).

The differences between the manner in which these women articulated their use of Nonoxynol-9 as 'their protector' is in striking contrast to the clinical trial report of the aforementioned safety study, the Van Damme trial report and the WHO statement. The use of Nonoxynol-9 is embedded within women's vulnerability to HIV infection, their specific sex work economies and the hope they have for an effective tool to protect themselves, where the power to demand condom use is scarce. The candidate as a nonhuman 'protector' articulates a specific scenario in which women participants struggled to negotiate condom use, namely the specific power relations between sex worker and client which put these women at risk of HIV infection. Moreover, it is exactly this use of Nonoxynol-9 without a condom that would further the extent to which trialists are able to show the candidates efficacy, as this is based on women's HIV infections. The women participants' use of a microbicide candidate in a context where they are unable to negotiate condom use and are as such vulnerable to HIV infection is anticipated in the trial's design and the central place it affords to statistically significant sero-conversions. Furthermore, taking into account a history of struggling for funding, women trial participants' vulnerability to HIV infection also makes the trialing of microbicides more affordable and thus realizable. In other words, this Nonoxynol-9 candidate as women's protector and as an (in)efficacious compound were mutually constitutive. But this specific woman/microbicide hybrid as a human/nonhuman relation is vastly removed from the field's promise of empowerment.

Women's vulnerability to HIV infection in the Van Damme trial is compounded by the bioethical decision that the women who seroconverted in the Van Damme Advantage-S trial, possibly due to the use of Nonoxynol-9 and the resulting vaginal lesions and ulcers, were not given access to anti-retroviral (ARV) treatment. At the time, ARV treatment was not available in the countries participating in the study. Making this treatment available for the women in the trial would therefore, in line with bioethical standards of care, be coercive (Van Damme et al., 2002: 976). In other words, making treatment accessible for the women who were infected with HIV possibly due to Nonoxynol-9 induced ulcers was considered unethical according to the bioethical logic of the time. In the clinical trials after Nonoxynol-9 as ARV treatment slowly became more accessible globally, to some extent, this ethical standard has been changed and women in the trials now do have access to ARVs when they seroconvert (UNAIDS and WHO., 2000; Heise et al., 2008; McGrory et al., 2010). However, the Nonoxynol-9 trials do raise major ethical and political questions regarding the role of women trial participants and their specific vulnerability to HIV infection.

The advocacy response

After the van Damme trial, the GCM made an effort to explain the complexity of the trial results and focused on the removal of Nonoxynol-9 lubricated condoms and sexual lubricants. The GCM did not publicly engage with the protocol that failed to provide ARVs to the women who seroconverted in the trial. Rather, the GCM's point of focus was the extent to which the trial was harmful to women. As such, Heise and Forbes (2000) published an article in Reproductive Health Matters entitled *What's Up With Nonoxynol-9?* and the GCM website devoted a page to Nonoxynol-9 in which they disseminated information. Both the GCM website and the article by Heise and Forbes (2000) situate the difficulty of the trial results within a larger HIV epidemic. Specifically, they make a statement that the RCT in itself does not increase women's risk:

> It should be noted, however, that the incidence of new HIV infections in both study groups was lower than that seen in the wider population of sex workers from whom the women were recruited. This contradicts the fear expressed by some AIDS activists that participation in microbicide trials may

> in itself, increase women's HIV risk. The challenges associated with designing ethical prevention trials are complex, given the fact that some sero-conversion among participants is likely to occur despite condom promotion and other safeguards. But they are not insoluble (GCM, 2010c; Forbes and Heise, 2000).

The extent to which the RCTs increase women's vulnerability to HIV infection, was the GCM's primary engagement with the biomedical field (see for instance GCM, 2007b). However, the statement above shows that the GCM's ethical deliberations did not focus on the biomedical process of testing microbicide candidates through the RCT or, specifically, the set of relations this type of testing invites, such as the need for women's HIV infection, the specificities of women's high risk behavior and the role that the microbicide candidate necessarily plays (and in part is anticipated to play) herein. Thus, the role that women's vulnerability to HIV infection plays in the clinical trial is not placed under scrutiny, and with this the constitutive power of biomedical trialling practices is not placed under interrogation.

The women participating in the trials are sought out on a global scale because of their vulnerability to HIV infection which, as advocates tell us, is understood as related to their lack of resources and diminishment of power that renders them vulnerable to HIV infection. Despite its preventative (empowering) measures, the trial depends on this vulnerability for its scientific validity and anticipates this vulnerability in the central role it affords to statistically significant sero-conversion. Although the advocacy aim was to create a feminist science, where the trial would be a site of empowerment, the GCMs response to the Nonoxynol-9 trials, their comparison between the inside and the outside of the trial, maintains the trial as a scientific space cut off from processes of power. Thereby they reiterate the 'gold standardness' of the RCT and facilitate the exclusion of the GCM's own social concerns from the RCTs they conducted. Consequently, the ethical and political ambiguity between ideals of empowerment and biomedical knowledge-seeking practices, intrinsic to microbicide testing, is not addressed. As Mike Michael and Marsha Rosengarten (2012: 40) write, "the RCT entails its own necessity, as it were – not least because of the exclusion of the very conditions that give rise, for instance, to infections". I suggest that the ability to question the extent to which biomedical process is constitutive of women's vulnerability to HIV within the trials is of vital importance to be able to engage the full ethical complexity inherent to the testing of vaginal microbicides through a biomedical process that centralises women's HIV infections and anticipates women's inability to protect themselves from HIV.

Of course, the field has had awareness of the ethical controversies of the trials, but the biomedical process inherent to the clinical trials and its specific practices through which the facts emerge is not seen as part of what makes these RCTs potentially controversial. The materiality of the female body and the efficacy of the microbicide to prevent the HIV virus from entering this body is understood as the only materiality at stake in the development of microbicides. Furthermore, biomedical knowledge seeking practices are understood as the only manner in which to gain access to this materiality. An agential realist conception of the RCT as an apparatus of bodily production, a socio-scientific milieu through which bodies come to matter, neither understands biomedical matter to be the only materiality at stake, nor does it gives sole authority to biomedicine to determine and describe this materiality. Rather, agential realism enables an analysis of the multiplicity of materialities enacted in and through the clinical trials, pertinent for an ethical and political assessment of how women's bodies come to matter in the trials, including their socio-sexual risk of HIV infection and in accordance to feminist ideals.

Concluding remarks: multiple materialities

In this paper, I have argued that agential realism is able to provide a robust analytical framework to interrogate the political and ethical effects of this ambiguity that the field's own discourse of empowerment does not sufficiently provide. In particular, it shows the need to take social science research seriously within the trialling of vaginal microbicides (and HIV prevention in a

more encompassing sense) instead of being either a secondary exercise or an afterthought, for instance in case of the Van Damme trial. Times have changed since the Nonoxynol-9 trials and microbicide clinical trials now often include a social research arm, which I indeed understand to be imperative. However, if we do not come to a multiple understanding of materiality, where biomedical knowledge-seeking practices and social science are understood to be of equal value and authority to determine what matters in the development of microbicides (and HIV prevention technologies more broadly defined), social science analyses run the risk of remaining secondary, or indeed complicit. Consequently, the power mechanisms in play within and through the RCT will remain obscured in such a hierarchy of value. This is what I understand to be one of the crucial contributions STS is able to make within the field of global health - it elucidates the constitutive power of science and technology and thereby engages the politics and ethics of how bodies come to matter under the rubric of 'global health'.

In the beginning of this paper, I asked: what happens to feminist ideals of empowerment when they materialise through biomedical practice? The concept of empowerment has functioned as a vehicle of entry for women's specific vulnerability and receptivity to the HIV virus to play a major role in HIV global health discourse. It has functioned, and still functions, as a driving force behind the development of vaginal microbicides. It has brought women's health advocacy and biomedicine in productive relation with each other. The promise of vaginal microbicides is indeed a promise that entangles the biological vulnerability of the female body to HIV and women's social risk of infection – a particular medicalisation of powerlessness and its promised transformation through the scientific development of a technology that is envisioned to transform the body and sexual power relations. However, this feminist inhabitation of science and the aim to materialise a feminist ideal through biomedical process is where an intrinsic ambiguity emerges between the promise of empowerment and the effects of a biomedical search for facticity through clinical trial testing – here women's HIV infections within the RCTs and vaginal ulceration specifically.

But how does this feminist ideal of empowerment stand in relation to neomaterialist feminist work? Empowerment as a concept emerging out of the second wave feminisms of the 1960s and 1970s stands in awkward relation to neomaterialist theory (although I appreciate Rosi Braidotti's (2011b) unapologetic use of the concept), in particular with regards to underlying understandings of power as predominantly a social force - gender (although there are of course exceptions to such understandings of power as second wave feminism is not a singular field, see Van der Zaag, forthcoming). I do not wish to end this paper with a call towards empowerment, or an argument that hinges on a 'return' to such discourses and ideals, but I do argue that there is purchase for paying serious attention to the politics of materiality and the various exclusions that might be enacted if we fail to do so. Although feminist neomaterialisms encompass a rich multifarious posthuman landscape, increasingly the breach of nature/culture dichotomies have come to stand in for feminist analysis, a certain immanent politics that runs the risk of neglecting attention to specific problems pertaining to sex(uality) and gender (Squier and Littlefield, 2004; Hinton and Van der Tuin, 2014), including matters of postcolonialism and race (Willey, 2016; Leong, 2016). Such an understanding has direct impact on which problems are understood to be significant for analysis and the discourses available to articulate such an analysis. If what is at stake in feminist neomaterialisms is only understood as biomatter, i.e. systems of meaning prevalent in the natural sciences, materialities of sex(uality) as a lived and gendered project of survival (Bell, 2008) as those foregrounded by Judith Butler (1990, 1993) run the risk of being neglected if not fully excluded. This exclusion, I argue, is problematic in terms of feminist theory as a political project.

In particular relation to STS and its predominant focus on the celebration of human/nonhuman hybridity, Nonoxynol-9 shows that a celebration of human/nonhuman mingling does not substitute a political analysis. The human/nonhuman relations in the story of Nonoxynol-9 do not only matter as biomateriality, but also within the articulated lived experiences of women in the HIV epidemic - biomedical bodies are not the only materialities

at stake. What the story of Nonoxynol-9 shows is the importance of a feminist neomaterialism that is focused not merely on Science as the privileged zone of materiality, but on multiple materialities: the materiality of lived reality, sex work economies, HIV infection, (in)efficacious microbicide candidates, the vulnerability of bodies, vaginal ulceration and the potential materiality of a different future less tainted by HIV. Such a focus on multiplicity is indeed a 'politics of materiality', and ethics, I would add, that invites a pertinent critical self-reflection regarding the worlds we bring into being and those we exclude from mattering as feminist theorists located in the scenes of STS.

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NOTES

1 A thorough discussion of these theoretical debates is beyond the scope of this paper, for a more elaborate discussion see Van der Zaag forthcoming.

West-Centric Divide, Global Health, and Postcolonial Intervention

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"West urges curb on Indian clinic's untested treatment."[1] This statement of *The Guardian* about an embryonic stem cell therapy clinic in Delhi that I have been studying for the last five years presents a very familiar claim. I have heard such invocations of the West even by my students and colleagues and they are commonly used by politicians as well as academics. Yet, in spite of its familiarity, the statement is also intriguing. What does the utterance "West urges" mean? Is it a set of representatives of the West - people, institutions, or countries - who are urging? As one reads this newspaper article one can see the denotative reference shifting from "Western researchers have called for" to "Experts in Britain expressed concern."

Who is included or excluded from the category of the West seems obvious. *The Guardian* article quotes Stephen Minger and Alison Murdoch, two university-based British scientists, Simon Best of the UK Biotechnology Association, and an editorial of the *British Medical Journal* to express its concerns not just in relation to this particular clinic, but to the wider practice of overseas stem cell therapy "stretching from Mexico to China. " The particular clinic, which is the focus of the article, thus becomes a metonym for the Global South and the non-West ("stretching from Mexico to China"). And in doing so the article replicates a common trope through which the Global South and the non-West is seen/shown as the source and site of the problem for unproven stem cell therapies, in the media reports as well as academic writings. Discursive situating of this clinic in the Global South/non-West is further reinforced in *The Guardian* article in its short profile of the Director of this particular clinic, Geeta Shroff, that states: "Hanging from her office walls are Indian medical diplomas, training certificates from Asian research institutes, and a picture of her with India's prime minister Manmohan Singh, who is a friend of the family."

In this commentary I analyze *The Guardian* article neither to de-legitimize its claim nor to suggest that it is biased. My concern is simply how the utterance "West urges" is performatively enacted to present a West-centric divide. One could argue, following Bruno Latour (1993), that we should not see the work of 'purification' (e.g. that of the category of the West) as separate from the work of 'translation' – through which mixtures and hybrids are produced. If we focus only on the former, we, as Latour further reminds us, remain condemned to a modernist critical stance that simply recreates and reinforces the purifications and misses the proliferating hybrids.

The Guardian article that I quoted above does indeed present traces of such 'translations.' The article, for example, discusses the experiences of a "Briton with motor neuron disease" who received treatment at this clinic. The name of this patient (Jaspal Toor) indicates that he is possibly of Indian origin. In fact, the name of the author of the article (Randeep Ramesh) suggests that he too is possibly of Indian origin. One can complicate the story even further by mapping the associations of diverse human and non-human actors that must

have made not only the writing of this article possible, but also provision of stem cell therapy at the clinic in Delhi. In short, if we map the historical, geopolitical, and social processes that constitute the 'West' (and its 'other') we can show how the category hides, and also appropriates, translations and hybridity.

Exploration and description of the hybrids is arguably an effective analytical strategy to move beyond the dualist divides of not just West/non-West, but also many other binaries, such as nature/culture and so on (Latour, 1993). For postcolonial science studies, particularly under the influence of Warwick Anderson, a focus on hybrids, multiplicities, and translations has become one of the most important approaches.[2] Suman Seth, building on the approaches of Anderson and other postcolonial theorists, calls for "postcolonial history of colonial science and medicine" to investigate "not the blurring of extant boundaries but the socially imbricated, tentative, and complex coming-into-being of the categories and binaries" (Seth, 2017: 77). Intrinsic to Seth's call is further historical and empirical investigations in order to unravel the multi-layered and situated roles of the binaries as well as their erasures and transgressions.

My commentary weaves together and responds to the above-mentioned postcolonial science studies concern with those expressed in this special issue titled "STS and Global Health: Critique and Complicity." The special issue is aimed at bridging several boundaries – between STS and global health, activist and academic engagement, critique and complicity, Global North/Global South, etc. The editorial (Sariola et al.) through a fictional dialogue between Dr. STS, Dr. Activist, and Dr. Epi(demiology) unravels the underlying intersections, in spite of the seemingly unbridgeable tensions, between the fields of STS, activism, and epidemiology. Sariola, Engel, Kingori, and Montgomery show how the overlapping interests of the three domains and their representatives could (should) result in collaborations. "Just think about it, we could start something together, we could apply for funding to do just that," they write through the fictional voice of Dr. Epi addressing Dr. STS and Dr. Activist. Such bridging, for the editorial collective, does not gloss over the hierarchies between the fields and the attendant anxieties: The activist, for example, remains "worried that her position could become more exploited." The articles in the special issue similarly underline and trouble the implicit boundaries that undergird a range of global health discourses and practices.

In this commentary, I aim to contribute to the concerns raised in this special issue and postcolonial science studies' engagement with binaries and hybrids by analyzing discursive emplotment of West-centric binaries in relation to a fast growing sector of global health, namely overseas stem cell therapy. Specifically, drawing on Edward Said (1979), I argue that we need to explore *imaginative* history and geography that inevitably have a component that remains latent, which, nevertheless, is central to the articulations of the West-centric divide. I focus on the discursive framing of overseas stem cell therapy because, unlike most other sectors of global health, overseas stem cell therapy complicates the West-centric divide. A significant section of the experimental subjects in this case are middle-class (often also white) patients from the West. This situation prompts an anxiety that finds expression in a complex discursive emplotment of West-centric divide. In the first section I situate my approach in relation to postcolonial engagements with hybrids, translations, and circulations of science, technology, and medicine. And then, in the concluding section, I return to *The Guardian* article to further analyze its enactment of West-centric divide, particularly the use of the phrase "miracle cures" for stem cell therapy at the clinic in Delhi.

Situating Hybrids and West-centric Divide

"The more articulations develop with human and non-human actors," Warwick Anderson argues following Latour, "the more stable and robust the object becomes. Society, nature, and geography are thus the outcomes, rather than the causes, of these mobilisations, translations and enrolments" (Anderson, 2009: 391). Anderson calls for a focus on 'conjugated subjects' rather than 'subjugated knowledges.' Conjugated subject, for him, "is meant to hint at postcolonial hybridity and heterogeneity, suggesting a more complicated state

of affairs" (Anderson, 2009: 389). The broader goal, as Anderson argued in a co-authored article with Vincanne Adams, is "to situate technoscience within differing global, or at least multi-sited, imaginaries, using postcolonial perspectives" (Anderson and Adams, 2008).

Suman Seth (2017), acknowledging the role of "postcolonial science studies and postcolonial theory more generally" in "dismantling, troubling, and blurring the categories and binaries that are taken to characterize colonial modes of thought and governance," suggests "an additional approach":

> One that does not reify them [binary logics of colonialism] but, rather asks about the changing contexts in which, and the means by which, such boundaries and dichotomies were produced and maintained in the first place (Seth, 2017: 64).

"The postcolonial history of colonial science," Seth adds, "must not be merely resuscitated; it must be re-formed" (Seth, 2017: 64). I agree with Seth and applaud him for carefully and deftly bringing together a diverse set of postcolonial studies to further echo the call for postcolonial approaches in not just history of science and medicine, as he suggests, but also in other disciplines. Anderson and Harding, among others, have been highlighting the lack of traction of postcolonial analytics and methods within science and technology studies (STS) and have forcefully made the case, albeit differently, for integration of postcolonial approaches within mainstream STS (see e.g. Anderson, 2009; Harding, 2011a). It is in the spirit of re-forming postcolonial science studies I make this intervention.

Let me return to Seth's article, in particular his analysis of an exchange between Itty Abraham and Warwick Anderson. Seth rightly points to Abraham's concern with "postcolonial as a mode of analysis…linked to a fixed site of irreducible knowledge claims," which thereby "articulates an ontology that ties knowledge to location as a singular and essential quality of place" (Abraham, 2006: 210; Seth, 2017). That is, postcolonial critique cannot limit itself simply to reversing the binaries, wherein the non-West (and the West) continues to have essentialized relationship to knowledges and practices. The issue for Abraham, however, is not only of empirical/material and epistemological suturing of knowledge and place. It is not just that "[c]ritiques of globalization and an attention to transnational technoscientific movement were in; and essentialized ethnosciences were out" (Seth, 2017: 70). Abraham's broader concern is failure "to see the power of modern science in political terms, as ideology" (Abraham, 2006: 210). More broadly, how should postcolonial science studies (and STS in general) investigate the role and impact of say West-centric binaries beyond their manifest empirical/material expressions in the making of scientific knowledge(s)? And the concern is not simply in relation to what would postcolonial science studies miss as a result of ignoring the role of ideology, but also our own slippages, as analysts, into the binaries that we wish to transgress and move beyond.

My concerns are similar to those of Abraham, but I am wary of using the concept of ideology, because of its dependence upon dualist separation between, to use Marxist terminology, 'super-structure' and 'base,' even when these two are shown as coeval and co-constitutive. I prefer the Foucauldian concept of discourse and its articulation through *dispositif* – arrangement of people, things, spaces, norms, etc. (Foucault, 1979; Foucault, 1994; Said, 1979; Butler, 1990). In particular, I would like to draw upon Said's concepts of imaginative history and geography in the articulations of the discourse of Orientalism and West-centrism (Said, 1979). Imaginative geography and history, Said (1979) writes, "help the mind to intensify its own sense of itself by dramatizing the distance and difference between what is close to it and what is far away." Consequently, in Orientalist narratives (fictional or non-fictional), "there is something *more* than what appears to be purely positive knowledge" (Said, 1979: 55).

Said's formulation of imaginative history and geography as fusing of fantasies, myths, and desires with "positive knowledge" will hardly come as a surprise to STS scholars. STS scholarship has consistently highlighted socially constructed nature of scientific facts and posited symmetry between not just facts and beliefs, but also true and false beliefs (Bloor, 1991; Latour, 1987; Haraway, 1991; Shapin and Schaffer, 1985; Knorr

Cetina, 1981). Latour (1999: 306) uses a neologism – factish - to signify "types of action that do not fall into the comminatory choice between fact and belief." "The two [fact and belief]," he argues, "have a common element of fabrication" (Latour, 1999: 306). The concern for Latour is "to take seriously the role of actors in all types of activities" (Latour, 1999: 306).

In spite of such radical re-orientation in our understanding of the interplay between facts and fetishes, reality and belief, STS rarely, if ever, investigates this interplay in the constitution of discourses and subjects. Hence, to return to *The Guardian* article, with STS tools we can unravel how stem cell therapy is provided and the role of the social in constituting knowledge and practices at the clinic and in India. We can also argue that West-centric divide presents a false binary. However, in doing so we would ignore, on the one hand, how such a divide operates through excess (i.e. more than its empirical/material manifestations) and, on the other, the continued power of this discursively constructed West-centric divide in geo-biopolitical control (i.e. disciplining of individuals and population beyond the nation-state). In relation to the latter, i.e. geo-biopolitical control, we would need to excavate how its power is articulated not simply through, for example, the law, but also through a chain of significations.

Homi Bhabha points out how Said's elaboration of latent (desires, myths, fantasies, etc.) and manifest ("positive" knowledge in literature, history, anthropology, etc.) re-presentations uncovers Orientalism as "a static system of 'synchronic essentialism'" (Bhabha, 1994: 102). Bhabha (1994), focusing on the inherent instability of the Orientalist discourse as a result of "diachronic forms of history and narrative," unravels the ambivalence of the colonial discourse and stereotypes. He, thus, draws our attention to "*the mode of representation of otherness*" and its biopolitical implications (Bhabha, 1994: 97). My concern is similar, though, I analyze the mode of representation of otherness somewhat differently. I follow a deconstructive-empirical approach (Prasad, 2014). Deconstruction of, for example, Euro/West-centrism provides discursive clearing, which instead of attempting to transcend Euro/West-centric divides puts them under "erasure," thereby opening up possibilities for empirical/historical investigation of circulations of knowledge that simultaneously highlight and challenge the power of such discourses. The phrase "imperial technoscience" signals this inherent tension that, I think, best describes the situation that we are in at present, within and outside the academia.

Let me briefly illustrate my approach with an example and thereafter, in the next section, I will further elaborate it in the context of overseas stem cell therapy. Recent historicizations of modern Western science, including its purported origin in the Scientific Revolution, are important interventions that have reoriented our understanding of "origin" and circulation of science (see e.g. Shapin, 1996; Elshakry, 2008; Elshakry, 2010; Raj, 2007). Indeed, as Steven Shapin (1996: 1) puts it: "There was no such thing as the Scientific Revolution". Shapin (1996), thereafter, goes on to historically situate the transformations in seventeenth century Europe. My concern is different, but complementary. The issue for me is how are we to understand and analyze the invocation of the Scientific Revolution as a historical project, for example by Herbert Butterfield (1957), at the time of dramatic (post) colonial transition, when European powers were losing their prized colonies?[3] Moreover, isn't the discursive emplotment of the Scientific Revolution a mode of representation of 'otherness'? The goal then becomes, along with historicization of the Scientific Revolution, analysis of its West-centric 'translations' and circulations through difference and deference – *diffêrance* in Derridean terms (Derrida, 1981a; Derrida, 1978; Derrida, 1981b). This West-centric emplotment of 'otherness' finds expression not only in, for example, diffusion (Basalla, 1967) and dependency (Rostow, 1960) theories, but also in everyday scientific practices and their histories (Prasad, 2014). *The Guardian* report, with whose analysis I started this commentary, exemplifies a West-centric emplotment of 'otherness.' I further deconstruct this emplotment in the following.

"Miracle Cures," West-Centric Divide, and Stem Cell Therapy in India

The headline of *The Guardian* article that I quoted and analyzed earlier is blunt: "Row over doctor's 'miracle cures'."[4] Interestingly, the word miracle is

not mentioned in the rest of the article. Moreover, presentation of the phrase miracle cures within quotation marks signals the author's (and the newspaper's) ambivalence. And yet the deployment of the word miracle is significant, particularly since it has been ubiquitous in characterizations of stem cell therapy at this clinic. On May 21, 2012 CNN, for example, had carried a primetime documentary on this clinic that was titled "Selling a Miracle."

I have also read and heard patients use the term miracle to characterize the changes that they witnessed in their bodies as a result of embryonic stem cell therapy at this clinic. As one patient put it: "This feels quite miraculous."[5] According to another patient, "[w]hen I first moved my toes, I was blown away…The doctors in Australia told me I would never walk again, but now I actually think I will be able to – without calipers some day."[6] In fact, *The Guardian* article also quotes a patient, who after a month of stem cell injections at this clinic experienced significant changes: "'I can sit up, feel sensation in my legs. I could not lift my legs, now I can take a few steps,' she said."[7] The clinic and many of its patients, however, present therapy at this clinic not as outside science, but as the outside of science – the frontier with which present state of scientific research will catch up.

The term miracle used in *The Guardian* article and also in other reports, thus, embodies ambivalence. Indeed, as Jacalyn Duffin (2009) shows through an examination of 1,400 cases, which Roman Catholic Church recognized in canonization, most miracles pertain to medical care. A necessary feature "for an event to qualify as miraculous," Duffin argues, is that "it must remain unexplained by science" (Duffin, 2009: 5). *The Guardian* report is certainly not making a case for Shroff's canonization. Geeta Shroff, the Director of the embryonic stem cell therapy clinic, is not seeking canonization either. She wishes to be recognized as a scientist and in the last two years she has published more than forty papers documenting clinical outcomes. Embryonic stem cell therapy at this clinic, nevertheless, has been marked by criticism and ambivalence and it remains to be seen whether and to what extent publication of clinical outcomes will alter that in the future (Prasad, 2015; Prasad, 2016).

One can of course empirically investigate the associations of human and non-human actors, which cut across West/non-West divide, in the provision of stem cell therapy. I, however, do not wish to dwell here into how therapy is provided at this clinic. My concern in this commentary is limited to unraveling the discursive emplotment of West-centric divide and to highlight that any analysis of stem cell therapy at this clinic cannot be simplistically extricated from this emplotment. I must clarify I am not suggesting that ethical, juridical, and biomedical concerns in relation to stem cell therapy at this or other clinics in India should not be raised or that they are necessarily biased. I also do not wish to argue that all invocations of miracle in relation to therapy at this clinic are similar and express a West-centric divide. It is, nonetheless, important to map how latent and manifest Euro/West-centrism suffuses re-presentations of therapy at this clinic and, more broadly, stem cell therapies in India/non-West.

Invocation of the term miracle, very similar to what Derrida shows for *pharmakon*, springs "up from without" and does not "have any definable virtue of its own" (Derrida, 1981a: 102). The discursive emplotment of miracle, as is evident in *The Guardian* article, remains ambivalent because stem cell therapy at this clinic troubles the "accepted" (Western and modern) boundary between science and miracle. How are we to understand and characterize the changes that patients have claimed as a result of therapy at this clinic? The deployment of the term miracle is aimed at purging such therapies, as *outside* science and not as the outside of science. And it does so through a chain of significations that create and reinforce a West-centric divide. The excess in the invocation of miracle, thus, has to be read through "a *certain* displacement of the series" (Derrida, 1981a: 104). A *60 Minutes*, Australia, report on Shroff's clinic, titled "Chasing a Miracle," for example, started with the claim: "On the ancient streets of Delhi, a city more accustomed to mystic healing than 21st century medicine, a Brisbane mother is seeking out a modern-day miracle."[8]

In short, claims of miracle cures do not simply have denotative reference. Rather, such claims acquire meaning and discursive force as a part of a chain of significations. And in the process this

chain of significations discursively frames overseas stem cell therapy through the trope of "gullible dupe and guileless maverick" (Bharadwaj, 2012: 312; Prasad, 2015). However, we have to be careful and not analyze these stereotypical constructions of stem cell therapies in non-Western countries such as India simply as "false images." The excess and ambivalence of, for example, the term miracle, which has been deployed in relation to "unproven" stem cell therapies not just in this clinic but also other such clinics in the Global South/non-West, are crucial for the very articulation of the West-centric divide. And the discursive emplotment of such a divide undergirds a geo-biopolitical strategy that is signaled through the phrase "West urges."

'Otherness,' discursively constructed through a chain of significations, can, particularly in the absence of an international law, force national governments to take action. In *The Guardian* article "the top civil servant in India's health ministry," for example states: "'We have our concerns and worries about Dr Shroff's work.'" Such discursive constructions of 'otherness' have been far more effective in instituting geo-biopolitical control with regard to, for example, medical transcription 'outsourcing' (Prasad and Prasad, 2012). However, in spite of fervent calls for the enactment of a specific law to regulate stem cell therapies, neither has India enacted such a law as yet, nor have stem cell therapies in the Indian clinics stopped. We need to situate such calls for juridical regulation in the societal context (Jasanoff, 2005; Jasanoff, 2011; Tiwari and Raman, 2014) and also highlight their genealogical links to colonial construction of the non-West as a "zone of lawlessness" (Benton, 2010; Prasad, 2017). And in doing so it becomes even clearer how any analysis of stem cell therapy in India/non-West without a deconstruction of latent and manifest re-presentations of West-centric divide, advertently or inadvertently, risks slipping into the same binary.

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Notes

1 https://www.theguardian.com/science/2005/nov/18/stemcells.controversiesinscience, accessed 3.11.2017.

2 Postcolonial science studies constitute a very diverse field. The analytical and methodological approaches that are often included within this field, although broadly aimed at critiquing European colonialism and moving beyond Euro/West-centrism, differ markedly and may not even complement each other (see Abraham, 2000, 2006; Anderson, 2002, 2009, 2012; Harding, 1994, 1998, 2011b; Nandy, 1990, 1995; Verran, 2001; 2002). In this article I am specifically focusing on a particular postcolonial approach that draws on Latourian and actor network theory tools and aims at excavating hybrids, translations and circulations.

3 Derrida (1978) writes, "one can assume that ethnology could have been born as a science only at the moment when a decentering had come about: at the moment when European culture…had been *dislocated.*"

4 https://www.theguardian.com/science/2005/nov/18/stemcells.controversiesinscience, accessed 3.11.2017.

5 https://www.theguardian.com/world/2007/jun/03/health.india, accessed 5.11.2017.

6 http://www.couriermail.com.au/news/national/stem-cells-help-mum-walk/news-story/30a9844ef3257b6daeca3e4f98ab9dd0, accessed 5.11.2017.

7 https://www.theguardian.com/science/2005/nov/18/stemcells.controversiesinscience, accessed 3.11.2017.

8 http://sci.rutgers.edu/forum/showthread.php?83783-Dr-Geeta-Shroef-Stem-Cell-research-patient-results-examined-at-Spinal-injuries-unit, accessed 5.11.2017. The original video and transcript of this *60 Minutes,* Australia episode is no longer publicly available online.

Harry Collins and Robert Evans (2017) Why Democracies Need Science. Polity Press: Cambridge. 200 pages. ISBN: 978-1-5095-0960-7

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Postmodernist critique is often represented as incapable of producing meaningful alternatives to the phenomena criticized, which in turn leads to claims that overcoming postmodernism is necessary. Harry Collins and Robert Evans make a similar move in *Why Democracies Need Science*. They see government as informed by scientific values under the threat of erosion by the free-market ideology that leads to assessing science in terms of utility and economic value, as well as by the mass media, as distorting science for reasons of profit. Postmodernist critique claiming that there is no truth to be found, but rather that there are many approaches intertwining with politics, undermines scientists who attempt to assert themselves and their values.

In response Collins and Evans propose *elective modernism* as a kind of post-post-modernism in science and technology studies, a move that resists the devaluation of science by representing the latter as a case of moral choice. Elective modernism endorses the enriched critical understanding of science provided by the STS since 1970s, but draw implications allowing or even urging us to opt for science. While philosophical and utilitarian defenses of science often fail, this moral approach allows scientific expertise to be valued even in times of epistemological and practical weakness.

Collins and Evans draw on values, the formative aspirations of science as a form of life, such as observation, corroboration, falsification, and the Mertonian social norms of communism, universalism, disinterestedness, organized skepticism, and so on, even though these *are* aspirations and might never be achieved in scientific practice. These values are said to be "just good in a self-evident kind of way" (p. 48) when it comes to knowing the observable world. It is these values that make scientists do 'good' science – through being aspired to, not necessarily accomplished – and that make us prefer experts to non-experts, even though the latter may be no less wrong in their conclusions. Collins and Evans draw on common sense to demonstrate that holding those aspirations is self-evidently preferable. For example, one would self-evidently prefer a judgment of a person who has observed an object over the judgment of one who has not, and so on.

This choice is said to be a moral one as the authors see the formative aspirations of science as inherently connected to the way the Western societies and, more generally, democracies exist. Due to its formative aspirations, science "supports democracy through its very existence" and "gives substance to the way of being of democracy" (p. 145). Democracies thus need science not because of objective truth or economic utility, but because "it is, or can be, a fountainhead of good values" (p. 19), providing moral leadership to the society.

Collins and Evans further argue that it is important to keep science and politics separate (as a formative aspiration) to minimize political bias. They distinguish between a technical phase

of decision-making, involving scientists and other experts, and a political phase, where the findings of the technical phase are to be considered, adopted or overruled. In order to provide this separation, they propose a new institution. The particular expertise of 'The Owls' informs democratic policy-making through identifying the current state of scientific consensus on a certain issue. Of course scientific discourse is open-ended and every finding might be revisited in the future, but consensus is a social fact, and not a natural fact, so it is a well-honed understanding of *social* processes of science that is the expertise of the Owls. The institution should consist of natural scientists who understand STS, and social scientists who adhere to both the postmodernist critique of science and elective modernism. These scientists, capable of understanding both the perspective of practical science and of the STS, are similar to owls, capable of turning their heads to 180° and looking in the opposite direction.

The authors stress that elective modernism (the 'Third Wave of STS') adheres to the Second Wave critique and the disagreement is only about implications. Elective modernism defends scientific values even at times of epistemological and practical weakness representing science as a case of moral choice. At the same time, it allows one to proclaim the cultural status of science without being accused of unreflective scientism – by adhering to the Second Wave critique and rendering scientific values as formative aspirations.

However the difference in implications between the two approaches—what the authors name as the Second and Third Waves of STS, seems to be more significant than the authors acknowledge. They basically seem to *reject* the Second Wave claim that it is necessary to "reorder power relationships: to make the exercise of power more reflexive, responsible, inclusive, and more equal [through new approaches to science and technology]" (p.104), by instead stressing the need to keep science and politics separate. They argue that to "preserve science as a distinctive form of life, scientists have to ignore, in a determined way, what the reflective analysts of science say [...] Natural scientists […] have responsibility only to their world" (p. 76).

Collins and Evans argue for the preservation of science's traditional values that are seen as "eternal" (p. 19). For the authors this means a moral choice connected with the preservation of the way the Western societies exist. An opposite choice is equated with "the dissolution of our society. A society in which the weight of an opinion is not increased according to the expertise of the opinion holder […] is a society that would have quite different institutions and procedures from those of the developed and developing world" (p. 58).

The authors base the defense of their arguments on the common sense of science as a good. However they refer to science as a process of co-production—a process in which the practices of knowledge-making "produce both the objects that make up our world and the social institutions and norms that give those objects their meaning" (p. 106 f) and in which common sense might be seen as co-produced by science as well. It is then problematic to claim that 'self-evident' arguments are irrefutable as the practices of knowledge-making are often "drawing on and reproducing pre-existing hierarchies of power and status" (p. 106 f). The authors do not recognize this contradiction and praise the choice of science as the only morally correct one. Yet the possibility to criticize such a choice is bounded already in the introduction: "the alternatives [to the moral choice of science] cannot be proved to be abhorrent but if they do not seem immediately abhorrent to you then there is something wrong with you – in the same way as there was something wrong with the person who was going to torture children gratuitously" (p. 21).

The book makes an important claim that valuing science is a moral choice – a claim I have never met in such an explicit form before, the implications of which are worth investigating. Also the interrelation between valuing science and the ways the Western societies exist is an important issue to raise. However, the book is written in a very programmatic and ultimate way bounding the possibility of critique, expressing a particular *political* agenda which does not necessarily correspond to the authors' stressing the need of keeping politics and science separate and opting for 'science debate' instead of 'science war' (p. 151).

Otobong Nkanga's Exhibition 'The Encounter that took a Part of Me', 31.03-28.05.2017, Aarhus, Denmark

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In the spring of 2017 Otobong Nkanga was featured at Kunsthal Aarhus in Denmark with a 2-part exhibition entitled '*The Encounter That Took a Part of Me*' curated by Irene Aristizábal and co-produced with Nottingham Contemporary. On show was a new version of the installation and performance piece *'Taste of a Stone*' from the 2012 Sharjah Biennial, but also a new commission: an installation consisting of a large-scale wall drawing, a diptych tapestry and sculptural display structures. While the exhibition only took up two relatively small show rooms, it was easy to lose yourself in her intriguing work.

The exhibition

Her new piece revolves around ethnography, cartography and topography. The sum of these parts is a complex figure of tectonic investigation. When entering the room, you barely register the tapestry at your right-hand side (See figure 1 & 2). Then, slowly, you realize - this diptych tapestry is mesmerizing. When looking closely at it, it seems almost like glistering cobber threads are woven into the black textile (in reality the tapestry is woven from twisted yarn, polyester, wool and a kind of reflective thread used for high visibility apparel). Seen from a distance rusty desert- or mountain-like geographical structures seem to emerge. The tapestry mimics a satellite photo of earth. A potent piece which both triggers an urge for topographic investigations and makes me question the relationship between scales. It is simultaneously close, detailed almost fractal-like and offers a distanced overview or encompassing gaze. I lose sense of time trying to find the exact spot where one view gives way to the other.

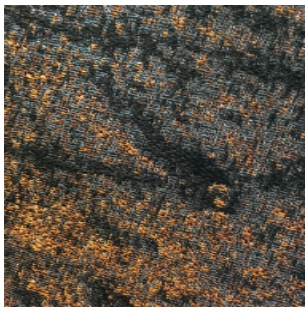

Figure 2

The wall drawing is in fact not painted on the wall, but mounted on large wooden squares arranged on a colour scale from dark grey to white (See figure 3).

Figure 1

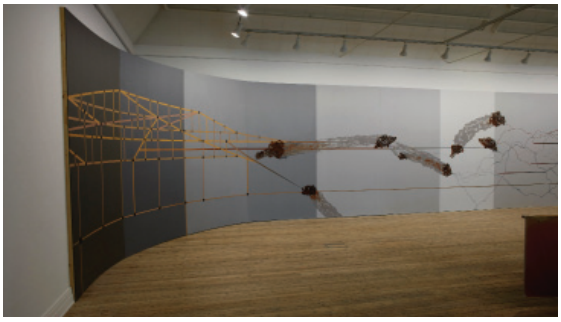

Figure 3

On the darkest couple of squares, bamboo-like lines and dots create an outline of industrial construction in orange hues – maybe a hut or a cabin?[1] It seems as if the painted structure is gradually disintegrating and turning into organic rusty flecks of iron, which slowly moves outwards leaving grey traces on the changing backgrounds. Gradually the traces turn into a giddy mesh of thin roots. The piece seems to outline the procedural changes between constructions and connections *and* natural decay and decompositions.

Centrally placed in the room are three hexagonal display cases mounted with metal poles (See figure 4). The first case contains earthy

Figure 4

Figure 5

Figure 6

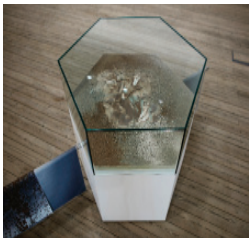

Figure 7

shapes of decayed metal scraps placed on top of now lightly miscoloured white felt (See figure 5 & 6). Industrial material on the brink of total decomposition. Simultaneously soft, hard, organic, constructed, clean and soiled. The next display contains thin beautifully coloured slaps of clay placed in brown, grey and blue (contaminated?) dirt, stones and gravel. The broken clay plates resemble cartographic

Figure 8

structures or maps - complete with altitudinal indications, rivers and lakes. Nkanga is making maps of earth with clay (See figure 7 & 8). The last display holds a hexagonal pyramid structure of rusted blue iron plates. The hard, industrial steel plates and the porous, organic rust creates a beautiful composition in blue and yellowish (See figure 9 & 10).

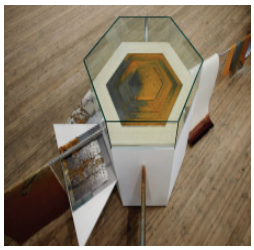

Figure 9

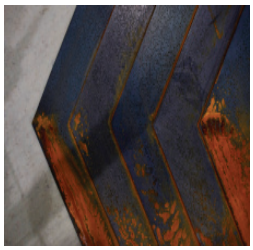

Figure 10

The titles of the three cases are *'Steel to Rust', 'Rust to Debris'*, and *'Debris to Dust'.* The cases thus mimic the process outlined on the wall, but in reverse. From dust to steel. Regressing decay. Nkanga is tracing connections and tractions between the industrial and nature, but in a non-environmentalist manner.

The transition from one stage to next is indicated by flag-like pieces of imprinted cotton mounted on steel rods braced on the sides of the cases (See figure 11). The nonfigurative prints follow the colour-trajectory of the case content from yellowish, orange and blue towards grey and brownish. The flag like constructions touch upon a recurrent theme in Nkanga's work. The distribution of ownership in regards to soil and land.

Nkanga's work explores ideas surrounding land and natural resources along with the social and topographical changes of her environment. She observes inherent complexities included in these changes and investigates how resources such as soil and earth, and their potential values, are subject to regional and cultural analysis.

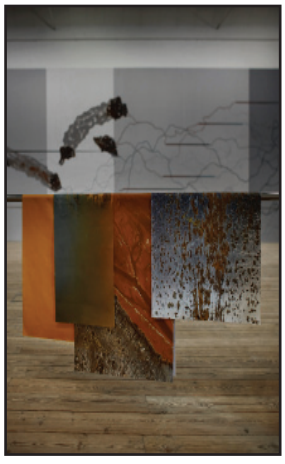

Figure 11

Figure 12

Figure13

Presently, the leap from topographical or environmental changes to environmental crisis is a small one. The radiant (overheated?) threads in the tapestry and the unnaturally blue dirt discretely evoke a sense of crisis.[2] It is hard not to think of this installation as land art or earthwork. Not surprisingly other commentators have connected Nkanga's work to this art movement[3] However, this installation seems bereft of any colonial or political aspirations and more like an empirical narrative visualized as an installation. It might even be labelled as artistic science communication?! Visiting this part of the exhibition as a STS scholar certainly feels a lot like going to work with a committed colleague or meeting with a crafty researcher. It is both intriguing, analytic and triggers an academic ethos worth entertaining.

Entering the installation *'Taste of a Stone'* is a more emotional encounter (See figure 12 & 13). The floor of the white room is covered with white stones. A part from a single white weaved tapestry with green flowers, different embossed stone plates and attenuate plants are scattered around the gentle white stone terrain. The quieting white stone court creates a soothing, contemplative atmosphere. But Nkanga is not offering a spa retreat.

Discreet conversations are taking place in the installation. The aforementioned plants are both situated next to- and printed on the Galala lime stone plates. The florae are different types of 'airplants' or *epiphytes* belonging to the family 'Tillandsia'. Epiphytes absorb water and nutrients through the leaves so their roots need no soil and are mainly used as anchors. The juxtaposition is tactfully powerful. The plants appear tenuous, even fragile, next to the harsh stone plates situated on top of more stones (some even with stones imprinted on them). They are mockingly delicate, while being strong, soil-independent and able to domesticate cracks in stones and barren hostile landscapes. This conversation also seems present in a Haiku poem imprinted on one of the stone plates:

> Here you stand, head high, still erect.
> Some caress your cracks leaving a trace.
> Some desire your style keeping you near.
> I have had a taste of you
> in the corners of your court
> "How can I forget you?"

Is this erotically alluring 'dialogue' between a plant and a stone a comment on their internal relationship, a reference to mobile frailty versus anchored solidity or maybe even a dip towards the Anthropocene? The softly curated *'Taste of a Stone'* asks more questions than it answers leaving the guest quietly intrigued. It lingers on. As guests leave the installation they literally carry it with them and powder the remaining museum with white dusty footprints.

The stone court is both a piece in itself and a space for encounters or a stage for various performances by other artists invited to contemplate 'The taste of stone' (See figure 14). In Aarhus

Figure14

the different performances included, amongst other things: essay and poetry readings, dance and sound performances (one performance was inspired by Donna Haraway's notion of 'companion species'). Otobong Nkanga sometimes serves as the protagonist in her performances, videos and photographs, acting as a catalyst that sets the artistic process in motion. She also attended Kunsthal Aarhus with a performance in which she wore a potted plant on her head (by now almost a signature symbol) and sang (opera like). The way she wore a potted plant resonated both with the rootless air plants and the ownership theme from next door while being a metaphor pregnant with displacement and adaptability.

A familiar taste of rust

> "Each time a story is told, someone else filters it and tells it in a different way. I consider storytelling not as an end of a journey but as a continual process that ripples and affects our way of looking at the world" (Nkanga quoted in: Elderton, 2014).

Nkanga's work in general and this two-part exhibition in particular would be a great point of departure for any scholar intrigued by STS or topographical investigations (Latour's (1999) exemplary study of soil in Boa Vista springs to mind). While the conversations taking place in 'Taste of a Stone' center on experiencing a space through the materiality of a stone it also provides an intriguing take on the notion of taste. Here 'taste' seems much like an encompassing STS-like term in which (amongst other things) the tactile textures, the fragile contrapuntal vegetation, the sounds of gravel and the emotions stirred are all folded into each other, intertwined and interdependent.

'The Encounter That took a Part of Me' exhibits a keen understanding of human – nonhuman interactions. While human actors are physically absent in the pieces, they are made present through industrial materials. Rust seems to be the pivotal notion here. Transformation, decay and displacement is investigated through the 'taste' of rust. Like Latour and Haraway she recognises hybrids and breaks down familiar dichotomies.

If STS is an attitude, as Gad (building on Foucault) has stated it (Gad, 2005), the encounter with an exhibition like this resonates in many ways such an attitude. The discrete language, the familiar grips evoke a sense of conversancy. It reminds us that our grappling with theoretical controversies needs not be dealt with in written form. Here, the conversation is both skilfully aestheticized and pleasantly familiar. Some things are meant to be lost, as Nkanga has stated it elsewhere, but the narrated encounters ripples and affects our way of looking at the world - and our attitude.

Accreditation

All photos by Kåre Viemose, Kunsthal Aarhus and the author

The artist

Otobong Nkanga (born 1974 in Kano, Nigéria) is a visual- and performance-artist based in Antwerp (Belgium).

Nkanga has been featured at numerous high-profile institutions including the Tate Modern, the KW Institute in Berlin, the Stedelijk Museum in Holland, the 11th. biennale of Sharjah in United Arab Emirates and the 20th biennale of Sydney. In 2015 she won the Yanghyun Prize.

Nkanga's works include a wide array of materials. In 'Kolanut Tales' from 2012 the list included: woven textile, photography, inkjet print on laser-cut Forex plate, bio cotton, mohair, viscose and cashmere wool. The listed materials for 'Taste of a Stone' (2017) reads: Woven textile, Polar white pebbles, sand coloured limestone, sand stone, Rein deer moss, Ficus pumilla 'Variegata', Muehlenbeckia complexa, Tillandsia Aeranthos, Tillandsia Usneoides, Tillandsia Straminea, Tillandsia Flexuosa, inkjet print on limestone.

References

Elderton L (2014) Interview with Otobong Nkanga, The White Review. 20.

Gad C (2005) En postplural attitude. Working Paper Series at the Center for STS-Studies, University of Aarhus, Denmark. Aarhus.

Latour B (1999) Pandora's Hope – Essays on the Reality of Science Studies. Cambridge, Mass., Harvard University Press.

NOTES

1. Train of thoughts: Am I actively exotifying this work due to the unfamiliar ring to Nkanaga's name, making me evoke bamboo and huts?
2. The use of reflective visibility-thread resonates with Ai Weiwei's in-your–face crisis-installation at Berlin Konzerthaus in 2016. Here Ai Weiwei mounted a collection of 14,000 bright orange life vests from refugees on the five columns of the Music hall as part of the 2016 'Cinema for Peace' event (http://www.cinemaforpeace.com. They both evoke a sense of crisis. However, Nkanga's version is both subtle and discreet while Weiwei's is brutally rash. Nkanga's crisis is a slowly migrating process folded into itself, while Weiwei's is an urgent cry for help.
3. See, for example, Dieter Roelstraete, 'Future Greats: Otobong Nkanga', *ArtReview*, vol.66, no.2, p.88; Clémentine Deliss and Yvette Mutumba (ed.), *Foreign Exchange/Ware & Wissen (or the stories you wouldn't tell a stranger)* (exh. cat.), Zurich and Frankfurt: Diaphanes and Weltkulturen Museum, 2014; and Karen E. Milbourne, 'Strategies of the Surface', in K. Milbourne (ed.), *Earth Matters: Land as Material and Metaphor in the Arts of Africa* (exh. cat.), New York and Washington DC: Monacelli and National Museum of African Art, 2014.

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