Science & Technology Studies

3/2017

Science & Technology Studies

ISSN 2243-4690

Subscriptions

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The subscription rates (2017) for access to the electronic journal is 40 euros for individual subscribers and 100 euros for institutional subscribers.

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Science & Technology Studies

Volume 30, Issue 3, 2017

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Critique and Complicity: STS and Global Health

Catherine M. Montgomery
University of Oxford, UK / catherine.montgomery@phc.ox.ac.uk

Patricia Kingori
University of Oxford, UK / patricia.kingori@ethox.ox.ac.uk

Salla Sariola
University of Turku, Finland / salla.sariola@utu.fi

Nora Engel
Maastricht University, The Netherlands / n.engel@maastrichtuniversity.nl

Define STS. Define Global Health. Both terms are greatly contested.

Scholarly accounts of Science and Technology Studies and Global Health reveal that despite being very distinct and at times disparate pursuits, common ground exists between them. In the History and Philosophy of Science, both are relatively recent fields – STS emerged in the 1970s and Global Health in the late 1990s, early 2000s. However, one of their most obvious common grounds is the lack of consensus on their definition and whose interests they serve. So imagining how two such variably defined and saturated terms can be brought into conversation – let alone a happy working relationship – with each other is difficult. And yet, for an increasing number of scholars who self-identify as working in STS, Global Health forms the empirical ground of their research. This special issue attempts to demonstrate the productive tensions central to this endeavour while problematizing the very undertaking itself.

As the title of this special issue highlights, a spectrum of normative positions underpins the multiple standpoints from which STSers are working for, with and against Global Health projects. Certainly, it is not unusual to find an STS scholar co-authoring (with 25 others) a paper on clinical trial outcomes in the *Lancet Global Health*, whilst simultaneously sole-authoring a critique of trial ontology in *Social Studies of Science*. *Is* this Global Health? *Is* this STS? While some might argue such practices amount to double-handed dealings, are intellectually bankrupt or even immoral, for others it is simply evidence of the 'publish or perish' ethos of academic life or symmetry in practice, the pinnacle of Bloor's Strong Programme (Bloor, 1991).

Referring to the Strong Programme will have many readers twitching in their seats. Haven't we moved on? How passé! We were never SSK/EPOR/SCOT/modern/postmodern/[insert label of choice]. And yet, it is impossible to deny that debates about normativity, reflexivity, and

symmetry, the social in science and an agnostic relationship with scientific claims have formed a core stratum of the STS bedrock, from feminist techno-science to postcolonial science studies, from user studies to Actor Network Theory (ANT) and post-ANT – and that they have come to be fundamental to what it means to do social studies of Global Health. This is not least because many STSers working in Global Health arrive at this juncture through concerns with social justice, humanitarianism and a principled objection to the inequalities, which Global Health institutions argue that they seek to address. How can a field, grown out of radical epistemological relativism, find common purpose with a field based traditionally on positivist approaches? STS, formed as a Eurocentric endeavour, originated at a time when the current techno-scientific landscape which structures Global Health could not have been imagined. Can and should we reconcile the fact that while STS tells us practices are not general and always situated, Global Health entails the search for generalisability and universally applicable solutions? If so, how? Never before has it been more relevant to ask whether we can – or should – disentangle the methodological from the political when doing STS, or put another way, whether symmetry and agnosticism are possible or desirable in this pursuit.

We explored these questions at a workshop in Maastricht in 2013 with various participants working at the cusp of STS and Global Health (see list of participants at the end of this editorial). This special issue presents and builds on some of the discussions held at the meeting. Below, we briefly consider the divergent history, goals and methods of the two fields, always with the uncomfortable awareness that each is many things to different people and that both domains incite great passion in their practitioners. It is this very prospect that excites us here, and gives us cause to believe that STS and Global Health might act as accelerants to each other's intellectual fires.

What *is* Global Health?

We understand Global Health to be many things. At the risk of repeating what remain contested definitions, one way of describing Global Health is through its evolution from international health – medicine related to health conditions relevant to the Global South[1] and diseases of the poor. More recent economic and epidemiological developments and their impact on health systems situate the concerns of Global Health also in the Global North. This shift in focus and a more inclusive approach to the eligible actors acknowledges the boundlessness of diseases and changes in illness patterns globally; what used to be thought of as 'lifestyle diseases' of the Global North, such as diabetes and cardio-vascular disease, today are also heavily present in the Global South, while diseases long-forgotten in Europe or North America are making a return e.g. malaria and tuberculosis. This shift is also constituted by growing concerns over ageing societies, exploding healthcare costs and human resource shortages in high-income countries and the potential to learn from healthcare provision in more resource-constrained contexts. Almost any health-related concern, therefore, can come under the all-encompassing interests of Global Health: cancer, mental health, reproductive conditions, tuberculosis, workforce migration, and on and on (Biehl and Petryna, 2013; Adams, 2016b). So how useful is a category that is this broad? What makes a healthcare problem a Global Health issue is the focus on interactions and entanglements between *local* and *global* dimensions or determinants of healthcare challenges that transcend disciplinary, geographical, political, institutional and sectorial boundaries (Engel, van Hoyweghen and Krumeich, 2014).

Now a central feature in contemporary biomedical practice, Global Health both generates and consumes vast resources. Key to its rise has been the mushrooming of non-governmental actors in the field, from NGOs and pharmaceutical companies to public-private partnerships and mega-philanthropists, or 'philanthrocapitalists' (Buse et al., 2009; Labonte et al., 2009; McGoey, 2015). Furthermore, interventions and activities guided by medical diplomacy increasingly feature in relations between states seeking political and economic influence through medical interventions (Erikson, 2012). The arrival and continued presence of these players has altered public and private domains, with a corresponding recon-

figuration of biomedical knowledge-production, value-creation, capital and expertise.

In addition to the diseases and health-related concerns themselves, Global Health is a mélange of patients, providers, institutions, research subjects and researchers; short and long-term research organisations and their corporate partners; research interventions and health care programmes; neoliberal funding schemes; and modes of governance for how these should be managed and ethically overseen, that connects sites across the globe over cultural and economic differences (see McGoey et al., 2011 for an incisive analysis of the Global Health complex). On the one hand, methodologically, Global Health research and thus also practice is heavily informed by metrics: statistics, randomised controlled trials (RCTs) and particular, evidence-based ways of proving what works (Adams, 2016a; Fan and Uretsky, 2017), a space owned by epidemiologists and statisticians. It is also possible to argue that, on the other hand, Global Health has responded to critiques and suggestions from social scientists as applied and analytical collaborators and research partners in its practices (Benatar, 2016). Indeed, all the four guest editors of this issue, trained as sociologists, anthropologists and STS scholars, have worked in and on Global Health collaborations. Precisely how these vast structures and networks are handled in designing and enacting Global Health research and solutions offers exciting opportunities for STS scholars and social scientists.

Scholars like Adams (2016b) have proposed a stance for 'Critical Global Health' from anthropological perspectives. As medical anthropologists acquainted with working on suffering and non-Western contexts, Adams and her colleagues describe a looming sense of seeing Global Health potentially repeating the mistakes of international health. For instance, that concerns of donors dominate over those of recipients, that investment in projects with technologically-oriented, disease-specific and quantifiable solutions happen at the expense of systems strengthening and attention to context, and that community engagement is considered politically necessary but scientifically irrelevant (Biehl, 2016). Critical Global Health, Adams (2016b) suggests, could investigate how the global is produced on the local level, despite its expansive and boundary-crossing reach. Moreover, Adams proposes that a critical Global Health ought to pay attention, via the ethnographic method, to who the 'speaking subject' is. Through the commitment to ethnography, she proposes, it is possible to also maintain a reflexive connection to the objectives of Global Health and support its objectives in an ethical way.

What *is* STS?

Just as Global Health is an amalgam of fields, so it would be wrong – and very much against the spirit of STS – to represent it as a stable, fixed or unified discipline. The history of STS is one fraught with competing views on appropriate subject matter, its ontological and epistemological underpinnings and its role in contributing to science policy. Writing of the intersections between anthropology and STS, Emily Martin (1998: 25) has observed that *"the field of social and cultural studies of science is…thickly dotted with the flags of explorers from disciplines in the social sciences and humanities, many wielding selectively some of the analytic categories and practical techniques of anthropology"*. Certainly, some of the seminal works of STS have employed the ethnographic techniques where scholars would become embedded in laboratories, scientific communities and the implementation of technologies in investigating the everyday life of science and technology (See Harry Collins 1974 classic work on tacit knowledge in science). In recent years, STS has expanded beyond its traditional choice of topics and locations, such as scientific laboratories, controversies, and the development of particular technologies in the Global North, and has begun to engage with new disciplinary spaces and places. At least part of the rationale for doing so has been to extend STS influence and recruit new audiences for a set of approaches that far exceed their original analytical focus. This extension, beyond the natural and physical sciences, is not just a case of intellectual promiscuity or magpieing, but rather a form of provocation seen to keep STS on its toes. It is also a response, in some cases, to criticisms levelled at the field that its analyses are insular, and based on 'weak' scientific programmes and regressive

asymmetries and a pertinent example being STS subsequent (and ongoing) dialogue with postcolonial studies.

In 2002, a special issue in '*Social Studies of Science*' on postcolonial technoscience brought together a series of papers that attempted to redraw the map of European and North American technoscience. This followed a previous call by, among others, Sandra Harding (1994: 327) to *"relocate the projects of science and science studies that originate in the West on the more accurate historical map created by the new postcolonial studies"*. Introducing the special issue, Warwick Anderson (2002) emphasised analytical symmetry and inclusion between metropole and postcolony and a focus on global flows of knowledge and practice as key concepts. A postcolonial perspective, he suggested, *"might show us how scientific and technological endeavours become sites for fabricating and linking local and global identities, as well as sites for disrupting and challenging the distinctions between global and local"* (Anderson, 2002: 644). Although numerous other special issues on related topics have ensued, we find this the most succinct expression of STS endeavour to move beyond the boundedness of cultures towards an appreciation of mobile and multiple knowledge practices (see also e.g. Savansky, 2016; Hayden, 2003).

Such studies have engaged with STS ideas and concepts to, among others, unpack how subjectivity and Eurocentric ideas are embedded in how science is enacted in the Global South (Chakrabarty, 2012). Beyond postcolonial-inspired work, STS endeavours to engage with Global Health and/or the Global South have focused on three main approaches: 1) examining how science and technology travel by considering technological fluidity and global flows; 2) bringing to prominence voices from regions of the world which have traditionally been absent from STS; 3) 'provincializing' STS by seeking and appropriating new theoretical concepts from places outside the Global North.

The first – and most influential of these bodies of literature – addresses global flows between North and South, much of this based on ethnographies of science and technology in the Global South. For instance, Marianne de Laet (2000; also de Laet and Mol, 2000) has provided insightful analyses of how science travels, and how technologies can unravel as they travel. Prasad's (2006) analysis of the development of the MRI scan between India, the US and Europe, shows how the innovation process is much more characterized by circulation rather than a diffusion of knowledge from an 'advanced' country to a less-developed recipient. Similarly, drawing on Latour and Jasanoff, Ruha Benjamin's (2015) work on the San people in South Africa shows how ideas of asocial, objective and morally-neutral science still need to be contested even in seemingly high-end technologies such as genetic and genomics research.

Many of these studies center on public and private forms of scientific knowledge production, as well as on the role of science and technology in public policy. Authors predominantly probe the social nature of scientific knowledge, how populations are enrolled in scientific experimentation, and what becomes of citizenship and ethics in that process. Such examples illustrate a still-nascent movement in STS, where the productivity of science and technology in postcolonial settings becomes the main event rather than a neglected other. In doing these studies, there are additional challenges for STS analysts in gaining access, how results are interpreted and put to use. Here the tensions for STSers have been about the trade-off between gaining access to scientific institutions and compromising impartiality and agnosticism to maintain relationships with hosts. Furthermore, the tendency of STS to produce microstudies can make this work appear to perpetuate the practice of 'hyperlocalization' (Callon, 1990), where any challenges and failures are geographically situated among specific localities or populations diverting attention away from possible inherent flaws in the macro-level design and conception of a technology, research project and practice. To avoid these pitfalls, Strong co-productionist approaches to analysis of technology have highlighted the importance of shifting between different scales of analysis (local and national to global and back) and moments in time (past, present, and future) (Joly, 2015).

The second approach has been to problematize STS in terms of its geographic bias towards high-income countries. A prime example is the

2014 special issue in *Science, Technology & Human Values* entitled *'Voices from within and Outside the South – Defying STS Epistemologies, Boundaries, and Theories'* (Rajao et al., 2014). Akin to a present-day form of revisionism, the collection brings into the STS mainstream *"the region's historical and contemporary technoscientific challenges and local thinkers"* (Rajao et al., 2014: 770). It highlights how Southern voices resist and at times subvert Northern values embedded in science and technology applications as well as in STS concepts and analyses. There is a certain amount of mirroring going on between critiquing diffusionist ideas of how technology and innovation travel from the North to other places while simultaneously making northern STS concepts travel. Greater attention is needed in the way research teams are built and projects set up (Keim et al., 2016; Mavhunga, 2017).

A third approach has been to propose that STS expand and fundamentally shift its conceptual repertoire by considering the logic of 'other' (i.e. non-Western) knowledge practices. For instance Lin and Law's (2013) outline of a correlative STS, based on an analysis of a Chinese Medical consultation in Taiwan. While we agree with the approach to fundamentally rethink organizing assumptions and concepts of STS, in taking on board 'other' knowledge practices, we need to be aware that ontology does not exist out there awaiting its encounter with STS. As Lin and Law (2013) emphasize, both Chinese Medicine and STS are multiple and flexible. The analyst therefore needs to be mindful of the risk of orientalizing or essentializing the 'other'. Rather than provincializing STS and invoking a binary between metropole and provinces, urban and rural, advanced and backward, geography should be incorporated in a symmetrical way.

What each of the above approaches makes clear is that geography is a central organizing framework from which to critique or extend STS analyses of science and technology, particularly pertaining to health. In this special issue, we wish to move beyond the metaphor of travel, which presumes stable origins and destinations, and instead examine the diffuse and always entangled assemblages that arise when Global Health and STS encounter one another. There is, therefore, not a singular "thing" that travels, as multiple moments, directions, actors and practices are involved in the encounter. We contend that not only does such an encounter disrupt the conceptual apparatus of each field, but that substantial *work* is required to arrive at a 'smooth' narrative[2]. In the second part of this special issue (4/2017), we present a tongue-in-cheek dialogue in a 'rough narrative' that exposes some of the many layers of the involved positions and discussions, which caused moments of excitement, ambiguity, certainty, disagreement, self-critique and philosophical handwringing during the production of this collection.

A messy hybrid

The papers in this special issue represent various approaches to studying science and technology. We refrain from taking a stance on what the role of STS should be in and for Global Health; instead, we wish to stimulate reflection on what this encounter can generate in relation to Global Health. The latter, we suggest, can enrich STS analyses of how local and global dimensions interact in the development, evaluation and use of technologies across very different disciplines, geographies, epistemologies and ontologies. The papers collected here scrutinise in varied ways the features which often form the silent backdrop to Global Health interventions and research but not their object: ethics, experimentation and standardization. These mundane infrastructures of Global Health are the local elements of a well-oiled machinery, spanning geographies and interests, which transcend any particular locale. The analyses brought forward in this special issue thereby also trouble the grand narratives and assumptions underpinning many Global Health projects, such as race, gender, innovation, emergency and empowerment. Often, these universalising categories are used to justify intervention; to explain why things go wrong; or to make global standards appear self-evident. The papers here show how these categories are used strategically to organise work and thus play a role in creating, rather than merely representing, the realities they describe.

As STS scholarship has pointed out, the vantage point and the analyst's position often constitute what is defined as a problem. Strong objectivity (Strathern, 1991/2005; Harding, 2015) shows us that the tools and embeddedness of the social scientific observer need to be rendered subject to analysis and that what comes to be defined as a problem very much depends on the observer (the researcher being only one of them). Who defines the problem and how it is dealt with? Which disease priorities? Who defines which knowledge counts? How are units of analysis defined? Emphasis on priorities and designs set by Northern academics – irrespective of disciplinary background – is strikingly visible in international collaborations whereby aims and objectives between the groups and individuals involved can vary hugely (Kingori, 2015). The encounter with Global Health forces STS to continue its reflection about its own normativities and potential to intervene (Zuiderent-Jerak, 2015). This is not a question of positionality that can be resolved with a run of the mill reflexivity, identity politics and omphaloscepsis but rather requires a critical take on the positioning of social scientific enquiries along with the techno-scientific (Adams, 2016b).

Careful not to other or essentialise, with papers by Douglas-Jones (in the first part of the special issue 3/2017), Faulkner (3/2017), Montgomery (in the second part of the special issue 4/2017), and Wolf (4/2017), we propose that looking at different sites of techno-scientific interventions and knowledge production as symmetric can produce fruitful illustrations of how practices are made local and as such look very different. We don't suggest that treating STS objects as symmetric or 'flat' means that there is no hierarchy involved; on the contrary, we argue that shifting epistemic and institutional contexts with Global Health forces STS analyses to deal with power, hierarchy and cultural violence within those structures (Galtung, 1990).

Loaded with hermeneutics of suspicion and informed by post-colonial critiques, papers by Engel (3/2017) and van der Zaag (4/2017) in this special issue bring critical attention to the reasoning behind the selection of how locations for Global Health interventions are chosen: why are these sites and their peoples used as testing grounds for new innovation, or implanted with technologies that are irrelevant, unusable or even destructive of the context? They contest the often heard critique of certain strands of STS according to which it does not deal with ideology well, and show that when it comes to Global Health, confronting questions of power, structural violence and politics is at times unavoidable.

Where next?

Philosophical handwringing

The messy hybrid of STS and Global Health sees the debate about normativity in social research rear its head. It concerns a troubled confluence of agendas: activist and reconstructivist on the one hand and deconstructivist on the other. A long-running debate within STS highlights the epistemological tensions that are likely to arise when philosophical radicalism comes up against normative expectations in such a venture. Briefly, the debate has turned around how far certain principles of Bloor's Strong Programme – specifically impartiality, symmetry and reflexivity – should be taken; if extended indefinitely, what value does radical epistemological relativism hold, since it precludes any commitment to normative belief and action? Numerous writers have argued that symmetry and impartiality are illusory and that STS scholars, as much as the scientists and technologists they study, are engaged in knowledge-politics. For example, by reshuffling the dualities in scientific controversies, analysts necessarily involve themselves in the controversy, subverting the dominant view and elevating that of the underdog (Wynne, 2006). In the debates in the 1990s, Pels (1996:278) suggested that epistemological neutrality was *"a misconceived methodological cloak for…the situated distance and interested autonomy of third positions"*. Like Jasanoff's (1994) call for co-productionist accounts[3], Pels (1996) suggested a re-conceptualisation of the symmetry principle that retains a commitment to deconstruction while admitting normative positions. In addition, Lynch (2000) also critiqued the emphasis on reflexivity as a critical weapon, source of epistemological or methodological advantage, or as a mark of distinction exclusive to the social sciences as unnecessarily divisive. Instead, he argues that

reflexivity is an ordinary, unremarkable and unavoidable feature of action across all scientific pursuits and accepting this helps to promote peace and epistemic democracy (Lynch, 2000).

More recently, in the so-called post-truth era, the debate about STS interventions and normativity is resurfacing, leading prominent STSers to question how to engage, intervene, and what position to take vis-à-vis the creation of scientific 'facts' (see EASST Review 36(1), April 2017). Law's (2017: 17) proposal provides one answer: *"try to intervene in modest ways in particular places. Directly by standing up and shouting, or by writing, voting, commenting, criticising, persuading or seducing. (The modes of analytical-political practice are many). Or indirectly (perhaps this is our unique selling proposition) by re-articulating and reframing. By chipping away at common sense to show that other ways of being might be possible…".* Fuller (2017) has argued how STS should intervene by embracing its own sensibilities of thinking about science as a game, which STS is also part of. Harding (2015), among others, suggests that STS work should address questions of social justice by redoubling efforts to understand scientific methods as well as advancing ethical concerns. Then again, STS work on design, user engagement and citizen participation point to ways in which STS concepts can be embedded in research from the start that provides new prospects for Global Health (e.g. Hyysalo, Elgaard Jensen and Oudshoorn, 2016; Suchman, 2002; Sariola and Reynolds 2018). The vast differences in Global Health across economic, epidemiological, geographic, disciplinary, political, cultural and public-private dimensions outlined above certainly add complexity and will inevitably also challenge engaged STS scholars. Yet, as the papers in this special issue show, being suspended/torn/oscillating between critique and complicity makes for fertile research grounds offering both empirical and theoretical opportunities.

Questions at the Intersections

Global Health presents manifold questions for critical researchers, many of which remain unasked within the field itself, yet for which STS scholars are well equipped to provide answers. For example, how can societies that play little or no part in originating biomedical intervention, including new biotechnologies, nevertheless gain meaningful roles in governing the trajectory of innovation? At present, Global Health tends to focus on 'capacity building', but this presumes an expert North and lay South, where knowledge and skills are transferred from one to the other with little acknowledgement of existing 'capacity' (Beran et al., 2017). Secondly, how can a dialogue be forged between health technology designers and users, such that the process of technology and user configuration is more equitable? The current model in Global Health research is for technologies designed in the North to be introduced in the South and acceptability studies carried out alongside clinical trials. The tagging on of such acceptability studies has burgeoned in recent years, and been a great source of employment for social scientists. The problem with this approach, though, is that it ignores the contingent and interactive nature of innovation processes that STS has pointed out. The technology is already deemed 'finished' by the time these studies take place, and users are presented with a *fait accompli*. 'Acceptability' thus becomes a question of tolerability, with little recognition that (non-) users may re-configure new technologies in ways that meet their needs and desires. What is more, involving users is never uncontested nor does it necessarily democratize technology development (Hyysalo, Elgaard Jensen and Oudshoorn, 2016) and there are many more actors involved in Global Health than just users and producers in complex webs of relationships (Montgomery, 2012). Third, how do technology design and development mutually interact with (non-)existing infrastructure? Increasingly, there is a trend to develop Global Health technologies that promise circumventing the need to build, sustain or strengthen communication, sanitation, transportation or health system infrastructure (for instance m-health interventions using mobile phones, the water sterilizing LifeStraw, or point-of-care diagnostics). These promises often overlook what it means to enact these technologies in practice (Redfield, 2016; Engel, this special issue). Finally, Global Health might consider the processes that enable, hinder or otherwise affect the traffic in knowledges between interventionists and the users of new biotechnologies such

as vaccines and drugs. This is particularly the case during the testing phase of new drugs, for example during large RCTs. A greater degree of reflexivity about how data is created and moves between the networked geographical spaces of transnational trial teams, and the translations that take place across the North-South divide, might lead to improved procedures and more reliable results.

Conclusion

The encounter between STS and Global Health has been happening stealthily for a number of years. While various authors and edited collections have dealt with elements of this meeting, a full and frank discussion has been lacking. In our ambition to treat the two fields at a high level, we will inevitably be accused of partiality and superficiality. However, whatever is sacrificed in lack of attention to thematic detail we hope is outweighed by the larger provocation of disciplinary self-identity and the practices this engenders. In this introduction, we aimed to make three arguments. First, Global Health is not so much a place to which STS concepts travel, but a set of actors and practices with which STS can engage in fruitful encounters. Second, these encounters imply mutual conceptual disruption and require work to function. And lastly, symmetry in study design and research teams across geographies and the way STS concepts are being put to use is required to avoid the risks of simply diffusing STS concepts and orientalising, without creating new ideas. The papers that follow illustrate what can be gained when we disrupt the status quo in both our conceptual homes and our empirical workplaces; that things fall apart not just in 'other places' but in our own backyards; and that critique and complicity need not be mutually exclusive, but can be the start of a productive dialogue.

Workshop participants:

Abrishami, Payam; Adams, Samantha A.; Akrong, Lloyd; Bastos, Cristiana; Beumer, Koen; Bijker, Wiebe; Craddock, Susan; Douglas-Jones, Rachel; Erikson, Susan L.; Engel, Nora; Faulkner, Alex; Fiereck, Kirk; Graham, Janice E.; Hinterberger, Amy; Horstman, Klasien; Hutchinson, Lauren; Iyer, Parvathi K.; Kingori, Patricia; Krumeich, Anja; Linde-Ozola, Zane; Makoge, Valerie; Maldonado Castaneda, Oscar Javier; Meershoek, Agnes; Melnikova, Olga; Montgomery, Catherine; Park, Songi; Pastrana, Tania; Popova, Evgeniya; Reis-Castro, Luisa; Reubi, David; Sariola, Salla; Vernooij, Eva; Vimal, Manoj; Wolf, Meike; Yates-Doerr, Emily; van der Zaag, Annette-Carina; Zvonareva, Olga

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Notes

1 While using the terms Global North and Global South as shorthand, we nonetheless find these terms problematic. The Global North is commonly used to refer to the 57 countries with so-called 'high human development'. Most, but not all, of these countries are located in the Northern Hemisphere. The Global South is said to refer to the countries of the rest of the world, most of which are located in the Southern Hemisphere. It includes both countries with 'medium human development' and 'low human development'. As analytical categories, 'North' and 'South' are problematic, since they are commonly used as coherent and unified cultural categories when it is impossible to delineate who, what or when North and South, or Northern and Southern, refers to. For example, not all nations comprising the 'North' are in fact located in the Northern Hemisphere (e.g. Australia and New Zealand) – so the divide is not wholly defined by geography. Nor is the demarcation static; as nations become economically developed, they may become part of the 'North', regardless of geographical location.

2 For an example of smooth and rough accounts, see Woolgar et al. 2009.

3 "To destabilize dominant stories, as science studies often does, is a political enterprise, whether or not the new account is designed explicitly to advance a well-defined political agenda or set of interests" (Jasanoff, 1996: 412).

Making Room for Ethics: Spaces, Surveys and Standards in the Asia-Pacific Region

Rachel Douglas-Jones

Technologies in Practice, Department of Business IT, IT University of Copenhagen, Denmark/ rdoj@itu.dk

Abstract

This article examines the work that goes in to 'making room' for ethics, literally and figuratively. It follows the activities of a capacity building Asia-Pacific NGO in training and recognising ethics review committees, using multi-sited field materials collected over 12 months between 2009 and 2010. Two queries drive this article: first, how are spaces made for ethical review –politically, infrastructurally, materially – as committee members campaign for attention to ethics and access to offices in which to conduct their meetings? Second, how are the limits of 'local circumstance' negotiated during a review of the committee's work: what does the implementation of standards in the area of ethics look like? I then discuss what standards of ethics practice mean for more fraught questions of the universal in bioethics. Rather than regarding ethics systems as backgrounds to global health projects, this article's STS and ethnographic approach reveals ethical review as a site of contested standardisation.

Keywords: Asia-Pacific, ethics review, standards

Introduction

This article examines the geographic expansion of ethical review as what the editors of this special issue call a 'silent backdrop' to, or 'mundane infrastructure' of, global health projects. Based on multi-sited fieldwork with an ethics capacity building NGO in five South and East Asian countries during 2009 and 2010, the two lines of argument examine efforts to "make space"—literally and figuratively—for ethical review. While the histories and evolution of ethical review have become objects of vigorous attention across the medical and social sciences (Dingwall, 2007; Taylor, 2007; Stark, 2011b; Schrag, 2011; Hedgecoe, 2016), the practicalities of expanding ethics review practices into novel sites and spaces are less frequently examined. Rather than exploring the ethics *of* global health projects (Crump et al., 2010), or the particular challenges that global health projects present for research ethics (Stephen and Daibes, 2010), I use an STS focus here to consider ethical review as a material practice with increasing international presence, taking place in meeting rooms and offices around the world. I am particularly interested in the making of physical spaces dedicated to ethical deliberation, which I consider along two axes.

The first explores material arrangements as signs of hard won political, infrastructural and institutional support for the work of ethics review committees. Rather than focusing on or evaluating

the specific content of committee decisions—a well elaborated theme—I am interested here in the framing of ethical review as a set of practices that mark out space both in terms of claiming "real estate" for ethics in university and hospital premises, and in the political landscape of how questions of ethics come to matter in the administration of research. The second argument explores the rooms of ethics as sites where international standards for conducting review are negotiated and met (SIDCER, 2005; WHO, 2000, 2002). Global health research is often oriented towards standardised solutions (Engel, Van Hoyweghen and Krumeich, 2014: 5), and in the last twenty years the language of standards has also emerged in ethical review. Committee rooms and offices are sites where committees are assessed according to such standards, but are they best viewed as "artifacts? Practices? A mode of governance?" (Dunn, 2009: 118). What are the challenges to the 'universal' forms designed to universally accommodate 'local' content? (Riles, 2002) And what happens when we bring together the universalising ambitions of standards into the domain of ethics, where the idea of universals has a fraught history? Through these two foci, I seek in this article to illuminate tensions around what counts as the limits of local circumstance, as a growing number of ethics committees across the Asian region materialise 'global' standards in their rooms for ethics.

My analysis builds on 12 months of ethnographic research and interviews with an organization aiming to foreground standards in ethical review: the Forum of Ethics Review Committees of Asia and the Pacific (FERCAP hereafter). The Forum was first proposed in 1999, during a World Health Organisation Special Program for Research and Training in Tropical Diseases (TDR hereafter) seminar on the *Ethical Review of Clinical Research in Asian and Western Pacific Countries* held in Chiang Mai, Thailand (Chokevivat, 2011: 6). At the seminar, the group noted the comparative absence of ethical review committees (and lack of standard operating procedures for those that did exist) at a time when multi-sited clinical trials were rapidly growing in the region. The international group of researchers and committee members agreed to start building regional capacity in ethical review themselves. They could have chosen to pursue an occasional workshop, the capacity building initiatives that were beginning to arise with global health discourses and funding (Eckstein, 2004; Brada, 2011), or trainings that came with (often unequal) international research projects (Crane, 2014; Hyder et al., 2004). Instead, the researchers at this early meeting defined their intentions as "grass roots", and committed to improving standards within the region, providing "home grown protection" from potentially unethical or predatory research for the region's human subjects. Rather than, as one researcher I spoke to put it, "allowing the power to remain with ethics review committees in Geneva", FERCAP's work became based in Asia-Pacific researchers who knew the region and its institutions. It was a time of international movement in the field. In November 1999, the draft of the WHO/TDR *Operational Guidelines for Ethics Committees Reviewing Biomedical Research*–a document jointly proposed by the WHO and the Council for International Organization of Medical Sciences (CIOMS) and foundational for FERCAP's subsequent work–was discussed and finalized in Bethseda, Maryland (USA). By early 2000, instead of attempting to work through governmental bureaucracies to try and establish national systems of quality assurance for ethics committees, the participants of the Chiang Mai meeting were busy establishing FERCAP (Chokevivat, 2011: 7). The founders, many of whom were also involved in the establishment of the TDR based Strategic Initiative in Developing Capacity in Ethical Review (SIDCER hereafter), recognised that "no one model will work for all ethics committee around the world" (Karbwang-Laothavorn, 2011: 12). "Nevertheless" wrote Karbwang, a founding member and leader of the SIDCER initiative, "ethics committees have an obligation to raise their standards and improve their practices by working more closely with one another and those who carry out the research" (Karbwang-Laothavorn, 2011: 12; see also Petryna, 2005).

The location of ethics was a pressing question for those setting up and running ethics committees across Asia in the early 2000s. They asked one another "Where can and where should we have our discussions?" Tied up with this material question was another, more figurative sense of

making space: "how can we make others see ethics as important?" As Brada writes in discussion of medical pedagogy's role in the making and doing 'global health[1]' in Botswana, "[s]paces and subjects emerge in relation to one another" (Brada, 2011: 306; see also Margolis et al., 2002). Finding and making these spaces and subjects was work that FERCAP set itself, and its snowballing growth, which coincided with my field study, meant that making space for ethics—both in terms of importance and physical location—was a matter of high concern. Following ethics approval from ethics committees in the UK at the universities of Cambridge and Durham, as well as committees in two fieldwork sites, Colombo and Manila, I traveled in my necessarily multi-sited fieldwork. I moved between the hospitals, universities and offices where FERCAP conducted its work, observing training sessions. Initially a welcome outsider, studying the ambitious, growing network, I met with committee chairpersons, secretaries, laypersons and lawyers at conferences and recognition activities. Following and observing activities taking place in Thailand, the Philippines, Taiwan, mainland China and Sri Lanka, I interviewed more than 30 members of ethics review committees in the network. As time went by, I trained alongside these committee members, attending workshops in basic and advanced ethical review, Standard Operating Procedures, Conflict of Interest, and in techniques for assessing, or surveying, an ethics committee. These experiences became the foundation for my analysis, which began during fieldwork and continued throughout 2011-12. Analysis work took a variety of forms, including typing up extensive field-notes, transcribing recorded interviews, supplementing understandings of organisations with document searches, drawing diagrams of connections between people, ideas, and projects, and conducting further historical desk work as I explored the 'unlooked-for' (Strathern, 1998: 3), working to produce descriptions not only of the work of the NGO but their conceptualization of their work within a field.

An additional form of observation gave the study a further reflexive dimension. Towards the end of this period of fieldwork in 2010, I became part of FERCAP's extensive transnational network of ethics committee volunteers who form Survey teams, leading groups looking at the rooms of ethics committees, the documentation of committee decisions, and follow-up practices with investigators. I thus briefly participated in implementing the SIDCER 'Recognition Program' (known colloquially as the Survey), an initiative that began in 2005 to assess and recognise ethics committees for adherence to a set of standards oriented at 'quality and effectiveness' (SIDCER, 2005). At the time of my fieldwork in 2009-2010, FERCAP had recognised the work of around 50 committees. Today that figure stands at over 200—across 10 different countries across the Asia-Pacific Region (FERCAP 2015)[2]. Coordinated by just two full time employees, members of the network—ethics committee members and administrative staff—volunteer to "Survey" or review one another's committees according to the SIDCER standards. These standards were derived in 2005 from three key documents: the *WHO Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000), the WHO complementary guideline *Surveying and Evaluating Ethical Review Practices* (2002) and the ICH-GCP *Harmonised Tripartite Guideline for GCP E6/R1* (1996) (SIDCER, 2005). Surveyors conduct this assessment in English, which is the network's operating language, and in order to not raise barriers to entry to the recognition program, FERCAP do not require full translation of all documentation at their assessments, just the presence of a local translator. Research thus took place predominantly in English, though occasionally committee members would assist with real-time translation of live ethics committee meetings, or of documents in Thai or Mandarin.

Having a designated room is a precondition for participating in the sought-after SIDCER Recognition Program and in this way; it also comes to serve as a symbol of the commitments of an institution or its faculty to the process of ethical review. Committees know, and can leverage the knowledge, that if their ethics committee loses its room, it will also lose its recognition status. Furthermore, during the Survey, committee offices themselves become a site of contestation, within which local and international participants negotiate compliance with SIDCER standards over

what counts as a 'recognition ready' committee—and by implication a 'good' ethical review (Douglas-Jones, 2015). As we see in the second two sections of this article, the Survey prompts committees to make their "inner workings" (Dunn, 2009: 121) visible[3], and—through the possibility of withholding recognition—the Survey has the power to compel changes in future behaviour. In this way, we can read the rooms of ethics as participants in, and tools through which, the standardisation of space becomes part of disciplining practices (Foucault, 1983).

Framing global health and ethical review through STS

The pairing of 'global' with 'health' to form 'global health' begets a world of practitioners and funds, economies and spaces, even if there is no common definition of global health research, nor agreement on how such research should be governed or evaluated (Stephen and Daibes, 2010; Buse, Hein and Drager, 2009; McInnes et al., 2012; Neufeld et al., 2014). Where ethical review meets global health, it is easy to read global health projects as providing simply a new dimension to existing ethical debates – with some scholars taking the meta-ethical position that global health projects are ethical in themselves, and others seeing global health research as posing new and challenging questions of inequality for research ethics (Crump et al., 2010; Stapleton et al., 2014; Lairumbi et al., 2011; Yassi et al., 2013). Within research ethics, the emphasis in recent years has been placed on the need for 'local' review of 'global research' (EMA, 2012) as a way of dealing with ethical questions around the origin of data. Like the phrase global health, such a statement about 'local' review of 'global' research appears self-explanatory.

From the viewpoint of STS and anthropologies of science however, the terminology of global health invites critical distance. As Donna Haraway (1995: xix) argued more than twenty years ago, "[t]he global and the universal are not pre-existing empirical qualities; they are deeply fraught, dangerous, and inescapable inventions". Yet the 'global' often "summons no further exemplification: it is a macrocosm, a complete image, and requires no theoretical underpinning" (Strathern, 1995: 169). In the same way, the local of 'local ethical review' "points to specificities and thus to differences between types of itself — you cannot imagine something local alone: it summons a field of other 'locals' of which any one must be only a part" (Strathern, 1995: 167). When we turn, with these observations in mind, towards the push for global health, we begin to recognise the way in which the label 'global health' choreographs particular kinds of imaginaries. As Brada (2011: 286) argues, perhaps what makes "global health" "global" is more to do with configurations of space and time, and the claims to expertise and moral stances these configurations make possible. Discussing pedagogical training in Botswana, she points out that the category of the 'international' structures medical practice (Brada, 2011: 296). Yet the stakes are high in taking on this language using the critical vocabularies of STS and anthropology: ""Global health" is shaping practices, subjectivities, and power relations […] changing the way policymakers as well as medical practitioners […] see the world (Erikson, 2008)". Following Brada's lead, I contend that we must pay close attention to the language used in describing these worlds and the way it brings them into being. In my case, the attention extends to the organising effects of calling parts of ethics committees practices 'local' and others 'global' (Latour and Callon, 1981; Kearney, 1995; Strathern, 1995; Jensen, 2007), the role of 'international' guidelines in forming standards, and the effects these standards have for the spaces in which the idea of ethical review is cultivated.

A critical STS approach also positions a capacity-building NGO such as FERCAP within the broader frames of changes in the financing and policy environments of global health (Erikson, 2008) and statecraft (Jasanoff, 2004). FERCAP's capacity building orientation derives from its founding aims and its links with WHO-TDR, an organisation that has for a long time been committed to building capacity for health research (Langsan and Dennis, 2004; TDR, 2008). As former TDR director Robert Ridley wrote in a 2010 WHO newsletter, "the role of TDR and other international research-funding agencies is less and less to bring external research to developing countries but rather to

foster and help build on the research capacity already within them and to assist countries in addressing their own needs and priorities" (Ridley, 2010: 2). As well as contextualising the role of NGOs in carrying standards, in work elsewhere, I have sought to highlight the self-evident nature of capacity building, an increasingly globalised practice in itself (Douglas-Jones and Shaffer, 2017), enmeshed with the worldwide growth of NGOs (Mertz and Timmer, 2010; Delise et al., 2005; Higgins and Tamm, Hallström 2007). NGO capacity building is seen as a central feature of global health projects (Stephen and Daibes, 2010) along with social justice, community engagement and partnership, "often underpinned by a principle of solidarity" (Benatar and Singer, 2010). FERCAP is paradigmatic of this NGO-based capacity building, yet arises from within the region. It states a clear ambition "to develop […] capacity building for ethical review practice across the continents to address the fundamental ethical gaps and challenges encountered in global health research" (SIDCER, 2005). The organisation itself, as much as its activities, can be seen as part of the wider global health apparatus, assembling a 'mundane infrastructure' for research ethics in tandem with research projects (Garrett, 2007; Brown et al., 2006).

In the opening two sections of this article, I examine more closely this backgrounded work: the less noticed infrastructural (Star, 1999; Carse, 2012; Furlong, 2010). In contrast with the sensitivity and controversy of ethics universalization debates in the 1990s, the standardisation of ethics *processes* is more easily regarded as 'mundane' and routine, desirable for reasons of committee reliability or from the point of view of work process management. Increasingly required by institutions, funding bodies and publishers alike, ethical review now constitutes a passage point through which projects falling under the 'global health' umbrella must pass, both at home and abroad (EMA, 2012; Dingwall, 2007). Yet from the analytical standpoint of STS, we know that such 'infrastructural backgrounds' only appear as background from certain, usually privileged, positions (Star, 1990). Making them visible requires attention, or 'infrastructural inversion' (Bowker, 1994). Within the domain of biomedical infrastructure for example, Street's (2012) analysis of the affective and colonial materiality of Madang Hospital, Papua New Guinea demonstrates one such making-visible, as she brings forward the tie between buildings and nation-building: spaces as "purveyors…of power relationships" (Street, 2012: 54; see also Street, 2014). Other recent work in the burgeoning infrastructure studies genre, crossing between anthropology and STS, has extended the term from the built and resource environment (Harvey and Knox, 2012; Anand, 2011) towards the 'poetic', the environmental and the digital (Larkin, 2013; Harvey, Jensen and Morita 2017). The accounts and presentations of ethics committee members in this article demonstrate how convincing institutions and colleagues to 'make space' for ethics is the work of everyday politics, rooms and offices becoming what Larkin (2013: 336) terms a "metapragmatic object, [...] deployed in particular circulatory regimes to establish sets of effects". As I show, holding ethical review practices to international standards is part of a 'circulatory regime' within the Asia-Pacific region, generative of such effects as aspiration and collegiality, as well as compliance and recognition. Establishing ethical review as a form of research infrastructure is neither mundane nor background for those striving to create or improve practices and processes. As such, an STS reading of the building of ethics capacity foregrounds the ways in which global health projects are often premised on the presence of existing material and social arrangements of ethical review, or local capacities for the practicalities of internationally auditable research itself (Simpson and Sariola, 2012: 563-564).

In the second two sections of the article, I explore the relationships between standards and standardisation within research ethics. Standardisation—its consequences and politics—has been an important area of STS-informed research for more than two decades, particularly in the domain of health technologies and 'solutions' (Hogle, 1995; Bowker and Star, 2000; Dunn, 2005; Engel and Zeiss, 2013; Timmermans and Berg, 2003; Timmermans and Epstein, 2010; Busch, 2011). Scholars have been critical of solutions "framed in universalized terms- applicable anywhere, anytime" (Engel, van Hoyweghen and Krumeich, 2014: 5). STS researchers have also been adept at

producing critiques of implicit universalization in technology design, or in expectations of adoption. Indeed, as Timmermans and Berg (1997: 273, 297-298) wrote twenty years ago, "[u]niversality through standardisation is at the heart of medical and scientific practice" yet, as they showed, such universality is always local.

The overlap in discursive arenas—universalisation and standardisation—is important, and forms the basis of my discussion about the place of standards in ethical review. Moving on from debates of ethical imperialism (Angell, 1988), wranglings about the universality of ethics principles (Macklin, 1999; Benatar, 1998) and discussions of the local in ethical decision-making (Benatar and Singer, 2000; Nuffield, 2002) the researchers involved in developing both SIDCER and FERCAP have prioritised training committees with the capacity to conduct ethical reviews themselves, and raising their standards of review. As I show here and in my broader work (Douglas-Jones, 2013, 2015), in doing so they found themselves standardising not ethics principles (a universalising move), but ethics processes and practices. To make claims about universal ethics principles would go against the commitment of FERCAP's founders to 'institutional and national health research governance that should take into consideration the local culture and traditions' (Torres, 2011: 44). Encapsulated in this commitment is the tension Kleinman pointed to in 1999: the need for both "a method for accounting for local moral experience *and* a means of applying ethical deliberation" (Kleinman, 1999: 73, emphasis added). While many across the Asia-Pacific region feel that biomedical research projects are important for ensuring global health outcomes, and agree that the protection of human subjects is best sought through adopting ethical review, there is concern that "differences in the standards and practices of ethical review in different institutions have contributed to inhibiting progress in health research" (Karbwang-Laothavorn, 2011: 11). Committees took enthusiastically to the pursuit of recognition and standards, and FERCAP gained rapid success with its training schemes and the SIDCER Recognition Program. Yet at the same time as committees sought recognition for their practices, the *content* of their decisions—into which debates about the universality of ethics principles would fall—was considered out of the scope of the Recognition Program (Christakis, 1992). Indeed, as Star and Lampland (2009: 8) point out, "[t]o standardize an action process or thing means, at some level, to screen out unlimited diversity". Thus, the challenge of setting standards for an ethics committee and its review while, at the same time, showing "consideration of local culture and traditions" (Torres, 2011: 44) translated into attempts to maintain a separation between principles (not always universal) and practices (standardisable). So where and how are process and content separated? Does a focus on the standards of committee practice successfully evade the ethical content of committee decisions?

To develop these questions and two lines of argument, I have divided the remainder of the article into four empirically driven sections. The first two, *Making space for ethics* and *Making rooms,* develop the earlier infrastructure point, using ethnographic material, interviews and observations from Colombo and Shanghai to show struggles in making both figurative and literal space for ethics in sites of research. In the third and fourth sections, *Standards for rooms* and *Global health, global ethics?* I use a vignette from a FERCAP Recognition Survey in Manila, Philippines to illustrate how the offices of a committee become a site of standardising negotiation. I use this account as a means to return to the discussion I have begun here about of the relationship between standards, universals and standardisation initiatives in the domain of research ethics.

Making space for ethics

Since their early meetings in 1999 and 2000, FERCAP has grown into a network of over 300 members, hosting an annual regional conference which brings together committee members from over ten countries engaged in its work. It has been highly successful in recruiting and galvanising committed volunteers to convene workshops, host seminars, encourage capacity building and undertake Survey assessments. Yet at the annual FERCAP conferences I attended in 2009 and 2010 - in Chiang Mai, Thailand and Shanghai, China respectively - participants still grumbled that their institutions paid little attention to ethical review. Coming together in increasing numbers every

year, conference delegates themselves evidenced the growing interest of ethics review for researchers across the region, but lunchtime conversations and formal presentations revealed anxieties about being taken seriously by managers, bosses and institutions. At the 2010 conference in Shanghai, Da —a Chinese volunteer working with committees through FERCAP—told me that it had taken a long time to draw the attention of both researchers and institutions. "In the early times", he commented, "most [committee members] said 'We don't have support from the institution, nobody notice[s] we are there.' Year after year, at conferences and trainings, he heard how investigators dismissed newly formed committees or showed 'no respect': "Could you just stamp this letter?"", they were asked. It is telling that being asked for a stamp, rather than for deliberation, was insulting to committees who were invested in protecting participants in clinical trials. Committees who engaged with FERCAP's activities were not those at whom the international academic community had levelled critiques of "rubber stamping" (Kass et al., 2007; Jafarey et al., 2012). Across the literature, scholars pay little attention to the often substantial efforts required by committee members and researchers in their own institutions to change the conversation about research ethics—indeed, even to begin it. In what follows, I bring these efforts to the fore.

During the 2010 conference in Shanghai I came to appreciate how challenging it was for some researchers to begin conversations about research ethics within their institution. While numerous informal conversations had implied as much, this insight took its most memorable form as a conference presentation by Hyeon, a delegate from a fast growing medical centre in Daegu, South Korea. Her animated slide show outlined the great efforts to which she and her colleague had gone to persuade members of their institution that research ethics mattered. In South Korea, the name IRB, or Institutional Review Board is used for committees that convene to deliberate the ethics of biomedical research proposals, as it is in the United States.[4] She illustrated their achievements through an animation (figure 1) she had set to the theme music from *My Neighbor Totoro,* a popular Japanese anime. As the presentation played, Hyeon narrated the images on the screen:

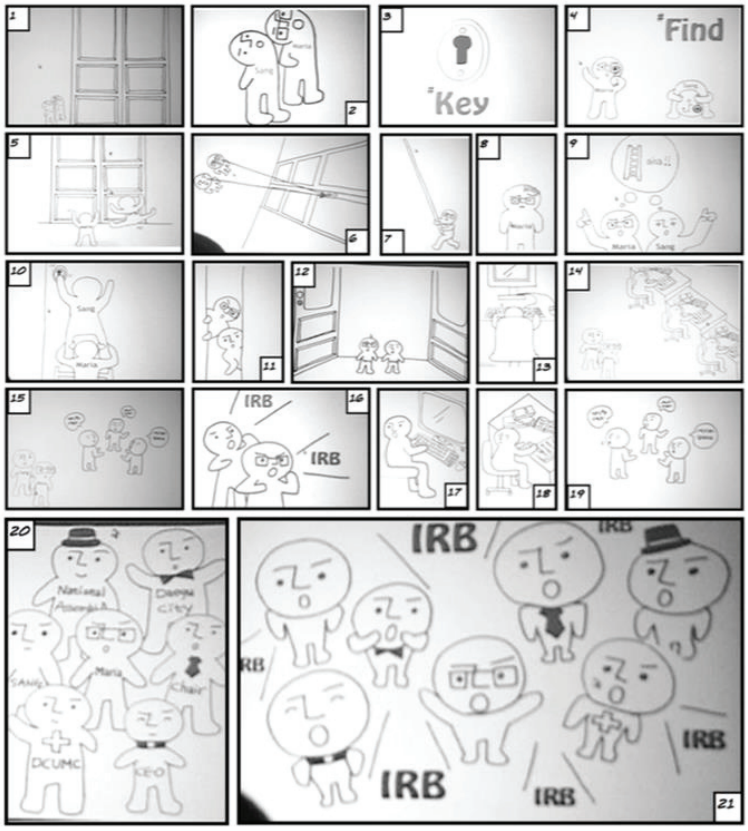

Figure 1. A series of stills compiled by the author from a recording of Hyeon's animation.

> Here is the door [1]. The door is really a difficulty. If you don't overcome this difficulty, I can't work on the IRB. So at that time my friend Sang is coming. Everyone told me she is a very good doctor in Emergency Medicine. She is coming to me. And we are trying together: how to open this door? [2] It's difficult. We have to find the key: the key is the main solution to opening the door, of overcoming difficulty [3]. Now, we find the key, but the door is really, really big. [6] So we don't know how to reach the keyhole. We can't reach. So we have to find a way: what is a good way to reach the key[hole]? We try over and over again [7, 8]. We are cooperating together, but we get a ladder and the key to open the door [10]. We open the door, wow! [11]. But when we open the difficulty, another difficulty is in front of us [12]. At that time, nobody is interested in us. Every time we are shouting, they are indifferent. They are just doing their job. They are just in front of their computer [13]. Writing some document [14]. They are talking among themselves [15]. But we never stop here. We have to overcome. We are shouting "IRB,", IRB" over and over again [16]. At that time we try and speak about the meaning of IRB. Protection! Why we have to do? With our effort they try to understand what IRB is [17, 18, 19]. At first we are just the two, but every persons are getting together and they are shouting together so it impossible to make them understand why human projection subject is so important for developing medical [20]. And what is the right way, and they really understand [21]. I don't think they can understand it fully but they are trying.

Hyeon and Sang's story conveyed—with indirect criticism—how, after a long time, they had successfully brought the need for ethical review to the attention of new actors. These new actors—with their clerical neckbands, bow ties, glasses and top hats—gave authority to the endeavour. Told as an animated adventure, the negotiations and case making were made explicit: a struggle for legitimacy in the face of turned backs and rows of computer-locked workers. Making figurative space for ethics, leading to (for example) funds for trainings, conferences, invited speakers or committee formation, was not always an easy thing to champion, as I now go on to show.

Making room(s)

This challenge—of clearing conceptual and institutional space for ethics—was an oft-repeated lament; not all committees succeeded in the manner depicted in the Korean animation. For many, regardless of their institution or country, a turning point was persuading their organization to dedicate permanent physical space to ethics committee activities. A dedicated room became vital when it was made a formal precondition for participating in the SIDCER Survey, or recognition program in 2005 under the standard on the structure and composition of the committee: "1.4 EC/IRB Office: The EC/IRB should have an office space with necessary equipment and staff for good functioning" (SIDCER, 2005).

Equipment, staff and office space were not always easy to come by. In April 2010 I took part in the Survey of an ethics review committee in Manila, in the Philippines. The committee had invited FERCAP to their city and to their offices, in order to undergo the four-day review of their committee and its activities. The tone at the opening event was welcoming, supportive, in line with the organisation's emphasis on building capacity. As usual, the opening remarks by the lead trainer emphasised the ethos of the FERCAP review process:

> FERCAP exists for the improvement of IRBs, this is not a pass or fail [situation]. If the IRB level is like this [holds hands waist height] we encourage them to improve like this [lifts hands above head]. If the IRB is like this [high hand] we still encourage. There is still room for improvement. For example, if you do not have a separate room, you cannot be… [trails off]

Cannot be what? The trainer left his sentence hanging, communicating into the silence a sense of unspecified lack. 'Recognised' is the straightforward answer; the requirement for a dedicated physical room marks another mode of (literally) "making space for ethics". To illustrate some of the intricacies of this "cannot be…", I turn to an incident from the beginning of my fieldwork.

The first committee I encountered in the field did not have a room of its own. Soon after I arrived in Sri Lanka, in early 2009, I had become a regular

visitor to the Medical Faculty in the University of Colombo, setting up practicalities and making new connections. Late one afternoon, thirsty and hoping to fill my water bottle before leaving the faculty, my colleague and I had stepped into the Senior Common Room in search of a water cooler. The monsoon rains were pouring down the windows, drowning out the low discussion of the meeting happening at a table opposite. As we crossed the common room, we looked at the group's table, piled high with paperwork, around which a dozen or so people were sitting. "Looks like an ethics committee," I joked to her quietly. It *was* a joke, because less than two weeks into fieldwork, I was still very much focused on finding and getting access to these committees. I had no reason to imagine I might literally walk in on a meeting. Yet as I stood, filling the bottle facing away from the table, murmurs of the 'benefits to Sri Lanka', and talk of 'risk' drifted across the room. "You know, I think it actually is!" whispered my colleague, having turned to face the deliberators at the table. She had started research in the country over a year beforehand, and recognised people I too would soon come to know. I filled the bottle slowly, wishing I could stay, but unnerved enough to leave—knowing that my own ethics application for research had been reviewed by that same committee, in the manner it was now reviewing another proposal, just a few meters away. Not only had my plans for research been discussed by this group of people, but I would also, I hoped, soon be interviewing them about their committee. Deeply conscious of the research ethics of my (even unintentional) presence, my colleague and I quietly left.

That the committee was meeting in a common room—a room that, while partially restricted by being 'senior', was still open—had little meaning for me at the time. In an interview a few weeks later, during a discussion about the idea of 'capacity building' that was part of my project's title, that the first hints of a link between the 'where' of ethics—its physical institutionalisation—and its social robustness began to emerge. I was interviewing Dr Suraj, a chair in the Psychiatry department at the same medical faculty. He had been involved in establishing the field of 'ethics' within the University: as we talked about 'research ethics capacity', he emphasised the need for local capacity, and a willingness to build up institutions through training others. He drew his examples from histories of his own department, Psychiatry, as well as reaching for Sri Lanka's histories as a colony, to explain how he had gone about introducing research ethics to the medical faculty where he worked:

> Psychiatry was not a department in the 1970s [when I graduated]. It was one person. Now, there are six. It is a separate subject in the undergraduate curriculum, people can get interested in it. It is like this local knowledge can develop. For example, [here in Sri Lanka] there were all these dams built. One by the British, the French, the Dutch, all of them said, 'We'll come in and do capacity building, we'll teach you how to do it yourselves, so Sri Lankans can do it.' That never happened.

These descriptions of growth in the discipline of Psychiatry acted as a parallel for our discussion on how research ethics, as a set of knowledges, was being introduced:

> Something happens in the UK or the US, someone comes [here], gives a lecture, goes away. That is useless. It is not of help to Sri Lanka. We need a group of people here, developing knowledge, discussion. Without indigenous institutions as the knowledge base, no subject will live.

Dr Suraj then proceeded to 'ground' this knowledge base both in people and in the institutions that he had supported, particularly through the institutionalisation of Psychiatry within the physical buildings of the university:

> Dr. Suraj: It is a value system. You must value ethics as important. And then you are interested in it and learn. So it was a 'sensitisation process', people realising that ethics is related to clinical work and to policy. We started talking about equity systems, and public health, organised in different ways. This lasted five or six years. Lots of people were exposed. Ethics became something not alien, exotic, [but] something to do with day-to-day work. At that time they had no guidelines, institution, workshop. So I got the WHO funding, books, computers, training programs. I got that room.
> RDJ: Can I ask you why that is important?

> Dr. Suraj: Otherwise it is just a person, there is not a system. The ERC, I recruited them, but unless we have commitment to the development of ethics.... [shrugs]

Dr. Suraj's thorough critique of the brief 'capacity building' initiatives led by international visitors in both colonial and more recent times had produced both his commitment to developing ethics expertise as 'local knowledge' and an intention to physically ground that expertise in material artifacts- the books, computers, resources and a room. Leaving the offices where Dr. Suraj and I had talked, I stopped by the room he had mentioned. In the one of the high ceilinged colonial buildings of Colombo's Medical School, the tall wooden door bore a small printed sheet reading "Ethics Committee Room". Though the glass was dusty, through it I could see a pair of interconnected rooms. Paint peeled from the walls and wooden furniture was piled up against one of the windows. It was a site of disarray. When I asked around about this room, I was told that progress on turning it into the ethics committee offices was slow going, funds were difficult to find. The suggestion was that some of the barriers to financing the room were also barriers to the formalisation of ethics. But, with dedication it would happen, commented those locally engaged in pursuing recognition, indeed, it had to happen in order for the committee there in Colombo to invite FERCAP for the Survey.

By the time I returned to Sri Lanka, just over six months later, this dusty room had been transformed. The space, on the ground floor of the Colombo Faculty of Medicine's Pathology building, had been cleared, freshly painted and a new floor laid. It was filled with new furniture and equipment, chosen with the FERCAP Survey in mind. On arrival, I went to find Thilini, one of the ethics committee secretaries I knew, only to be redirected to her new committee office. The overhead fans were whirring, and brand new, locked filing cabinets were lined up behind her desk. A second secretary had been recruited to join her, and we talked about their experiences of the (then) recent FERCAP survey. I moved to take a look at the adjoining committee meeting room through wooden slatted swing doors, to which Thilini had just delivered some snacks from the canteen. As I did so, she blocked me with her body and a smile. "Confidential meeting," she said.

In this transformation of both room and staff, steps had been taken to institutionalise ethical review in a way that materially laid new hopes for home grown ethical compliance over dusty floors and colonial pasts (Stoler, 2008; Street, 2012). For Suraj, the room was a change in the status and permanence of ethics in the institution. Unlike the visitors who had previously come and gone, carrying knowledge of ethics literature and practices, the room and its filing cabinets, reference books and computer systems were evidence both of 'institutional buy in' and of a new 'persistence to behaviour patterns' (Gieryn, 2002: 36). As both material marker and site for the conduct of ethical review, this new office had paved the way for the committee to invite a FERCAP Survey team, since they now fulfilled the self-assessment criteria. In this way, spaces themselves are made into a means of doing ethics—and this is both the focus of a FERCAP Survey team visit, and of the following section.

Standards for rooms

So far I have focused on the rooms and offices of ethical review that result from the efforts of staff at universities and hospitals across the Asian region. Small and large acts had to come together for committee members to persuade their hospitals or institutions of their importance: keys for an office to be dedicated to ethics committee work, renovation works, timeslots in meeting rooms for deliberation, budgets for administrative secretaries, funds for new filing cabinets that could be locked. Far from a background concern for global health projects, the material infrastructure that supports ethical review activities is in itself the culmination of years of political negotiation with colleagues and administrations. But once the room has been acquired, and committees thereby granted access to the recognition process, FERCAP can be invited to conduct the Survey for the SIDCER recognition program. I now move my discussion to the way in which committee rooms become the sites of negotiation over how the five standards set by SIDCER would be seen to be met.

When FERCAP surveys a committee, it takes the five standards of its parent body, SIDCER, as its reference point. These standards, as I noted above, were based on international documents, and agreed by delegates from FERCAP, the WHO and American IRBs in 2005. The SIDCER standards inform what the surveyor groups look at, and structure the final presentation made by Surveyors on the committee's performance. There is therefore a great deal that must be looked at and assessed during the four days of review. To overview briefly what surveyors are looking at, I list the five core SIDCER standards here. The first is concerned with the structure and composition of the ethics committee: are the staff and their skills "appropriate to the amount and nature of research reviewed"? The second examines adherence to policies: are there operational procedures in place "for optimal and systematic conduct of ethical review"? The third explores the completeness of a committees' review: are documents reviewed in a timely manner, according to an established procedure? The fourth concerns communication: what is the nature of the correspondence between investigators and the committee? The final standard addresses documentation and archiving: is it systematic and are documents stored for an appropriate length of time? It is these standards, suggest members of FERCAP, that make ethics 'operationalizable' (Torres, 2011: 49), a term indicating the "putting into action" of abstract principles. Operationalization is one of the terms that helps FERCAP and its surveyors avoid evaluating the content of ethical decisions committees make, and focus instead on improving *how* those decisions are made, under what conditions. However, as I will argue, this operationalization, which takes the form of holding committees to the SIDCER standards, is a negotiation (Douglas-Jones, 2015; Engel and Zeiss, 2013; Hogle, 1995). By the time I joined the 2010 Survey in Manila, I was aware of the significance of 'a room' and its role in legitimating and securing the activities of an ethics review committee. Curious about how the Surveyors—the majority from countries other than the Philippies—would read and assess the

Figure 2. The sign outside the committee's office in Manila.

space, I joined each of the three Survey groups on their trips into the Manila Ethics Committee office. Each group received instructions from the Survey Leader, Cristina, before the tour:

> When you visit the office, everyone will check. Use your eyes. They should separate the active and closed files. That's the purpose of archiving. The flow of the office and the job of the office staff: do they have a job description? Do the staff know what to do? If there's only one office, maybe there is no confidential issue on [the staff]. If there is more than one [staff], who takes care of the lock and the key, who receives documents, who knows the password, who communicates with the PI? In the office, you can take a protocol at random and then you check whether it is complete or not.

The visit was guided by a checklist of questions and visual examination. We shuffled through our Survey packs to find the appropriate sheets of paper. The Ethics Committee office in this Manila Institute was along a main corridor, and clearly labelled with a sign that hung proudly out into the hall perpendicular to the wall. 'Institutional Review Board,' it read.

As we entered, we checked off the first box: "Is the location appropriate"? Appropriateness here was confirmed by its accessibility and obviousness—the proud sign was an indicator that the location was indeed acceptable.

While the room had its own lockable door, it was partitioned off from a larger room with a five foot wall. In this partition there was another door. Both this second door and the partition caused comment from the Surveyors:

> There should be a wall there! This is a confidential space, [it should have] only one door, not two. Someone could jump over the dividing wall, or get through the door from the other side!

With the invocation of the space as 'confidential', the partition wall became discussion point at the end of day summary meeting. Assembled in the conference room the committee used for their own meetings, the Surveyors argued back and forth about its relative significance. One group of surveyors (I will call them "A") thought the partition ought to be made higher, "because you can reach over". Others ("B") disagreed, arguing that the secretaries of the EC were sharing a photocopier with the office next door, and the door in the partition was convenient for them.

A member of Group A said: "So [the secretary] has to go out and round. We say [in the recommendations] "limit the access to IRB office from other staff"". This direction was aimed at Daniella, a trainee member of the Survey team, who was diligently noting the recommendations in a template powerpoint slide. She in turn paused on the bullet beneath, which to follow the layout, needed to be filled in with a reason for the recommendation. Daniella looked up expectantly, and conversation continued. "If you are a mix of other people you cannot keep confidentiality," the person from Group A continued: "That's why we want a separate building and independent structure." Addressing Daniella, he instructed her to write: "Partition should be higher." At this point the secretary of the committee being Surveyed called out, as she was in the room delivering documents to the usually closed end-of-day meeting. Having overheard the recommendation, she said in dismay: "But we only have one air-con! If you make [the partition] higher, cool air won't get through!" The possibility of someone "reaching" over the wall then turned into "jumping", as a way of maintaining the recommendation : "in that office before, researchers actually came in at night and looked for their protocol." Group B protested. They had been shown by the petite female staff in the neighbouring office that the partition was far too high for them to reach over. With this disagreement hanging about who could access what, and how, the meeting closed for the evening.

On the second night of the Survey, the partition came up again. Group B had spoken to the secretaries likely to be affected, who felt it would be difficult for the committee to comply with a raised partition or a wall because one boss was responsible for all the workers in the conjoined space: "The boss needs to see if they're sleeping!" Raising the partition might be possible, they said, on the condition that the new, higher section was transparent. The following exchange then took place:

> A: I say close the [partition] door permanently. They can go out the real door. The entrance to the ERC should be separate.
>
> B: How can they close [the partition door] permanently?
>
> A: Throw away the key! It's up to them to think how they can implement it. Before recognition, [we'll] ask them to take photos. They should send evidence for us to see they've revised it. Maybe that partition wall—I will ask for a picture that they made it higher.

On the final day of the Survey, the lead surveyor presented the results. He had included the recommendation that the partition should be raised by *ten inches*. During questions, the ethics committee members asked the surveyors to explain the 'rationale' behind this *ten inch* change to their partition wall, to which the lead surveyor replied:

> It is better to have [an] isolated, secluded space where no other irrelevant people can have access. Now you have two doors so the other side's office has access [to you]. It depends on the composition of people in the other room. The partition is to restrict access, so there should only be one door [into the committee room]. We think it is reasonable to keep the confidentiality of the room. In other IRBs if they share office space, they have to have mechanisms to keep the confidentiality of those people.

These criteria—"isolated", "secluded", "irrelevant people" bespeak the lead surveyor's concerns about the confidentiality of the *room*. People feature in the estimation (and enforcement) of 'confidentiality' through their ability to overhear, but the interventions proposed are upon the partition wall itself. The committee worried about how to comply, with the chairperson stating:

> Our building is overflowing with people and offices. There is no space for an exclusive IRB office. If we had a higher partition, someone can just climb over. We thought putting files under lock and key would suffice. The IRB is competing with other offices for desired space, we're bursting. It's difficult to say it can be done. There is also a leak which has been unresolved for a year.

Photographs of this (physical) leak—a fallen-in ceiling, a rainbow of buckets collecting drips on a crackled floor— had been shown in the Powerpoint slides, as recognition by the Surveyors that the committee was doing what it could, under challenging circumstances. Nonetheless, the surveyors replied that it was not space in square meters, but the security of that space which concerned them:

> But the recommendation is not asking for *more* space! We know your constraints. The only recommendation is to make it more secure. Make the partition higher and correctly close the door.

Why is the height of this wall so problematic for the Survey team, and what does it have to do with making the physical space meet SIDCER standards? As the team tried to encourage modification of the ethics office, the local committee members raised practical problems: they didn't have space in the hospital to give over to ethics alone; there wasn't an AC in the "ethics part" of the room; how would their boss see if they were sleeping? What the surveyors' recommendation reveals is a concern with both the physical and symbolic segregation of ethics. This is not merely securing space in the sense of claiming it (for the storage of ethics related documentation, technologies and processes): what is at stake here is the achievement of *closing* space. Throughout the account, the desire for a *confidential* space drives anxieties about the room divider, and ultimately the recommendation for a ten inch addition. Here, the space is being evaluated for the kinds of behaviour it can ensure or invoke. Modifying the height of the wall may not close the space entirely – there is no full wall after all– but the ten inches are a negotiated compromise that leans both towards making a space confidential through inaccessibility, and recognising the 'local circumstances' of immoveable A/C units, and watchful bosses. We might also observe the way that the Surveyors' desire for the committee office to be a 'confidential space' replicates ideals held by committee members for the trials they review. Since the Belmont Report in the USA (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979) identified confidentiality as falling under the principle of "respect for persons", ethics

committees have been charged with examining how the confidentiality of information collected during research will be maintained (CIOMS, 2002: 75; WMA, 2013). Here, in the Survey, confidentiality also became a quality that the committee and its space needed to exhibit, even though the ethics committee would hold its meetings to deliberate in a meeting room elsewhere. So while a separated office room was preferable, where space simply wasn't available, Surveyors accepted the limitations on committees and—as in the account above—negotiated over how this standard would be implemented[5]. The limits of local circumstance–of leaks, A/C and labour transparency–met compromise in a ten-inch partition raise.

This account of disagreement during the Survey in Manila illustrates the ongoing negotiation of expectations. The SIDCER assessment has formalised a set of standards to which committees are assessed during the recognition program, "aim[ing] at making actions comparable over time and space" (Timmermans and Berg, 1997: 273). These requirements for comparability and reproducibility of rooms of ethical review become inscribed both in Surveyor's checklists and in the weight of its assessors arguments during the course of the four day visit, with standards showing themselves as "simultaneously overdetermined and incomplete" (Timmermans and Epstein, 2010: 81). As STS scholars have long since observed, negotiation is part of what a standard is when it is put into practice (Star, 1995; Lampland and Star, 2009; Engel and Ziess, 2013). I now move to reflect on the distinction between form and content when considering ethics standards during the SIDCER recognition program, by returning to the question I posed about the relationship in ethical review between standards (here, targeted at practices) and universals (a project of principles).

Global health, global ethics?

Efforts to produce standards for ethical review are active parts of current research discussions across Europe (SATORI, 2015), and arise within growing certification and accreditation programs targeted at committees and ethics professionals worldwide (Rodrigues, 2015; Ghooi, 2015). In their review article, Timmermans and Epstein drew on the literary theorist Raymond Williams to note that while standards connote authority and achievement, standardisation – while functional for industry, "connotes a dull sameness" (Timmermans and Epstein, 2010: 70-71). It therefore matters that it is the sphere of ethics where standards are being brought into use, since 'sameness' has long been a contentious matter in ethics discussions. Throughout the 1990s, philosophers debated the possibility of global ethical principles, spawning branches of bioethics concerned with international, then global health (Macklin, 1999; Benatar, 1998). Troubling anthropology with a what seemed to be a "dangerous break with local moral worlds" (Kleinman, 1999), the universalization debates about ethics in biomedicine have tended to foster controversy, bounded by disciplinary language, professions and institutions (Marshall, 1992). In contrast, standardisation is a more familiar language for biomedical researchers and clinicians themselves, part of the professional worlds of people who sit on the ethics review committees, and often regarded as a neutral inherent good through which diverse settings and systems can become 'interoperable'. Indeed, one committee member in my study memorably lamented to me that there was no International Organization for Standardization (ISO) standard for ethics, as there was for his haematology laboratory. These distinct genealogies for universalization in ethics and standardisation in biomedicine mean that they carry opposing moral valences, which play into distinctions between standards for ethical review and 'universals' of ethics drawn by members of FERCAP. By "not doing bioethics" members of FERCAP stated they were deliberately not delving into the "philosophical debates" about universal or "Asian bioethics" which many felt were unresolvable, and a way of avoiding concrete action to improve standards (Douglas-Jones, 2013: 35). Instead, by working with the SIDCER Recognition Program, they were staying focused on operationalised standards, set according to ethical principles laid down by others, elsewhere, in international guidelines.

So what might it mean that, instead of "doing bioethics", standardisation language is being applied to ethical review? Introducing this

paper, I asked whether a focus on the standards of committee *practice* successfully evades the issue of universality in committee *decisions*. By providing insight into the priorities of committees participating in this standards oriented NGO recognition program, I have shown that a separation between the form of ethical review and the ethical content of decisions cannot be entirely clean. Concerns about how ethical *research* is done inform concerns about how ethical *review* is done. If I have emphasised in this article how the *form* of doing ethics is at stake here, in the rooms of ethics and the material standards to which they will be held, then attending to where bifurcation between standards and universals takes place becomes a methodological question. In 2005, the year FERCAP launched their implementation of the SIDCER Recognition Program, Petryna (2005: 187) wrote that the debate between ethical imperialism and ethical relativism "as it stands, is unresolved". I would suggest that the recognition program, tied in to global accreditation regimes and increasing attention to standards of review, is one formulation of resolution. When tied to the *content* of ethics, standards were highly contentious. By revising the genre and language, by focusing instead on standards of *practice*, the Recognition Program deftly shifts the terrain. It enters the realm of sought after accreditation, the sense of participating in a "global" economy of achievement, reputation and forward momentum. In principle, it leaves committees free to exercise discretion for the ethical content of their review while they work hard at achieving the standards for the *form* by which decisions are taken.

However, to return to Brada's (2011) attention to the creation of subject positions that linguistically and affectively generate spaces of global health, I would argue that the power of the 'international' standards brought into play in this account re-locates what will count as the limits of local circumstance. As she puts it, labelling something international "marks a rational, standardizing, and benevolent, if also distant, zone of transition between the unmarked setting, resources, and guidelines" (Brada, 2011: 296). FERCAP implementation of the SIDCER recognition program, by requiring a room for ethical review, recognises that the form taken by review practices has consequences for the content of it. In the requested ten inches of material change, we see an effort to standardise local ethical review, meet international standards and produce global comparability, while sidestepping the fraught questions of universal principles for ethics. It is precisely this innocuous terrain shift that gives me analytical pause: does standardisation of form also sidestep a discussion of the ethics committee as one of many potential ways of pursuing ethical deliberation, its suitability in a given setting, or other ways in which communities might wish to deliberate and decide upon which research projects they invite, and which they refuse?

Conclusion

Making space—literally and figuratively—for ethical review is bound up in the shifting priorities and pressures of biomedical research. An STS focus on an NGO operating to build capacity in ethical review in the Asia-Pacific region allows us to examine more closely the relationships and processes that go into making the 'mundane' infrastructures of global health projects. Opening this article, I made the case that it was important to look at how ethical processes and ethics committees are gaining and making spaces as part of regional collaborations to address "challenges encountered in global health research" (SIDCER, 2005). Inspired by Brada's (2011: 286) argument that what makes "global health" "global" is to do with configurations of space and time, the first part of my argument has ethnographically examined the spaces made and claimed for ethical review. FERCAP members challenge existing social and infrastructural arrangements, and use their rooms as a symbolic achievement that qualifies the committee for assessment by FERCAP under the SIDCER Recognition Program. This analysis adds to STS further illustrations of the social and infrastructural implications of the expansion of biomedical sciences around the world, and to use Street's phrase, encourages us to attend to spaces as "purveyors…of power relationships" (Street, 2012: 54). It also opens up the scope for critical debate on the purchase, relevance and of STS analytics in sites beyond Euro-America, through which the 'global' of global health is made and

understood, and ethics is given meaning in practices. Just as the tension between a desire to implement standards while "tak[ing] into consideration the local culture and traditions" (Torres, 2011: 44) plays out in these spatial negotiations of local circumstance, this same ethnographic material prompts reflexivity about STS's own conceptual apparatus, and where *its* limits might be (Law and Lin, 2017). In this article I have also asked what, in the tension between a desire to standardise processes while continuing to respect differences in approaches to ethics, would count as the limits of local circumstance in ethical review? I have shown that the rooms of ethics become sites where, during recognition, the degree of compliance with or deviation from the SIDCER standards must be negotiated, and that this may entail a ten-inch addition to a room partition, or the way the gaze of a boss intersects with the flow of an air conditioner, as 'confidentiality' escapes its bounds of lock and key to be instantiated in room partitions too high to climb over. While STS has long carefully attended to standardisation, here at the intersection of ethics, audit and biomedicine, we find both practical manifestations of standards for the conduct of ethical review, and also their capacity to redirect focus to form, potentially evacuating from ethics the indeterminacy that stymied its crystallization into a universal settlement. Ethical review thus emerges as a site of ongoing attention and negotiation, standard making and aspiration, a site through which STS scholars are challenged to examine the question of universals, not only in scientific research but also in its governance. In the observations of this article, STS researchers might therefore find the familiar sense of making spaces for the otherwise, in conversations, material infrastructures, and even standards themselves.

Acknowledgements

The research upon which this article is based was made possible through the ESRC Doctoral Studentship at Durham University, under the International Science and Bioethics Collaborations project (ESRC RES-062-23-0215). I thank my colleagues, in particular Bob Simpson, Salla Sariola, and Achim Rosemann. For organising the November 2013 workshop in Maastricht and their work editing this special issue, I thank Nora Engel, Salla Sariola, Patricia Kingori, and Catherine Montgomery. Colleagues at the Nordic Institute of Asian Studies (NIAS) in Copenhagen read an early draft. Thanks to the Social Analysis of Health Network (SAHN) writing group at Cambridge University for the space to begin, and to the STS reading group within Technologies in Practice at the IT University of Copenhagen for critical comments. Finally, I thank the two anonymous reviewers for their careful attention and suggestions.

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NOTES

1 Like Brada (2011: 287), I do not wish to take the conceptual terrain of 'global health'as somehow 'outside' my analysis. Indeed, the construction of global health as a category, and as a form of classification, is what (in my reading) brings the editors to read STS and global health alongside one another in this special issue.

2 To draw up the standards by which the Recognition Program would be implemented, American and international volunteers trained in ethical review as well as Quality Assurance, auditing, and Regulatory Affairs met in Olympia, Washington in 2005.

3 And yet - arguably - not more open to public view, as the gaze to which a committee is opened is that of the Surveyors alone. The public dimension of ethical review is contested internationally, particularly in the USA. Stark (2011a) notes that some committees are considering holding meetings with public access, while others continue to closely guard their anonymised committee minutes. The principles of the debate fueling this desire for committee transparency were not present in the countries I conducted fieldwork in during 2009-10.

4 I acknowledge and agree with Hedgecoe's point (2012) that elisions between the different terms used to describe evaluative ethics bodies can lead to weakened analysis. However, in this case, I am reproducing the division that held in the field, which was largely between committees in countries where there was a history of American presence (e.g. the Philippines) or contemporary collaboration (South Korea) and countries that looked more towards Europe, Geneva and the WHO for guidance. The former called themselves IRBs, the latter Ethics Committees or ECs.

5 In a different instance I observed in a Chinese pre-survey, a Survey coordinator announced to a hospital considering seeking recognition that they did need "something that *separates*, a door you can enter." The reasoning was that, according to the Surveyors, 'science' and 'ethics' could not be found together: a 'marked division' in space was necessary.

Bioinformatics Imaginaries in the Engine-Room of Genomic Health Policy:
Integration and Heterogeneity in India and the UK

Alex Faulkner

Centre for Global Health Policy, University of Sussex, UK/ a.faulkner@sussex.ac.uk

Abstract

Bioinformatics comprises a diffuse field of technologies, knowledges, databases and software for medical and pharmaceutical innovation. It is becoming a major target of policymaking for global health goals, but experiences conflicts including over ownership and access; national versus commercial agendas; disease targeting; genomic versus clinical data. The paper draws on the political economy of states, and the performativity of policy and 'sociotechnical imaginaries' to identify diverging framings and imaginaries in a comparison of India and the UK. It argues that bioinformatics policies are diversified in India and increasingly co-ordinated in the UK; integration of clinical with genomic data is more prominent in the UK and more geared to hegemonic 'platform' technologies; India has more nation-focused, societal policy in disease strategies, and notable heterogeneity in the social production of genomic knowledge. The paper develops STS concepts by linking them to political state theory, highlighting social heterogeneity in technoscientific innovation.

Keywords: bioinformatics, sociotechnical imaginaries, India

Introduction

Biomedical innovation has become a priority in the industry policies of many states worldwide with scientific ambitions. States' pursuance of innovative life science research and bio-industries takes place under conditions of globalisation. A recent study identifying the 'top 10' biotechnologies that would further the UN Millennium Development Goals of 2000 (aimed at alleviating conditions of the world's poorest people, three of which are directly health-focused) included:

- bioinformatics to identify drug targets and to examine pathogen-host interactions; and
- combinatorial chemistry for drug discovery. (Daar et al., 2002)

The unravelling of the human genome is said to have stimulated a 'gold rush' in this field of bioinformatics (Howard, 2000). Visions of the potential impact of genomics- based medicine on public health objectives globally have consequently escalated. Sociological analysis proposes that bioinformatics changes the way scientific research is undertaken: "Laboratory life has changed to become more virtual, and the experiment has become redefined to rely increasingly on the con-

struction, curation and mining of large scale databases" (McNally and Glasner, 2006). The worldwide mushrooming of 'data science', 'big data', whole genome sequencing, and medical informatics is replete with utopian visions of a revolutionary impact on global health, perfectly exemplified by the founder of Microsoft Corporation:

> Today, we're in the midst of a remarkable transformation that will see computing revolutionize scientific discovery (…) In healthcare, data-driven medicine and the ability to compute genomics and proteomics on a personal scale will fundamentally change how medicine is practiced. Medical data will be available in real time to be analyzed against each person's individual characteristics, ensuring that medical care is truly personal (…) All of these advances will help medicine scale to meet the needs of the more than 4 billion people who lack even basic care today (Bill Gates, opening an academic computing centre in the US; Gates, 2009).

The type of techno-utopian, global vision shown by Gates is a familiar trope for STS scholars, but the huge resources at the Foundation's disposal means that its vision has to be taken seriously for its performative effects in the globalised health research and policy arena. This paper examines the framing of the emerging paradigm of data science, in the form of bio-informatics, in the bio-economic policies and practices of two contrasting democratic states, India and the UK. As Salter et al. (2016) have suggested, bioinformatics constitutes a new 'epistemic domain' in the life sciences, and is thus the subject of political initiatives that frame bioinformatics in terms of states' overarching ambitions and national visions. Conceptually, therefore, this paper envisages these policy framings in terms of 'sociotechnical imaginaries' (Jasanoff and Kim, 2009, 2013, 2015), images of technoscientific developments that are linked to projections of global innovations, nationhood, collective identities, institutional and infrastructural designs and societal visions, "collectively held, institutionally stabilised and publicly performed visions of desirable futures" (Jasanoff, 2015:4).

Bioinformatics comprises a diffuse, hybrid and unstable field of technologies (e.g. biochips, microarrays, supercomputers, 'the cloud'), skills, knowledges, databases and software tools aiming notably at the development of new drugs as personalised or stratified medicine. Apart from the sheer quantity of 'big data', the distinctive, novel characteristics of the turn to computational methods in biology have been conceptualised to lie in the "methods, infrastructures, technologies, skills and knowledge" now required (Leonelli, 2014). As national life science policies have become ever more ratcheted up governments' political agendas, it is clear that bioinformatics specifically is becoming a clearer target of policymaking through investment schemes, infrastructure-building and skills development. The development of this computational biology is increasing the scales of international collaborative activity and reconfiguring inter-disciplinary boundaries between biology, computer science, bio-engineering, and statistics. However, different countries and their nation-state polities are enacting this digital revolution in different ways (Hardy et al, 2008). In broad terms, it is important both to biomedical actors, and to the theoretical project of STS, to try to document and understand "why differences persist in (…) the constitutional position of science and technology in the political order" (Jasanoff, 2015:4). The national and transnational policy visions – 'imaginaries' - and actions driving policy trends in bioinformatics do indeed show wide geopolitical and societal variation, which this paper addresses, both conceptually and empirically.

Social science of bioinformatics

Bioinformatics has so far attracted little, though growing, attention from scholars in STS, sociology, anthropology and political science. Most of the work to date can be described as focused on 'internalist' accounts, describing and interpreting the epistemology, knowledges, disciplines, field-shaping claims, data forms and processes internal to the field. For example, Lewis and Bartlett (2013) emphasize the lack of 'disciplinary coherence' in the field, its service status in relation to biology within academia, and the disciplinary identities of practitioners of bioinformatics as either developers of tools or service providers; Mackenzie (2003) emphasizes the potential for private property

ownership in the field. Stevens (2013) has charted at length the emergence of bioinformatics focusing on the convergence of biology, mathematics, statistics and computing, producing virtual, computational experimental space. Zwart (2009) considers the implications for human identity. Less internalist, and from a perspective of economic innovation studies, Harvey and McMeekin (2009), have discussed tensions between property issues and 'the commons' in the field.

Conceptual approaches

In contrast to these accounts, the present paper draws together two main conceptual strands, first, theory of the political economy of states in the global context of biomedical innovation, and second, a methodological orientation to the performativity of policy discourse, here especially in relation to national health and related institutional projects, which draws also on the substantive concept of 'sociotechnical imaginaries' as noted above (Jasanoff and Kim, 2009, 2013, 2015). I introduce these approaches in the paragraphs below.

The paper undertakes a comparison of bioinformatics innovation policymaking in two democracies, the UK and India. This comparison enables the development of a theorisation of innovation policy that goes beyond simply politico-economic or neoliberal capitalist framings. While it is not necessary to rehearse in detail the well-known key characteristics of these two countries' recent healthcare, academic and medical histories, some important features can be noted here. Notably, the UK has a publicly funded national healthcare system (the NHS); recent years have seen the government-driven growth of infrastructures to embed highly-resourced bioscientific and clinical research enterprises ever more deeply into this system. At the same time, large pharmaceutical companies are based in or have major facilities in the UK, with a primary motivation toward new drug development and close academic ties. In contrast, India is known for its strong IT sector and as a destination for the outsourcing of clinical trials from the more advanced bioeconomic states. The pharmaceutical industry in India has since the 1970s been dominated by its 'generics' industry, supported by strong political opposition to restrictive patenting by foreign pharma companies, though this situation has become more complicated in the last decade (Sariola et al., 2015) . At the same time, the healthcare system in India is largely based on out of pocket payment along with public hospitals and some private insurance, with some strong private hospital chains emerging. The two countries, of course, have vastly different sizes of population, overall standards of living, and population disease profiles, although it is important not to overstate the latter – cancers in general, for example, being highly prevalent in both countries. However, the "rise of the middle classes" is having a significant impact on India's disease profile, especially diabetes and its related symptoms, and certain cancers show far higher incidence in one country than the other (Ferlay et al, 2015).

The geopolitics of biomedical innovation governance has become a clear feature of the emerging global bioeconomy. With the rapid rise of, especially, China and India in the life sciences, the position of the United States (US) and European countries is being challenged. As a result, a new political dynamic is emerging as states, multi-national corporations, academic research institutions and civil society organisations jostle to set innovation agendas, obtain and deploy resources and establish politico-economic positions (Salter & Faulkner, 2011), governance being defined as political processes in which a variety of actors may play a part, not confined to direct government institutions and agencies (Rhodes, 1996). This dynamic thus constitutes a key force in global health governance. Because their perceived innovation needs, capacities and population health ambitions are different from those of the states and regions of the West, BRICs countries such as China and India are likely to pursue their collective interests and particular strategies on scientific biomedical knowledge production in global health in distinctive ways (Salter and Faulkner, 2011).

Political economy of states

In terms of international political science, the UK has been conceptualised as a 'competition state'. In this perspective, the advanced economies of North America and Europe were understood to react to the uncertainties accompanying the shift

to post-Fordist modes of production and consumption with an approach to seeking national advantage around knowledge innovation itself in the context of globalisation (Hay, 2004). States such as Japan and South Korea were seen as 'developmental states' attempting to join the existing Western economy, and by contrast, India and other BRICs countries have been seen as moving to become 'adaptive', 'post-industrial developmental', 'flexible' or 'transformative' states (Weiss, 2000; Kim, 1999; Wu, 2004), seeking not only to participate responsively in existing markets but also to forge their own novel spaces, knowledge and technologies.

Although addressing states' and nations' issues of political economy from an anthropological and ethnographic rather than state theory perspective, and focusing on the workings of capitalism in the 'postgenomic' age, Sunder Rajan (2006) writing from a Marxian perspective, also has emphasized a 'market logic' as the fundamental and almost exclusive motivating force behind states' outward-facing ambitions, resulting in a claimed biotechnology-inspired expansion of the rules of global capitalism. This author's portrayal of (India's) state divergence from the hegemony of US free market economics is not wholly consistent, though his account does allow not only for embrace of, but also 'selective resistance' and 'remodelling' of the paradigm attributed to the US (Sunder Rajan, 2006: 232). However, the apparent significance of such moves Sunder Rajan (2006: 219). judges to be weak, public good goals such as food security and health targets of bioscience, for example, being deemed the dwindling preserve of a 'dying breed.'

However, market logic and a politico-economic capitalist dynamic should not be seen as a simple, one-dimensional process of competition. I will argue that the emerging global, regional and national biomedical innovation ecology is more complicated, and that some local and national innovations amount to ideologically driven counter-movements to such over-arching narratives. One alternative is a more 'modular', decentralised R & D system where different aspects of R & D are distributed globally and conducted almost autonomously in different locations' (Goodall et al., 2006; Sariola et al., 2015). Thus, while in bioinformatics what have been called the 'Rising Powers' are developing innovation governance strategies to compete for a place on the world stage, a variety of different sociotechnical imaginaries are emerging to achieve global reputation, scientific esteem, economic advance and health impacts. As Harvey and McMeekin have pointed out, for example, while Brazilian bioinformatics is not on the same scale as clusters and centres in Europe, Japan, and the USA, where major bioinformatics-based genome and proteome projects have been undertaken for over a decade, the opening up of distinctive innovation pathways with potential global significance offers the possibility of a geopolitical redistribution of scientific innovation. Crucially, "Processes of transformation of a given geopolitical economic order may be less about nation-states catching up leaders or swapping places in league tables and more about *creating new games, increasing the heterogeneity of the global,* rather than being subordinated to or converging with homogenized global leadership" (Harvey and McMeekin, 2005: 654, my emphasis). An example of this possibility in the case of India is discussed below.

Given this global biopolitical context, sociotechnical visions may relate to broad social and national imaginaries as well as health and science agendas per se. Inevitably, there are always tensions between different governance actors, whether defined in terms of a 'triple helix' of industry, government and academia (Etzkowitz, 2008) or more broadly in network governance terms incorporating a fourth dimension of civil society agencies. Given such diversity of actors, governance will be 'co-produced' with science in interaction with its societal and economic contexts. This means a focus on how "knowledge making is incorporated into practices of state-making (…) and in reverse, how practices of governance influence the making and use of knowledge" (Jasanoff, 2004). This in turn implies that in order to understand the dynamics of the contemporary development of innovative biomedical knowledge under conditions of scientific globalization, we must turn our attention to innovation governance policies that enact the sociotechnical imaginaries of policy actors.

The discourse of sociotechnical imaginaries

Hence, the second conceptual strand deployed here aims to draw on concepts of policy discourse analysis and developments in order to shed light on the different ways in which the various governance actors of the UK and Indian states co-produce, frame, configure and construct their bioinformatics-related endeavours. Governance processes are pursued through a wide variety of narratives that construct biomedical materials as contributors to future healthcare, conveying also broader imaginaries such as normative visions of the nature of a particular nation state and principles of socio-political value. As Sunder Rajan (2006: 57) pointed out, the production of biocapitalist value is "to a large extent a discursive act". The grand, and not so grand, narratives of governance policy enact not only visions of the governance object, in this case bioinformatics, but also enact and generate (see Faulkner, 2012) the realities of various social goods such as national identity, national health projects, economic power positions of stakeholders, empowerments of actors participating in the policy domain, and actual innovations in the conditions of knowledge production. As Gee (2014: 8) has it: "(…) when we use language, social goods and their distribution are always at stake, language is always 'political' in a deep sense". These various formulations accord closely with the concept of sociotechnical imaginaries introduced above. Discourse analysis techniques have been used to analyse governance initiatives in genetics, addressing "what sorts of social relations (these) policy documents are a part of; (…) and the dominant forms of representation of science, the economy and patients that they embody" (Kerr, 2003:145). Hence in the case examined here, we can ask: what are the dominant or less prominent policy framings and strategies for bioinformatics, in terms of the states' bioeconomic visions, life science entrepreneurship and population health projects, and what imaginaries of national or international science, bioeconomy and disease priorities do they project?

In the light of these considerations, the paper argues broadly that the innovation ecology, both emerging and imagined, of bioinformatics in the UK is relatively 'joined up', and that in India it is relatively diversified, 'dispersed' and 'modular'. More specifically, policies incorporating bioinformatics are increasingly co-ordinated in the UK, and distributed in India; integration of clinical with genomic data is more prominent in the UK; UK (and EU) initiatives are more oriented to hegemonic 'platform' technologies, whilst India has more nation-focused disease strategies and 'social' (and socialist) bioinformatics infrastructure. In terms of the global health academic field I assume that the innovation ecologies and co-produced governance actions of the two states discussed here are imagined and performed by the participating actors, in a context of a developing global bioeconomy and perceived health policies and problems which display somewhat different patterns between the two cases, and which mobilise different broad political cultures and values. Hence, via bioinformatics imaginaries, both states and their state governance, funding, commercial, biomedical, technoscientific, ethics and social actors participate in different ways in global health governance (Lee and Kamradt-Scott, 2014).

The structure of the paper is as follows. First, the research on which the paper is based is briefly described. This is followed by the two main substantive sections of the paper, the first on the UK's policy development and commitments to bioinformatics, and the second on India's. The two accounts are then discussed in terms of states' innovation ecologies and the co-production of governance through the sociotechnical imaginaries of policy and its discourses in the concluding part.

A note on method

This paper is based on research conducted as part of a UK Economic and Research Council (ESRC) funded team research project, conducted at King's College London and the University of Sussex, UK, from 2012-15, which examined strategies of governance of biomedical innovation in the UK, China and India (Salter et al., 2012). The project focused on regenerative medicine and 'personalised' medicine. Ethics approval was obtained from King's College London Research Ethics Committee (REP-L/12/13-10). A wide range of documents were assembled including government policies and

plans, stakeholders' position papers, scientific articles, media reports and commentary, and market analysis. Fieldwork consisted of semi-structured interviews, conference/meeting observations and 'policy workshops'. One multi-stakeholder workshop held at the University of Sussex in the UK was conducted on bioinformatics in 2015. Thirty interviews directly on bioinformatics/pharmacogenomics policy or referring to it were conducted by members of the research team including the present author, mainly in academic centres and with policymakers, in the UK, US, India (and China). However, the present paper draws mostly on systematic and comparative thematic content analysis, and data analysis, of the types of documentary and publicly available sources noted above.

UK imaginary of bioinformatics: genomic medicine and translation frames

The most prominent actors shaping the collective imaginaries of UK bioinformatics policy have been government departments, special government committees, charitable and government-based funders, and elite science institutions. Medical and health applications have superseded agribusiness in recent government policy development (Harvey and McMeekin 2002). Much of the policy development in UK bioinformatics is thus now framed in terms of 'genomic medicine'. A close connection between the UK's National Health Service, genomics and computation was signalled as early as the 1990s:

> The United Kingdom National Health Service (…) has the potential to serve as a unique resource for population genetics research (…) require appropriate scientific and clinical skills matched with large-scale computational infrastructure and proactive, transparent, and coherent policies for addressing the ethical, legal, social, and political issues arising (…) (Fears and Poste, 1999: 267-268; cited in Martin and Hollin, 2014)

It was also argued by Fears and Poste (1999) that public-private partnerships would be essential to realise this vision. Continuing in this vein, the UK's House of Lords conducted an inquiry into this topic in the late 2000s, to which the government responded (Secretary of State for Health, 2009). Their response included noting recent investments and a range of measures specific to bioinformatics, notably:

> In 2009 more than £9 million (…) awarded by the MRC (Medical Research Council) to support the UK research community's access to high quality equipment for DNA sequencing via substantial investment in the latest technology. Four regional hubs located across England and Scotland will provide technical support and bioinformatics expertise

> We recommend the establishment of a new (i.e. national) Institute of Biomedical Informatics to address the challenges of handling the linking of medical and genetic information in order to maximize the value of these two unique sources of information (…). The Institute would guide the NHS in the creation of NHS informatics platforms that will interface with databases containing personal genetic data and with publicly available genome databases (Secretary of State for Health 2009, Paragraph 8.23).

In the above we see how bioinformatics is being brought under the umbrella framing of genomic medicine, and also strongly linked to the public healthcare system of the NHS, with the transformation of patients' health records into research data. The emphasis on central and national imaginaries of data and data experts is clear.

The UK government also produced a national Life Sciences Strategy (having earlier created an Office for Life Sciences within its then Department for Business, Innovation Skills (BIS)), which was launched by the Prime Minister in November 2011. The policy makes some specific provisions for increasing bioinformatics capability in the UK, including involvement in key European infrastructures, which are based in the UK, notably:

> ELIXIR is a programme to assemble and manage biological and genetic information generated by research. (…) It is vital that this data is collected, stored and curated in user-friendly ways that allow its efficient retrieval and rapid exploitation. ELIXIR will allow us to do just this. (BIS Office for Life Sciences, 2011: 11)

In this policy vision, we see that the imaginary of national informatics-based genomics is linked to broader European infrastructures addressing the technical challenges of collecting and exploiting biological data. The central role of the UK is presented as fundamental to these developments.

> We recommend that the Government show leadership on leveraging sustainable funding to the European Bioinformatics Institute (EBI), through the European Research Infrastructure (ESFRI) instrument and through the UK Research Councils (…). This forms a key part of the emerging pan-European science project, the European Life Science Infrastructure for Biological Information (ELIXIR), an initiative involving 32 partners from 13 countries. (House of Lords, 2009: 50)

The UK's central role in the broad imaginary of the entire European 'Life Science Infrastructure' is envisioned here, highlighting the national dimension of a life science project broader even than genomics. In a sign of the joint, integrated commitment to EBI, it is funded by the Wellcome Trust, the Biotechnology and Biological Sciences Research Council, the Medical Research Council, the EU, European Member States, National Institutes of Health (NIH), the European Molecular Biology Organization, and the pharmaceutical industry.

Further, in 2012, Sir Mark Walport, then director of the Wellcome Trust, which spends more than £100 million a year on genomic research, endorsed the recommendations of the report on genomic medicine, emphasizing a link between genomic data and 'improvements in healthcare', in other words the much vaunted field of 'translational' medicine (e.g. European Society for Translational Medicine, 2014):

> We particularly support the proposal to link genomic data to patients' anonymised medical records through a secure national centre, which would create an unparalleled resource for research and diagnosis without compromising confidentiality or privacy. (Department of Health, 2012)

The centrality of 'translational research' in the genomics-related big data domain is exemplified by the way in which 'translation' has become an integral part of the vocabulary of biomedicine's and genomics' policy actors, becoming an 'actor's category' (Sunder Rajan and Leonelli, 2013).

However, tensions in the innovation model to take forward the genomic and life science visions are conspicuous in UK debates. For example, a representative of the Medical Research Council (MRC) asserted that for the true potential of life sciences in the UK to be realised, "industry and academia will have to engage in much more complicated partnerships that in the past (…). The science must remain at the forefront, but each company will see the science question in a different way, so a shared and very well-developed science agenda will be critical" (Mulkeen, cited in Taylor, 2013).

Similarly, medical media headlines have included comments such as:

> Health informatics is set to be a major driver of success for UK life sciences, but the sector - and industry in particular - does not yet have the necessary analytical skills, according to leading experts…"We need to build up a cadre of people who can do this," (government life sciences champion) …Sir John Bell called for the whole process to begin again "with a clean sheet," and to focus on "open and adjacent' innovation" (Taylor, 2013).

In 2012-2013 the UK government announced the formation of 'Genome England'. Genome England would be a company owned by the Department of Health that "will introduce high-tech DNA mapping for cancer patients and those with rare or infectious diseases and link that new data to the patient's medical records" (BusinessWire, 2013). It is the organisational form devised to implement the '100,000 Genomes' project announced in 2012. The £100 million funding would also be used to train healthcare professionals in the clinical application of genomic data, and new genetic scientists to develop novel treatments. From the outset, Genome England was planned to manage the contracts for specialist UK-based companies, universities and hospitals to supply sequencing, data linkage and analysis services. It would have responsibility for regulating issues of data storage and security and patient consent to participation. It was claimed that the project would

enable the UK to become the first country in the world to introduce genomics and bioinformatics technology into its mainstream healthcare delivery system. Furthermore, emphasizing the economic dimension of the genomic data imaginary, a prominent feature in the leading British Medical Journal stated that: "the project's broader goals are to kickstart a national genomics industry and make the UK the first country to routinely use DNA sequencing in mainstream healthcare" (Peplow, 2016).

Now called Genomics England, the DoH company is developing a range of partnerships with companies in different parts of the world, including three big pharma multinationals (namely Roche, GSK and AstraZeneca), and especially in the US:

> The new partners are Cambridge-based Congenica, developers of the Sapientia™ genome analysis and interpretation platform, and California-based Omicia, developers of genome analysis solution, Opal™. Berg Health and NGM Biopharmaceuticals will be joining its industry collaboration, known as the GENE Consortium (Genomics Expert Network for Enterprises). BERG is a Boston based biopharmaceutical company and NGM Biopharmaceuticals is based in South San Francisco (…). (Bazeley, 2015).

These developments in commercial partnerships mobilise the cross-national, and inter-institutional imaginaries that are shaping UK bioinformatics infrastructures for genomics. In parallel, it is important to note the development of initiatives aimed at further embedding genomics data and research in the UK's National Health Service. Key to this is the development of the Genomics England 'Clinical Interpretation Partnership' (GeCIP; Genomics England, 2016), with a growing range of clinical disease aims and some cross-cutting subjects such as health economics. GeCIP's 'research themes' also confirm that the main focus of research is on cancers and 'rare diseases', with infectious disease a more recent third priority. The infectious disease theme is being led by Public Health England, especially with its aim to eradicate tuberculosis from the country, partly associated with population migration (Public Health England, 2016). The attention to rare diseases is significant, because a great deal of entrepreneurial therapeutic pharmaceutical innovation is focused on such diseases, which attract various commercial and regulatory incentives (especially as 'orphan drugs') (e.g. Meekings et al., 2012).

Alongside government departments, charitable funders and scientific and commercial elites, civil society organisations and academic actors on ethical issues have been (and continue to be) prominent in the evolution of the UK's health-related bioinformatics policy. This has taken the form both of critically collaborative involvement, indeed including government-enrolled specialists, and of activist opposition to genomic personal data processing. While this is not the place for a detailed exposition of the ethical issues, I briefly refer to the most notable actors. Most notable at the outset was Genomics England's own in-built ethics working group, led by a prominent academic ethicist (Parker, 2013). This initiative went on to become an 'ethics and social science' theme of GeCIP (Genomics England, 2016). Likewise, a major independent ethical body, the Nuffield Council on Bioethics, convened consultations and reported on issues of data privacy, including bioinformatics applications (Nuffield Council, 2015). Opposition to the data privacy issues has come from various quarters, most notably activist group GeneWatch UK (e.g. GeneWatch UK, 2015). Thus, we can observe here signs of a participative engagement with institutional constituencies representing social and ethical concerns. Whether the involvement of such actors represents effective challenges to the genomics imaginary, or lends it legitimation, is open to debate.

Thus, overall we can see bioinformatics being strongly drawn into the agenda of a sociotechnical imaginary in the form of a future nation state-based vision for healthcare and medical innovation based on the genomic revolution. Its innovation ecology notably envisions an embedding of bioinformatics in healthcare delivery organisations through integration of electronic patient record data alongside the genomics research agenda, this integration typically being articulated in the terms of 'translational research'. Cancer and rare diseases are high on the medicopolitical agenda, with strong emphasis on

genomics-based drug development and identification of new biomarkers and diagnostics, in other words 'pharmacogenomics'. The location of EBI in England enhances the interconnectedness of bioinformatics in the UK with a broader stabilising and standard-setting network of academic and commercial institutions, and Genomics England further embeds a public-private model in international, Western private enterprise. We also see a strong agenda in developing platform informatics technologies with multiple possible applications. These features provide a striking contrast with developments in India, to which I now turn.

India's bioinformatics imaginary: nationalism, business, disease projects and social participation

The most prominent actors in shaping India's health related bioinformatics vision are government departments, national medical funders, pharmaceutical trade organisations, and elite scientific institutions. However, unlike the UK, the major government departments involved are said to be quite diffuse. One well-placed academic interviewee opined that:

> The Ministry of Health has a different approach [to biomedical innovation]. Within the Ministry of Science and Technology, CSIR (Council of Scientific and Industrial Research), which is a department in itself, has a different approach. DBT (Dept. of Biotechnology) has a different approach, and DSD (Dept. of State Development) has a different approach. And then you have the Ministry of Commerce which has a different approach. (Interview biomedical scientist, New Delhi, 2014)

As noted, India's well-acknowledged expertise in IT and its huge generics drug industry certainly shape the landscape in which its bioinformatics imaginary is developing as a national project. India was one of first countries in the world to establish a nationwide bioinformatics network, which comprised 57 connected informatics centres set up in 1987 from the government department of science and technology. This was initially a technological network allowing electronic network communications. Now, the government Department of Biotechnology (DBT) is the main responsible government department. DST (Science & Technology) is involved especially for supporting biochip technology aspects. The Bioinformatics Institute of India (BII) (which has no equivalent at national level in the UK) was formed in 2002 registered as a professional society under Indian rules, for "academicians, scientists and engineers" (Bioinformatics Institute of India, 2014). The Indian DBT published a national bioinformatics policy in 2004 (again, no equivalent in the UK), with an explicit aim of making India a significant presence on the global stage. The emphasis in these initiatives was clearly at the computational and IT, rather than the biological end of the bioinformatics epistemic spectrum. Nevertheless, the Indian Council of Medical Research (ICMR) has initiatives in the bioinformatics field, outlined below. Thus, developments in India's national imaginaries for bioinformatics strikingly combine attention to the field as a business sector and as a vehicle of (some) national health goals and 'social' innovations in bioinformatics knowledge production, as I elaborate below.

The worldwide market for bioinformatics tools and services was estimated by Indian sources to exceed US$40 billion by the year 2017. Leading industry observer and commentator ABLE/Biospectrum in their Biotech Survey in 2013 reported: "Bioinformatics is growing as an independent discipline and is fundamental to the growth of biotechnology. India has achieved remarkable success in the software industry. BioInformatics sector grew by 11% (2003-13). The fragmented bioinformatics market will see a growth in the coming years because of government's spending on R&D in addition to increase in private fundings" (ABLE/Biospectrum, 2013). It was claimed that over 200 companies have some involvement in bioinformatics in India, divided amongst three types of companies – pure research bioinformatics, IT companies, and CRAMS (contract research and manufacturing services). A "huge proportion" of the sector is said to be focused on outsourced work (RNCOS, 2012), echoing the well-known market for outsourced clinical trials, showing the importance of a commercial dimension to the Indian bioinformatics imaginary.

Alongside the commercial sector, India also has significant activity in bioinformatics in the academic scientific and biomedical sectors. The Indian Council for Medical Research (ICMR) instituted its own Biomedical Informatics Centre, formed in 1999 with support from WHO's tropical diseases research fund (www.who.int/tdr/en/), an early indication of a focus on national disease priorities. A number of disease targets can be identified in their mission - nine centres were initially created. One of the original nine centres (now comprising seventeen 'projects') is the Biomedical Informatics Centre (BMIC) at the Tuberculosis Research Centre (Chennai). The aim of this centre, typical of the model, includes: "to enhance understanding of TB and HIV/AIDS using computational approaches; to provide bioinformatics support for biomedical research; to impart skills in bioinformatics through training programmes / workshops" (http://bmi.icmr.org.in/DDTRP/bic@trc.php). The other BMIC centres include those with a focus on or being part of: the National Institute of Cholera and Enteric Diseases, Kolkata, established 2006; National Institute of Nutrition, Hyderabad; National Institute for Research in Reproductive Health, Mumbai; Rajendra Memorial Research Institute of Medical Sciences, Patna (nano-informatics); All India Institute of Medical Sciences (AIIMS), New Delhi (drug design, protein modelling); Institute of Cytology and Preventive Oncology, Noida; Regional Medical Research Centre, Dibrugarh (malaria and mosquito-borne disease); Regional Medical Research Centre, Bhubneshwar (filarial and dengue disease). Also focused on a disease of major national importance, DBT sponsors TBNet India, a network of thirteen centres whose aims include attempting to understand different strains of drug-resistant TB and gathering and curating published protein sequences, unpublished submitted sequences and cellular, molecular and biochemical data publications on mycobacterial proteins in a Tuberculosis Reference Database. Thus, we see that the academic strand of India's bioinformatics is mobilised by a national disease imaginary comprising a range of predominantly regionally important health issues.

The degree of linkage in Indian policy between bioinformatics and genomics is notably less than in the UK case. Nevertheless, the National Institute of Biomedical Genomics (NIBMG) was established near Kolkata as an autonomous institution by the Government of India in 2010, under the aegis of DBT. This is said to be the first institution in India explicitly devoted to research, training, translation and service and capacity-building in biomedical genomics. The main objective of the institute is to "promote better public health in India by conducting large genetic epidemiological studies on Indian populations on diseases of importance in India, including susceptibilities to infectious diseases and responses to vaccines against infections" (Shirodkar, 2010).

Thus we observe a range of different activity in the bioinformatics field in India, divided between commercial outsourcing enterprise and public government supported informatics activity most of which is targeted to 'Indian' disease issues, some of which is not. The arrival of biomedical *genomics* per se is clearly a very recent and relatively small-scale development.

Perhaps reflecting the diversity of activity in the bioinformatics field, there is notable criticism of the innovation pathway of bioinformatics within the country:

> The present Bioinformatics Policy lacks vision and fails to address the pertinent issues related to research and development in this arena. Hence, to realise this vision, it is essential to form of a stringent and functionary regulatory body, to systematise, control and facilitate projects related to bioinformatics and synthetic biology research. (Interview professor of bioinformatics, New Delhi, 2013)

So the extent of bioinformatics enrolment into the emergence of a national policy imaginary on pharmacogenomics in India is very recent. The Indian government has only since 2012 started addressing the translational issue of pharmacogenomics as part of national health strategy. The main action is to issue guidance on the design of pharmacogenomics clinical trials, which states that trial populations and the aims of trials must have relevance to diseases relevant to the Indian population, thus mobilising a national-level health imaginary. Likewise, the ICMR set up a task force on pharmocogenomics to focus on specific

research topics, including identification of genes and pathways involved in "pharmacokinetics and pharmacodynamics of common drugs, and validation of human single nucleotide polymorphisms (SNP) haplotypes of short-listed genes in Indian population" (Shankar, 2011:1). The task force also intended to research the development of an "Indian pharmacogenomics chip" (Parveen, 2010). Survey of commercial activity in the field shows a number of life science companies moving to work in the pharmacogenomics field (Parveen, 2010). However, there is strong internal perception that India, in 'competitive state' terms, is a latecomer to this field:

> India's pharmaceutical market, mostly deals with generic drugs (…) far behind in addressing the foreseeable challenge of drug response monitoring or even on biomarker discovery (…). (…) Scientific journal, *Nature*, in 2010 indicated that India is way behind in the global map of genomic technology landscape. (Banerjee, 2011).

Trade organisations such as an Indian Pharma Industry representative organisation likewise compares India's position to other 'Rising Powers':

> India at this point is ahead of China in chemistry but the impression (…) is that India is weak on biology front especially in genetically modified animals, biochips and basic molecular biology. The biology capabilities are mainly in government institutes with a handful of companies having skills in molecular biology and protein expression.

Commentary on this position also alludes to a need to bridge the gap between bioinformaticians and experimental biologists (DBT, 2011).

In 2014, the ICMR reported that via its taskforce "'we have established 20 Biomedical Informatics Centres of ICMR at various medical colleges and medical research institutes. Our initiative of establishing a centralised ICMR Computational Genomics Centre is in final stages of approval by the GOI (Government of India)" (personal communication, ICMR Bioinformatics Lead, 2014). The vision of this centre is to bring together genomic data with medical information: "(…) the objective is to setup a centralized genomics facility which will provide expertise and infrastructure to researchers in using genomics tools for medical research. Long term plans are to transform the facility in self -sustaining PPP project" (personal communication, ICMR 2014). In mid-2015, suitable private partners to join in a partnership for the envisaged national Computational Genomics Centre were still being sought, showing the practical problems with materialising the genomics-related imaginary being invoked here.

Nevertheless, significant for the Indian genomics-based drug discovery/development sector, is a remarkable initiative with symbolic significance, namely the Open Source Drug Discovery (OSDD) program, supported by the national Council of Scientific and Industrial Research (CSIR), part of DBT. This development in what I call 'social' innovation in bioinformatics can be seen as an example of increasing "the heterogeneity of the global" in the international landscape of bioinformatics, in Harvey and McMeekin's (2005) concept. It is thus an important and distinct institution in India's genomics imaginary.

OSDD is claimed in policy discourse as one of the world's first attempts to apply an open source/participative innovation model drawn from the IT world to pharmaceutical innovation 'neglected' diseases. OSDD aims to discover novel therapies for tuberculosis and other neglected tropical diseases. Its activities are stated to "spread throughout every stage of the discovery process (from 'drug target identification to lead optimization') and has 'initiated discussions with pharmaceutical companies regarding pre-clinical and clinical trials' (OSDD website). Its main achievements to date, according to independent academic commentators, are: "the re-annotation of the *Mycobacterium tuberculosis* genome and the generation of 11 models for prediction of anti-tuberculosis activity" (Årdal and Røttingen, 2012). Årdal and Røttingen's independent Europe-based evaluation of OSDD states that volunteers are attracted to the project by publicity in academic journals and utilizing social media and networks. It has also 'effectively paired up with' Indian universities and colleges, incentivizing students to volunteer as parts of classroom assignments or positioning participation as valuable hands-on experience. They have also "built in an element of patriotism" (Årdal and Røttingen, 2012) linking

finding cures for tuberculosis as an Indian responsibility due to the high prevalence of the disease. This effect is reinforced through marketing efforts, like the project's own music video and offer of prizes such as free holiday lets of property 'close to a bird sanctuary' (OSDD website). "Large number of students can participate and benefit from this activity. OSDD's focus is in Drug discovery and Development in TB, Malaria and other neglected diseases. Chemistry, Medicinal Chemistry, Biology and Informatic discipline plays a vital role…" (OSDD website). The OSDD Director is explicit about the local, national identity of this project: "it 'won't work in the Western world because it has to match the ethos of the society", "socialistic principles", "It will work with those students who are hungry to learn, not those who have been given plenty" (Brahmach, 2012; OSDD Director).

Actually, according to these evaluators, the OSDD innovation model is not open source *per se* because it uses a protective license system and in effect a 'gated community' mode of access. It aligns itself with the Indian generics drug industry business model: "The drugs that come out of OSDD will be made available like a generic drug without any IP encumbrances so that the generic drug industry can manufacture and sell it" (...) "(this) creates the environment of affordability"(OSDD website). OSDD claims that:"OSDD brings in the concept of open source, crowd source, open science, open innovation and product development partnership concepts on the same platform and leaves delivery of drugs to market forces" (OSDD website). Thus a societally participative and indeed socialist imaginary mobilises this part of India's heterogeneous bioinformatics vision, extending to social innovation in the institutional means of production of genomics knowledge as well as the national public health targets of its knowledge practices.

India's bioinformatics activity also encompasses not only infectious and tropical diseases, but also non-communicable diseases, now endemic in states such as India. India takes part in the global International Cancer Genome Consortium. Its director (based in the Sanger Centre, Cambridge, UK), referring to the ambition to identify all the genes critical in the development of cancer and emphasizing regional participation, has "hailed the role of the Kalyani-based Institute of Biomedical Genomics" (…) "It is playing an important role in focusing on oral cancer which is quite prevalent in India.," said Stratton' (The Telegraph, Calcutta, 2011). Thus while taking part in an international genomics project, India at the same time promotes disease research that is high priority in its national public health policies.

In summary, these examples of the bioinformatics developments informed by national political and health imaginaries in India show an emerging 'sector' of very diverse activity and visions. On the one hand we see the well-known pattern of outsourcing of clinical trials from the advanced states (cf. Sariola et al., 2015) being reproduced in a developing bioinformatics service sector, and on the other we see a more steered biomedical economy being shaped by government biotechnology and medical initiatives and infrastructures, with some unique national elements and some notable international collaborations. This section has not included any reference to ethical dimensions in the shaping of India's bioinformatics imaginary. Although India has recently tightened ethical regulatory systems in biomedicine, there is no evidence of an equivalent to the UK's institutionalisation of bioinformatics-specific ethics dynamics in the field, local arrangements around specific genomics research centres being the most developed aspect (CSIR centre interview, 2013). In this respect the field strongly parallels that reported for nanotechnology (Beuma and Bhattacharya, 2013). In terms of disease target strategies, it seems clear that the national imaginary of medical and health futures is being constituted as infectious and neglected diseases are being addressed to some extent, and as growing noncommunicable diseases such as cancer are also impacting on the bioinformatics agenda. The published critiques referred to above of some commentators evidences the internal perception of India's lag in competition terms on the global bioinformatics stage, especially in aspects of expertise in biology, though this is a notable critique in the UK as well. At the same time, India has, at least in policy discourse and its sponsors claims-making, established an example of a unique imaginary in the form of a national socialised approach to bioinformatics-informed

drug discovery targeting national health projects, through the OSDD. The OSDD in particular can be understood as a participative, national social imaginary that has no real equivalent in the UK (or the advanced bio-economies more broadly).

Concluding discussion

In this discussion, I compare the picture assembled to date in the cases of India and the UK focusing on the political economy and discursive sociotechnical imaginaries shaping bioinformatics in the context of medicine and health on the global stage. I point to the various tensions in the dynamics of the bioinformatics sector that are apparent, and conceptualise these in terms of the policy related concepts of state politics and sociotechnical imaginaries introduced at the beginning of the paper. I consider the significance of these developments for projects of national identity, economy, societal participation, and for specific population health and disease agendas. I highlight issues of policy integration and heterogeneity in the respective regimes.

This paper has shown some of the different stakeholders attempting to construct, through co-production of science and governance, a range of valued national bioinformatics objectives in a context of globalisation. These interventions are being constructed through various national and sectoral imaginaries mobilising bioinformatics work and its actors. Biomedical research is, to a greater or lesser extent, being brought discursively and in practice into the realm of 'translational' research, a metaphor that highlights the aspirational production of medical products while at the same time skating over the computational work involved, for example in centres for 'translational genomics'. Thus, as the comparison of India and the UK demonstrates, bioinformatics may be drawn into relationships with genomic research in a variety of forms, which may achieve an acknowledged status as one of the sectors of the global bioeconomy, alongside the other 'omics'.

In spite of the different emphases in policy discourse and actions, there is evidence that the genomic-related research agendas in India and the UK display a national imaginary geared toward the perceived health needs of the respective populations. The recent initiatives in the UK of Genomics England are most obviously geared toward introducing more personalised genetic/genomic testing directly into the healthcare system, notably in the field of cancer drug therapies. The governance frame in which bioinformatics is being co-produced is that of 'genomic medicine'. In India, the genomic medicine framing is not so strong, though recently being supported in policymaking, as is the ambition to embed genomics and thus bioinformatics into the fabric of healthcare delivery systems and clinical trialling, possibly because of the greater emphasis on commercial bioinformatics services.

The UK focus on 'rare diseases' in parallel to cancer, compared to India's on infectious and communicable diseases, responds to a discourse of 'unmet need' in the UK, in other words medical needs for which there is little research effort; in contrast, India's emphasis is on unmet needs for mass public health population needs. Further, the UK focus on rare diseases points to an emphasis on diseases where genomic science itself has a relatively high chance of progressing, thus supporting a national vision of developing platform technologies of eventual broader, global applicability.

The account provided in this paper provides evidence in terms of national policy of both inward and outward facing policies and actions. Technoscientific nationalist imaginaries can be seen in both cases. In terms of the sectorisation of bioinformatics as a technological zone (Faulkner, 2009), India appears to have currently a mixed bioinformatics economy model with a strong service element serving academic and commercial researchers globally, while the UK has a more public sector-based bioinformatics economy with strong outsourcing and a globally important node in Cambridge, with new nodes being built with new investments. India's plans for a national genomics focused medical bioinformatics central facility are at the time of writing still pending, while private commercial partners to the state commitment are sought.

There are some commonalities in India and the UK in the problems perceived for bioinformatics as a sector, notably the perceived need for more, and more advanced skill-building at the interface of biology and computation. Likewise,

both states appear to identify issues in the sector that require regulatory policymaking. In the UK we see an attempt to show that the NHS is "open for business" (to use a phrase current amongst UK government politicians) – the business of clinical trials. In India we see, in competition terms at least, a 'late' emergence of pharmacogenomics discourse compared to UK, and relative lack of an attempt to engineer an integration of national healthcare system, clinical trials and health informatics and bioinformatics in a genomics-driven imaginary of scientific advance.

On this analysis, is India 'less advanced' than the UK or the European collaborations noted in this paper? Or, are there signs of alternative innovation like those mentioned for Brazilian genomics in the introduction here? The self-perception by some critical commentators is indeed that India is 'lagging', although some analyses suggest that India is moving toward a somewhat more innovation-oriented, hybridised (Sariola et al., 2015) pharmaceutical paradigm by expansion of activity in the 'biosimilars' field (Kale and Little, 2007). Nevertheless, the perception of relative 'lag' may be one shaped by imaginaries of Indian genomic health ambitions that are not shared by those non-elite actors active in providing bioinformatics services to customers in the global bioeconomic marketplace. It is thus not easy to define these bioeconomic polities in simple terms as competitive or adaptive states, participating by default in a hegemonically dominated ecology, without considering the different dimensions of its bioinformatics project in more detail. Both regimes are experiencing internal critiques of the gap between computational and biological domains of expertise.

The example of OSDD from India, though it is only one developing initiative, is symbolically resonant in this context. It shows an alignment of emerging, novel genomic-based and disease-targeted science with the existing imaginary of economic interest and market strength of India in generic drug manufacture. The discursive, ideological link forged between a commitment to crowdsourcing participatory science involving bioinformatics, the generics industry, and the infectious disease targets is particularly striking as an example of an imaginary of communitarian *medico*-techno-nationalism. Thus OSDD can be seen as a novel niche in the global innovation ecology of bioinformatics, nurtured by the Indian state governance agencies, which points toward a post-developmental state, participatory form of genomic science where India can lay claim, as it does, to a globally significant stake with a high degree of value-based societal legitimation. In this initiative, India is contributing to the emerging global paradigm of crowdsourcing apparent in many disciplines of biomedical and genomic research (Afshinnekoo et al., 2016). Indeed, here we surely see an example of Harvey and McMeekin's (2005) expansion of the "heterogeneity of the global" innovation ecology of bioinformatics, in other words a partial redrawing of "the rules of the game". This game redirects our attention to the *social means of production* of bioscientific and genomic knowledge as a significant aspect of the sociotechnical imaginary of bioinformatics in the Indian context. This feature remains significant even though the scientific knowledge *products* may be commodified through the existing generics pharmaceutical model. The fact that this novel niche enshrines a strong participatory discourse and practice emphasizes that even if states are competing for position on a global stage in bioinformatics, this stage is not defined purely in terms of economic or political advantage, but admits of more 'social' performativity (cf. Faulkner, 2012). Pressing this interpretation further, it is clear that the OSDD, as a nationalist project, can usefully be understood in terms of the broad tendency in the evolution India's science policy to strongly embrace social' goals, and specifically in the context of postcolonial 'genomic sovereignty' (Benjamin, 2009).

In contrast to India's OSDD, the UK, which has historically prided itself on the socialist roots of the publicly-funded National Health Service, has been forced to develop approaches to the societal aspects of the ethical governance of bioinformatics-based genomics via a high degree of expert academic attention to 'ELSI' (ethical, legal and social) implications of the Genomics England initiative (Martin and Hollin, 2014; Parker, 2015). This initiative inevitably requires major commercial investments and partnerships in operations

that require the intimate genomic and clinical healthcare data of tens of thousands of citizens.

The UK's national bioinformatics imaginary, therefore, is characterised by primary attention to the building-up and coordination of infrastructure through public, charitable and private investment. The priority disease targets of Genomics England are those where the science is already most advanced and where therapeutic gains in the relative short term are most likely, at the same time enhancing the science base. Disease focus and infrastructure development are thus closely integrated in the frame of 'translational research'. As a director of a major academic biomedical informatics centre in the US told me, "we are agnostic regarding different diseases". This appears particularly strong in the case of the UK/EU developments, and is perhaps characteristic of genomic research effort focused more on a 'basic science' model of developing platform technologies. Nevertheless, as has been shown above, there are policy priorities and disease target agendas to be discerned in the health imaginaries shaping bioinformatics activity described above. As this discussion of the national political economies of innovation ecology and of the performative national and institutional sociotechnical imaginaries shaping bioinformatics has shown, the policy models of socioeconomic participation developed to pursue these ambitions has some broad commonalities, for example in the search for public-private partnerships, but some very distinctive disparities, notably the diverging models of participatory citizen science.

As the above accounts and analysis have shown, sociotechnical imaginaries work at different levels, through different framings, take different epistemic forms, and find expression through different political cultures, including those of the nation state. Bill Gates' apolitical vision presented at the beginning of this paper represents a very broad, Western, arguably hegemonic, informatics-driven imaginary. Similar dynamics, between powerful 'Western' globally influential institution-building and 'local' national heterogeneity, reinterpretation and resistance appears in other biomedical fields such as stem cell applications (Sleeboom-Faulkner et al., 2016). It appears from the analysis in this paper that the envisioned integration of data science with healthcare intervention is more prominent in the genomics-framed imaginaries of the UK than India, currently. However, one important feature of the 'technopolitical culture' of science and technology is the national style and valuation of social participation (Felt, 2014), and in this respect, India's participatory citizen science illustrated by the 'open source' drug discovery programme reflects a profound difference in political culture between the two states. Hence, we can understand that the ultimate political goals of bioinformatics in the genomics context may be seen not only in terms of the development of health and medicine, but also in the conveying of particular social values of civil society itself.

Acknowledgments

The research for this article was conducted as part of the project ''State strategies of governance in global biomedical innovation: the impact of China and India'', funded under the UK ESRC Rising Powers programme, grant ES/J012521/1. I also thank members of the research team, Brian Salter, Stuart Hogarth, Yinhua Zhou and Saheli Datta.

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Diagnosing at Point of Care in South India: Coordination Work and Frictions

Nora Engel

Department of Health, Ethics & Society; Care and Public Health Research Institute (CAPHRI), Maastricht University, The Netherlands/ n.engel@maastrichtuniversity.nl

Vijayashree Yellappa

Institute of Public Health, Bangalore, India

Nitika Pant Pai

Division of Clinical Epidemiology, Department of Medicine, McGill University and McGill University Health Centre, Canada

Madhukar Pai

McGill International TB Centre, Department of Epidemiology & Biostatistics, McGill University, Canada

Abstract

Point-of-care testing promises to cut diagnostic and treatment delays by ensuring patients receive a management decision based on a diagnostic test within one encounter with a provider. Adding to STS work on diagnostics and the sociology of diagnosis, this paper examines the work involved in enacting point-of-care testing, and how technology and the embedded assumptions regarding patients feature in these enactments. Using focus group discussions with providers and patients in India, the results reveal overlaps, detours and frictions along diagnostic pathways. Diagnosing at point of care requires coordination work by providers and patients and alignment of diagnostic ensembles in which bodies, tools, knowledge, infrastructure, social relations and testing sites mutually configure each other. Patients do not always leave the point of care with one disease or diagnosis. In the process, they are both turned into objects as well as powerful actors. Contributions to STS theory and implications for global health innovation practices are discussed.

Keywords: diagnostic cycle, point-of-care testing, India

Introduction

Point-of-care testing has attracted much hope and enthusiasm among global health actors, since it promises to cut diagnostic and treatment delays in settings with potentially limited resources and capacities. Devices that are believed to facilitate such testing are designed for easy and rapid appli-

cation at relatively low cost, with minimal user and maintenance requirements (Peeling and Mabey, 2010). Examples are the urine pregnancy test, glucometer for diabetes or the malaria, hemoglobin, syphilis and HIV rapid tests. Especially ease of use and rapidly available test results ("while the patient waits") are highlighted to promise diagnostic precision in primary care or remote settings, in communities, homes or hospital wards, in settings without laboratories, fridges, laboratory consumables, biosafety, continuous power supply or trained staff. Making tests available closer to where patients are is deemed important, in order to avoid losing patients and/or delaying treatment initiation. Promoters of point-of-care testing argue that this offers advantages to conventional laboratory based testing where long turn-around times and delays often result in the loss of patients from testing and treatment pathways (Squire et al., 2005; Bassett et al., 2009). In this way, point-of-care testing is thought to provide answers to concerns (especially relevant in contexts with lower resources), such as appropriate treatment in the face of drug resistance, continuous monitoring of chronic conditions and generally preventing delays in diagnosis and thus lowering healthcare costs.

While available point-of-care tests claim to be designed with low-resource settings and users in mind, not much is known about the work it takes to arrive at a diagnosis at point of care in such settings. Using focus group discussions with community health workers, tuberculosis and diabetic patients, laboratory technicians and supervisors, and medical officers in India, this paper examines the work that patients and providers do to diagnose at point of care. It aims to show that the theoretical development of the mostly Euro-American focused sociology of diagnostics and STS can benefit from studies engaging with a global health context. It also aims to highlight that some of the ideas attached to point-of-care tests disregard much of the work it takes to arrive at a diagnosis at point of care in the empirical realities of the Indian health system and the particular position that patients occupy in these processes.

Diagnostic technologies increasingly mediate the clinical knowledge production that originally took place during consultations between a clinician and his/her patient. In point-of-care testing, diagnostic technologies are moved out of the laboratory into consultation rooms, hospital wards, communities or patient homes and often into the hands of minimally trained users. Yet, research shows that merely having a rapid, simple or low-cost test available at clinics or in community settings does not mean the promises attached to point-of-care testing are fulfilled: HIV or malaria rapid tests, for instance, are not always used rapidly (patients are told to come back for test results), they get misused or underused (Chandler et al., 2012), they require additional infrastructural, financial, and operational support (Clouse et al., 2012) or the results are not used to impact treatment (Losina et al., 2010). Indeed, Pant Pai and colleagues have shown that how devices are applied at different points of care matters for promises of improved patient outcomes (Pant Pai et al., 2012). The technology per se does not define successful point-of-care testing, rather the aim is to complete diagnostic cycles (test and treat). Such a point-of-care continuum is ensured when a patient interacts with a healthcare provider and leaves with a decision based on a diagnostic test result that guides further care, for instance treatment initiation, referral, or follow-up testing. This can involve rapid tests or it might involve a laboratory-based test, if results can be returned within the same encounter (while the patient waits or at least the same day) (Pant Pai et al., 2012).

In order to capture the work in ensuring a point-of-care continuum, this paper discusses the challenges that the different actors involved in diagnosing at point-of-care in India identify in reaching each step of a test and treat cycle. Medical providers and test developers often envision a set of ideal steps to arrive at what in their view is a correct diagnosis, in a cyclical, albeit rather linear way: "a doctor orders a test", "correct test is ordered", "patient gets it done", "lab/health worker performs test", "results get reported quickly", "doctor acts on the results", "impact on patient outcome", and again "doctor orders a test", etc. Underlying are the questions of how technology features at each of these steps, what assumptions are embedded regarding patients

and what the implications are for ensuring a point-of-care continuum and development of new tests. Importantly, we do not focus our analysis on one specific technology but examine diagnostic processes for the variety of common diseases that actors encounter and their efforts in ensuring a point-of-care continuum. This means that we do not limit our analysis to the use of specific devices that might lend themselves to point-of-care testing in clinics, at the bedside or in communities (such as rapid tests or handheld devices). Rather, we are interested in the processes of diagnosing at various points of care with available technologies, including those that can be conducted on the spot or laboratory-based testing. Such an analysis offers an opportunity to probe what analytical value and possibilities STS can gain when engaging with such lesser-charted empirical domains of global health practice.

STS inspired work on diagnostics has pointed out that diagnostic tests do not exist independently of health systems and practitioners, but are a central part of and transformed through their application (Mueller-Rockstroh, 2007; Casper and Clarke, 1998; Graham, 2006; Angotti, 2010; Chandler et al., 2012; Mol, 2002; Engel, 2012; de Vries, 2008), while user representations are scripted into devices (Akrich, 1992). Similarly, small-scale technical devices of humanitarian design, such as the bushpump (de Laet and Mol, 2000) or the lifestraw (Redfield, 2016), embody assumptions and norms about the socio-technical landscapes in which they are made to work and which they configure. A similar point, that diagnostic tools do not exist independently of those that use them but are embodied in daily user practices, has been made by the sociology of diagnosis (Armstrong and Hilton, 2014; Schubert, 2011). Scholarly work associated with this literature examines diagnosis as categorization, as a social process and as a label with consequences (Jutel and Nettleton, 2011; Jutel, 2009). Several studies have discussed how disease classification systems interact with a changing social context, create new patient categories and impact illness experience (Salter et al., 2011; Jovanovic, 2014). Scholars have emphasized how the nature of provider – patient relations, relations between diagnosis and therapy and the wider social contexts permeate diagnostic processes (Jutel and Lupton, 2015; Cox and Webster, 2013; Bourret et al., 2011).

STS studies on diagnostics in particular provide insights about technology in use and the kind of work, including respective responsibilities and uncertainties, that are required to make a diagnostic test work in practice, such as the infrastructure that needs to be in place, the training that needs to happen beforehand, the maintenance that is needed, the regulation and monitoring involved (Mueller-Rockstroh, 2007; Pasveer, 1989; Engel, 2012; de Vries, 2008;). Diagnostics need additional work to function. What diagnostic technologies actually do remains an empirical question and thus there is not one way of using diagnostic technologies, such as ultrasound, appropriately, but different situated appropriations by different users (Mueller-Rockstroh, 2011).

Building on above literature, we draw on Mark Berg (1997) who showed that the medical work of diagnosing and making a patient's problem manageable is distributed among providers, instruments and criteria; and the work of Annemarie Mol (2002) who showed how multiple versions of a disease are enacted by different hospital departments but hang together and are being coordinated as to ensure singularity in disease and treatment decision. This smoothness and lack of uncertainty in the diagnosis seems to be presumed but is not self-evident (Street, 2011). Alice Street's (2011) work in a Papua New Guinean hospital ward highlights how uncertainty of medical facts is routinized, patient bodies and diagnostic technology often refuse to cooperate, and the doctor's aim is not diagnostic closure but improving patient outcomes with available resources - in itself an expertise.

In our case, the fragmented and disjointed nature of the Indian health system (see method section below) similarly pushes theorization of earlier STS studies on medical work and diagnosing based on European and American contexts. First, in ensuring a diagnosis at point-of-care in India, many more frictions need to be overcome and much more and different kinds of coordination work are required by providers and patients than in Mol's (2002) Dutch hospital setting or Berg's (1997) oncology ward. Different

steps of diagnostic processes and the elements that constitute diagnostic ensembles (bodies, devices, tools, knowledge, infrastructure, social relations) need to be continuously coordinated and aligned. Second, this coordination is not necessarily seamless and often disrupted and at each step there is the risk of patients opting out. Contrary to Mol (2002) and Berg's (1997) work, the coordination work does not always streamline or make manageable the multiplicity. At times, diagnosis is not achieved and the point-of-care continuum breaks down. And third, most of this work needs to be done by patients who need to be much more active participants in these dynamics. The paper reveals how patients are both rendered vulnerable and emerge as powerful actors. This also means that without investment in health systems, the coordination work becomes unbearable and the promise of overcoming absent infrastructure with point-of-care tests is flawed.

In the following, we outline the concepts used to analyze the work done by patients and providers to diagnose at point of care. After describing the applied methodology, we discuss the diagnostic work involved in seeking care, ordering tests, conducting tests and handling results. In the conclusion, we reflect on the coordination work necessary to make diagnostics work and ensure a point-of-care continuum in India and the particular position of patients therein. We discuss the theoretical contribution and the implications of the findings for global health innovation practices.

Coordination work and diagnostic ensembles

We take an approach that conceptualizes the work involved in making diagnostics work and arriving at a diagnosis at point-of-care. Marc Berg (1997) suggested that managing a patient's trajectory is a distributed task. Medical work transforms a patient's problem into a manageable problem that matches existing work routines at the hospital, the clinic or by providers and can thus involve diagnosis, adjusting a course of treatment or organizing care. This work is shaped by diverse, heterogeneous, interlocking elements, such as available data, organizational considerations and routines, medical criteria, patients' needs and financial matters and is distributed across doctors, nurses, laboratories, dispensaries, forms, medical instruments, records and criteria. The manageable problems that are being constructed are always provisional and the fit between the above mentioned elements is fragile and can easily be disrupted. Medical personnel are thus engaged in never-ending ad-hoc re-articulations, trying to perform their tasks, finding out what to do next, keeping patients on track with the data they have and making do with what they encounter. In this process they constantly reconstruct the course of the patient's track, which, understood this way, is not a step-wise sequence of conscious decisions that follow a particular plan, but a path that can be redirected at any point (Berg, 1997).

In this medical work, tools, such as diagnostic tests, need to be made to work. This involves tinkering work to manage constraints and to continuously negotiate among actors of different social worlds the rightness of the tool to answer to a particular problem (Casper and Clarke, 1998) and make practices and tools mutually fit each other (Berg, 1997). Since this work is distributed across different actors it requires coordination. Lucy Suchman has emphasized the importance of working relations, socio-material connections, that sustain the work required to design technologies and put them to use (Suchman, 2002).

To further conceptualize this distributed medical work involved in arriving at a diagnosis at point-of-care, we draw on Annemarie Mol (2002) to examine the different ways in which diagnosis is enacted and to demonstrate the coordination work necessary to arrive at a diagnosis. By studying the diagnosis and treatment practices of atherosclerosis in a Dutch hospital, Mol (2002) shows that different versions of the disease are being discussed, measured, observed and dealt with in different departments, moments and places. Diagnosis multiplies what atherosclerosis is, because practices are many and manifold. This multitude of knowledge, practices and diseases related to atherosclerosis does not mean fragmentation, because in this context the different elements are being coordinated. This coordination involves, for instance, adding up complaints, measurements, social needs of patients and

patient motivation to decide when to initiate treatment. To establish a hierarchy between potentially discordant laboratory results, patients complaints and doctors intuition/experience, doctors search for explanations (e.g. the patient's ability to experience symptoms, the doctor's way of conducting the patient interview or the forms of atherosclerosis the diagnostic instrument is able to detect). If there are different test outcomes, they are added up, put in a hierarchy, or translated with the help of correlation studies. These modes of coordination ensure that the patient ends up with one disease and a single treatment decision and ensure the singularity of the object atherosclerosis (Mol, 2002).

With a focus on diagnostic practices as coordination work we bring STS literature into conversation with an emerging literature on the sociology of diagnosis (Brown et al., 2011; Jutel and Nettleton, 2011) which suggests that diagnosis is a major classification tool of Western biomedicine that forms the basis of medical authority. Diagnosis validates disease, offers explanations, legitimization and coherence of symptoms. It enables accessing the sick role and related resources as well as facilitating resource allocation (Jutel, 2009). As such, this socio-political process of diagnosis can be contested, framed and enacted differently. Cornelius Schubert's (2011) study on the micro-level activities of diagnostic processes related to the stethoscope, for instance, highlights the formation of diagnostic ensembles around new diagnostic devices, in which bodies, tools and knowledge mutually configure each other. In these ensembles, diagnostic knowledge becomes embodied in doctors and patients and is built into instruments. The idea underlying diagnostic ensembles has been highlighted earlier by Abram de Swaan (1977) who described symbolic interaction and arrangements as necessary enablers of correct outcomes of a test. In a study on the use of X-rays and other medical scanning technologies by non-biomedical practitioners in India, Guy Attewell (2016) offers a similar concept of technology-practice assemblage. The X-ray machines are bounded with other, material, sensory and organization skills and technologies, and interact with social relations and financial considerations (Attewell, 2016). The focus was largely on credibility practices, and thus less on how these elements are being coordinated. The concept of diagnostic ensembles is helpful to show the different elements that need to be coordinated in reaching a diagnosis at point-of-care in India. But rather than conceptualizing diagnosis as an ongoing practical judgement (Schubert, 2011), we focus on the work involved in arriving at a diagnosis with an emphasis on ensuring a point-of-care continuum, including decisions to conduct tests and handle results. This involves reflecting on the coordination work that healthcare providers and patients do and examining the diagnostic ensembles involved.

Methods

India's health system is characterized by high medical pluralism, low government spending, high out of pocket spending (among rich and poor patients alike) and a large, unregulated private sector (Sengupta and Nundy, 2005; Balarajan et al., 2011; Das et al., 2012). Public primary health centres provide basic preventative and curative treatment and implement national disease control programs. They are staffed with one qualified physician and/or Ayush (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) medical officer, one to three staff nurses, two laboratory technicians, four community health workers and one pharmacist and usually have small, one-room laboratories attached for conducting basic tests. In reality, these clinics are often understaffed with insufficient laboratory facilities and funds for testing kits and laboratory consumables. This means that patients are frequently sent to the next level of care ((sub-)district hospital) (Engel et al., 2015). Private providers range from highly qualified specialists to unqualified practitioners and local healers (De Costa et al., 2008), and associated laboratory services are offered by large state of the art laboratory chains, medium sized facilities, and small neighborhood labs. They are largely profit-driven, diverse and lacking formal/official quality assurance or accreditation. The quality of care in both private and public settings is often low, and patients usually seek care with private providers first. Among private and public primary healthcare providers low levels of medi-

cal training, low adherence to clinical checklists, and frequent incorrect diagnoses and treatment prescriptions are common (Das et al., 2012). Interactions between private and public providers are structured by the pluralistic context, strong social and professional hierarchies and widespread paternalism of health care (Kielmann et al., 2014; George and Iyer, 2013). This complicates partnerships or referral systems between the providers (Yellappa et al., 2016; Engel and van Lente, 2014) and contributes to a fragmented system. As we will see, this fragmentation poses different conditions for enacting diagnoses and diseases than a Dutch hospital.

This paper is based on a set of 13 focus group discussions that were conducted between January and June 2013 with community health workers, tuberculosis and diabetic patients, laboratory technicians, tuberculosis programme staff and medical officers at primary care clinics in Kadugondanahalli, one of Bangalore's 198 administrative units, and Tumkur, a rural district in Karnataka (India). The urban site is a predominantly poor neighborhood in Bangalore, including one area that is considered a slum; with a population of more than 44,500 people spread over 0.7 square kilometers consisting of migrants from other Indian states as well as those that are more permanently settled. Available healthcare services in the area include two government health centres that provide outpatient care and outreach services, and 32 private providers from various systems of medicine including allopathy, Ayurveda, yoga, Unani, Siddha and homeopathy. The rural setting is located 70 km outside Bangalore with an estimated population of 2.7 million spread over 10'597 square kilometers. The area includes a dominant private sector with providers ranging from informal to highly specialized ones, as well as a public district hospital, nine sub-district hospitals and 140 primary health centres.

The data was collected as part of a larger project into diagnostic practices of different actors in hospitals, peripheral laboratories, clinics, communities and homes, consisting of 78 semi-structured interviews and visits to various sites in both urban and rural settings in addition to the group discussions. The interviews specifically examined diagnostic processes for each major disease (mainly HIV, TB, malaria, hepatitis, syphilis, diabetes, typhoid and dengue) occurring in the setting in great detail, including available material and capacities, time to result, and referral processes. The aim of the focus group discussions was to establish what particular problems participants experience or define with regard to diagnosing major diseases at their point of care, to understand potential needs or concerns of the different groups for point-of-care testing, to understand why the needs exist and to collect ideas about possible solutions for point-of-care testing in different settings. The material of the broader research project is used to complement, triangulate or explain some of the findings and observations where necessary.

The focus group discussions were held at specific points of care (community, home, primary care clinic and hospital, laboratory) and participants were selected into homogenous groups of community health workers (ASHA, ANMs, CHA, LINK are abbreviations for different cadres of community health workers in urban and rural areas), patients (one group of urban diabetic and one group of rural tuberculosis patients), hospital nurses, medical officers, laboratory technicians and supervisors who are located at rural public primary health clinics. Diabetes and tuberculosis patients were chosen because these diseases are highly prevalent in the study setting, yet with different dynamics (chronic vs infectious and non-stigmatized vs stigmatized). The focus group discussions with providers and the overall project were not disease-specific and focused on the major diseases found in the study settings, and discussion results refer to other diseases (HIV or malaria for instance) too.

Focus group discussion participants were given information sheets and consent forms[1] which were explained and discussed in the group. Those choosing to participate were asked to sign consent forms prior to the start of the focus group discussion. The discussions were facilitated by two members of the study team, a moderator accompanied by a note taker. The moderator introduced the topic, explained the procedures and rules of the discussion and facilitated the conversations. The moderator ensured that explanations and reasons for the challenges that participants

mentioned were explored as well as possible solutions.

Discussions were held in either English or Kannada, depending on the preference of the participants. The discussions were digitally recorded, the note taker noted down main points raised, non-verbal communication and general atmosphere. Audiofiles and notes were transcribed and if applicable translated into English. Data analysis was done using Nvivo 9 (QSR International). A coding scheme for the larger project was devised, based on overarching research questions and aims, the specific understanding of point-of-care testing and labels and concepts that emerged upon reading the material. The coding scheme was tested on a handful of varied interviews and focus group discussions and further refined. The first author coded the focus group discussion material in close communication with the study team and analyzed the data further grouping material into emerging themes. In a first round of analysis of the challenges of diagnosing, we identified the following subthemes: seeking care; ordering tests; human resources, money and material in conducting tests; interactions between providers; giving and taking: testing, treating and attending; being sent to and fro: referral processes. In a second round of analysis we foregrounded the interactions and frictions between the different steps, elements of diagnosing and providers and patients, which allowed refining the initial themes and identifying additional ones (coordination work).

Results

We have structured the results along a patient's imaginary pathway toward a diagnosis. They show that the presumed test and treat cycle is not straightforward, but that the pathway has frequent overlaps, detours and loops in-between the different steps. Making point-of-care testing work is also characterized by frictions in diagnostic encounters with different actors that challenge the point-of-care continuum, sometimes to the extent that diagnosis cannot be achieved. This requires much more and diverse coordination work than in earlier STS studies on medical work and diagnosing.

Seeking care and accessing diagnostic services

Seeking care and accessing diagnostic services were mentioned in all focus group discussions as challenges for diagnosing and often result in delays. The difficulties with these first steps of acting on symptoms, seeking care at a facility and being able to access diagnostic services are missing in the diagnostic process commonly envisioned by test developers that assumes patients have sought care and accessed diagnostic services when the diagnostic process starts. Providers and patients identify different reasons for delays in healthcare seeking and the ability to access diagnostic services. Providers locate reasons within communities and patients, such as stigma, gender relations, lack of education, superstitious beliefs, habits and lifestyle (such as alcohol, smoking or laziness), that prevent patients from seeking care. They argue that patients downplay symptoms because they are embarrassed to reveal symptoms or pregnancies. Community health workers emphasize that these factors make it difficult for them to convince patients accessing the primary health centre or having a sample taken in the field. Community health workers are often members from the community who work voluntarily and are being paid a small stipend. They regularly visit communities, inquire about symptoms and accompany patients to public clinics and thus function as links between the patients and the healthcare providers. They argue that they require repeated visits to patients' homes to build up trust and overcome these hesitations, at times pay for patients' transport charges to allow visiting the nearby clinic, demonstrate taking a malaria blood sample on themselves or use the help of other villagers or a laboratory technician that they brought along from the clinic to convince patients to provide a sample for malaria testing. They coordinate divergent knowledges, social relations and practices of health seeking. They at times doubt about their role in this process.

> …no matter how much we tell them [the patients], they will not come. Are they kids, for us to carry them and bring them here? (R2, FGD7 LINK workers)

Patients would emphasize the distance to the health centre and lack of money and transport facilities that they had to overcome in order to seek care and access diagnostic services when a test was required. Community health workers confirm that cost, permission to spend money on care and the loss of daily wages when visiting the clinic are major hurdles for patients (FGD13 CHA, FGD 6 MOs, FGD 7 LINK). This applies not only to remote rural areas but also to densely populated urban areas. Diabetes patients in urban areas in India are constrained in accessing the facilities in their vicinity, because of financial hardship, healthcare providers' negative attitudes, inadequate communication and inadequate care offered by a fragmented healthcare system (Bhojani et al., 2013). Our discussion with diabetic patients in the urban setting revealed that these diabetic patients are not able to access continuous diagnostic and monitoring services, because owning a portable glucometer is not affordable and government facilities that provide those services are too far away and often charge informally for glucose testing. The patients are forced to go to private laboratories nearby, yet cannot afford their fees and thus do not go (FGD 4 diabetic patients). The test and treat cycle breaks down.

Patients who cannot afford these efforts tend to access care very late, when symptoms are severe and conditions have worsened. Yet, at this stage they can often not be helped at primary healthcare levels anymore. They might have developed complications due to diabetes or during pregnancy, acquired resistance to antituberculosis drugs, or are that ill that they require hospital admission. The diagnostic devices, drugs and staff available at primary care centres are not geared towards these advanced stages of disease. The diagnostic ensemble at the primary healthcare centre, consisting of bodies with advanced stages of disease, tools and knowledge geared at early stages and initial symptoms, is misaligned. Instead, referrals to tertiary centres for further investigations or admissions are required. In the public system, these referrals often do not work (and higher facilities still cost money) as for instance some hospitals do not accept patients that have been referred from primary care clinics, for instance with complications during labour. Patients then roam around in search for another hospital, some end up in private hospitals to which they turn in their despair, amassing huge costs and having to take out loans (FGD 7 LINK). Patients consequently blame the primary healthcare centre for not being able to cure them and the community health workers for sending them there. They are likely not to come back the next time they need help. This can either reinforce what community health workers call superstitious beliefs, such as belief in evil spirits or going to the temple in seek of help (FGD 2 ANM), or create distress. It seems thus, that patients resort to traditional healers or spiritual help (as blamed by healthcare workers) only after or because the system frequently fails them. The diabetic patients we spoke to, who know that they should be monitoring their illness but cannot afford the efforts necessary to access diagnostic services, experience a lot of distress while their health deteriorates. Instead, they try to self-medicate based on a diagnosis done several years ago and a vague prediction about its future development by the doctor at that time (FGD 4 diabetic patients).

To sum up, seeking care and accessing diagnostic services are important first steps in making point-of-care tests work and ensuring a point-of-care continuum. Seeking care is not only the first step but it reemerges at other instances. Patients need to continue seeking further care, according to availability and nature of diagnostic services and follow-up testing, referral instructions by providers, treatment guidelines and reappearing symptoms. Seeking care and accessing diagnostic services also involve a considerable amount of coordination work by community health workers who need to mediate across different knowledges, healthcare seeking practices and social relations and by patients who need to coordinate perceived symptoms with ability to pay, available transportation and healthcare infrastructure and eligibility for accessing care. Accessing care late due to cost and distance, beliefs and social relations can render diagnostic tests available at primary health centres useless with implications for future acts of seeking care. In other words, misalignments in diagnostic ensembles between perceived symptoms, bodies with advanced stages of disease, diagnostic tools, infrastructure

and knowledge can disrupt the point-of-care continuum and diagnosis is not achieved. The way patients seek these services also requires coordination with how the other steps need to function. Trust in healthcare services can function as a coordination mechanism. If patients had only little trust when accessing diagnostic services, this trust will break down if the following steps (conduct of test including referral, handling results) get delayed or disrupted. The different steps towards a diagnosis ((re)-appearing symptoms, seeking care, accessing diagnostic services, conducting tests) overlap, interrelate and hang together and thus need to be coordinated.

Ordering a test

The first step in the assumed diagnostic process outlined above is "doctor orders a test" and then "correct test is ordered". Even if tests can be done at the bedside and 'ordering' a test does not involve filling out a laboratory form, a healthcare provider still needs to make the decision to use a particular diagnostic technology, ideally in consultation with the patient. Our material reveals that the way tests are ordered matters for the point-of-care continuum and how social relations at point of care interact with testing technologies.

The Indian health system requires patients to embark on potentially costly, lengthy and tiring diagnostic journeys and coordination work between laboratories and providers. In India tests often need to be conducted at a different site than where the test is ordered, risking disruption of point-of-care continuums. This also counts for rapid tests which we found are rarely conducted at the bedside, in a doctor's consultation room or in community settings, but mostly in laboratories where either the single patient encounter advantage is not realized or the rapidity is compromised, because human resources and equipment shortages lead to delays (Engel et al., 2015). When patients are asked to obtain a diagnostic test they need to go to the laboratory themselves, provide a sample there, pick up results once available and return them to the doctor. This is true for all settings, small private clinics as well as large public hospitals. We found that these journeys are complicated by the highly fragmented and largely unregulated Indian diagnostic landscape. Laboratory-based testing takes place across a multitude of providers ranging from small, ill-equipped one room labs in public clinics to large hospital labs, from small private neighborhood labs with limited testing equipment, to medium sized facilities and state of the art laboratory chains. Patients need to travel in-between those sites as carrier of the sample, of order forms, reports and communication between laboratories and different providers. They need to navigate and coordinate amidst a multitude of providers and often iterate between public and private providers and different levels of care. They are being sent from here to there and can lose time and money in doing so.

The tuberculosis patients who were following the public TB treatment programme when we convened the focus group discussion, all had long journeys behind them towards their diagnosis and treatment initiation. Most of them had visited around 4-5 (mainly private) doctors who were ordering malaria, blood and urine tests (but not sputum microscopy for tuberculosis, later some ordered X-rays) and prescribed tablets for cough, fever and malaria without success. This made the patients keep on changing doctors and losing money on unnecessary drugs and diagnoses (FGD 5 TB patients). Tuberculosis patients in India are on average diagnosed with two months delay due to these practices (Sreeramareddy et al., 2014). To justify this work by patients, it is crucial how and what tests are ordered.

Doctors have multiple incentives for ordering tests. Private doctors often prefer not ordering a diagnostic test initially, but rather treating empirically to save their patients cost and time and avoid losing them to another provider. In the case of tuberculosis, private providers prefer X-ray, a test that is not very sensitive and can miss a lot of tuberculosis, yet its cost to the patient is attractive to the doctors' profit. Sputum microscopy is generally avoided because of its stigmatized sample nature. This practice often leads to unsuccessful treatment; patients go from provider to provider and struggle with the consequences of late diagnosis and treatment initiation. In public clinics, the laboratory technicians complain that medical officers are not ordering enough tuberculosis tests because they are too focused on reaching targets for other global disease control

programs, such as malaria (in Karnataka primary care clinics conduct up to 900 malaria slides per month, irrespective of whether malaria is endemic in an area or not). Unnecessary malaria tests then overburden the laboratory technician and delay other testing in the clinic. As a consequence, patients need to be told to come back the following day for their results, completing the test and treat cycle in one encounter cannot be ensured, with increased risks that those patients will not return (FGD 12 STLS).

In the rural public hospital, doctors order the majority of the tests by specifying investigations for the laboratory on the admission sheet. However, in emergency situations in the labor ward nurses would conduct a rapid HIV test by themselves without the agreement of the doctor and the patient, largely to clear their own doubts about a patient hiding his/her status:

> We do the HIV test in the labor ward on our own. Some patient's will come without any investigations having been done. (…) Some would have come without the report. Some people will not tell us about it even if they know.(…) Some patients come after they start bleeding. We are at a high risk. Sometimes we do not have time to wear the dress and so we just wear gloves and go and catch the babies. Some people lie to us and just say that they have left all the reports at home just to hide the fact from us. We then get a doubt and do the test later. (FGD 1 nurses)

The specific characteristic of the diagnostic device, its ease of use (finger prick) and rapid availability of results (10-15min), its 'point-of-care character', enables the nurses to circumvent patients' agreement for a stigmatized disease, in order to, as they claim, protect their own safety at the workplace. Medical encounters in India are often characterized by strong social hierarchies and medical paternalism, wherein patients' involvement is limited and dependent on the provider's expertise (Fochsen et al., 2009; Datye et al., 2006), and counseling largely absent (Engel et al., 2015). Nurses claim that the test protects them from potentially dangerous transmission of the bleeding patient body. While nurses might operate in an environment of material scarcity and absent protective measures, given the widespread medical paternalism, it is also possible that the test becomes a tool for confirming suspicion of hiding a disease and reinforcing existing stigma of providers against patients. Here the specific diagnostic tool, the bleeding bodies and particular social relationships between nurses and patients in a context of social stigma align in a way that compromises patient agreement to test. It reveals the importance of social relations between patients and providers, how they interact with testing technologies, and how this step overlaps with conducting a test.

How and what tests are ordered is crucial for a successful diagnosis. The risk involved with the simplicity of rapid tests is that consent and rationale for "ordering" can be compromised. The diagnostic device shapes the diagnostic ensemble; knowledge of testing and consent of the patient is not always deemed necessary. This disempowers patients and makes them vulnerable to malpractices. When ordering tests, counseling and explanations for the importance of these tests is essential to justify the potentially costly, lengthy and tiring journeys and coordination work between labs and providers that patients in the Indian health system need to embark on. Next to the social relationship between providers and patients in diagnostic encounters, it matters what other testing technologies and devices are available for how tests are ordered and what the incentives are for using them, including the associated economic considerations and practices of global, vertically organized, disease control programs. Different diagnostic processes and different diseases are competing and interfering with each other.

Conducting a test

After tests are ordered "patients need to get it done". Infrastructure, human resources, money, and material need to be aligned when conducting a test. Laboratory technicians and medical officers highlight how conducting tests at public clinics is often challenged by non-existent or poor laboratory infrastructure including irregular supply, faulty kits and equipment, a lack of power, space, gloves, and tests, and wrong or low quality materials, and limited funding for rapid tests (FGD 9 labtechs; FGD 6 MO). This means patients need to get tests done elsewhere and come back, risk-

ing all the challenges of seeking care and ordering a test discussed above. Medical officers who run public clinics can coordinate these aspects only to a certain extent as they have limited power over allocation of their limited funds and some run out of budget for reagents and materials early on in the year.

Depending on the location of the clinic, a medical officer sees 90-120 patients per day. These patients wait in the general queue to see the medical officer who prescribes treatment, refers them to another level of care or advices them to get a laboratory test done either at the clinic laboratory or outside if tests are not available (at a private laboratory or higher level of care). The high patient load means medical officers often have no time to order investigations, take a patient's history and no physical space and privacy to concentrate and discuss symptoms comprehensively (FGD 6 MO). The small laboratories housed in public clinics are equipped with a technician and perform a range of basic tests for malaria, HIV, hepatitis, dengue, syphilis, urine tests, blood counts and some of them tuberculosis microscopy. If patients consult the medical officer and provide a sample to the laboratory in the morning, they might be able to pick up results in the afternoon, yet still need to be able to see the medical officer again. Public clinics close in the afternoon and some medical officers switch to private practice. Delays are also caused by a lack of trained human resources to match the workload; available laboratory technicians, for instance, are overburdened. If laboratory technicians are on leave, they are rarely replaced, meaning all laboratory work comes to a halt. The separate forms and registers for the different national disease control programs that have to be drawn and maintained add to the laboratory workload and to further diagnostic delays. A lab technician illustrates this:

> For ICTC [Integrated Counseling and Testing Centre for HIV] we have 5 registers, 4 registers for [tuberculosis] sputum, and 10 registers for Malaria. (Laughing). (FGD 9 labtechs)

Because of delays, more often patients are asked to return the next day, with the risk that they might not return. Conducting tests that cannot be done in the clinic or on the spot, requires overcoming a lack of transportation facilities for diagnostic samples and for patients to access referral centres. Without transportation facilities, samples dry up and become unusable and doctors stop ordering investigations (FGD 6 MO). Making point-of-care tests work thus requires coordinating infrastructure, human resources, money, testing kits and material with the particular testing site and the patient body. At present, the medical officers charged with this coordination work do not have the necessary means to realign these elements while some aspects, such as available transportation facilities and demands of global disease control programs, are clearly beyond their control. In finding out what to do next, medical officers need to make do with what they encounter and be able to coordinate.

Furthermore, conducting tests involves work by patients and providers in producing a sample. The diagnostic devices require very specific samples and materials to be conducted. At times there are difficulties in the way these samples need to be collected. According to the community health workers some patients do not want to have their finger pricked for malaria testing, but rather be given drugs (FGD 3 ASHA). Laboratory technicians also struggle with ensuring good quality and quantity of sputum samples. Producing a sample for a tuberculosis sputum microscopy test involves a violent coughing process, indicating for some patients a big (and stigmatized) disease (FGD 9 labtech). Providing a sputum sample also requires experience by the patient and the provider instructing the patient with implications for the accuracy of test results (FGD 12 STS).

For an accurate result, patients' ability to produce the required sample, knowledge of diseases and social stigma, social relations within communities and the specific requirements of diagnostic tools to function need to be aligned.

If efforts to align these aspects to conduct tests are unsuccessful, turnaround times are prolonged, tests cannot be made to work and point-of-care continuums are disrupted. Patients who are asked to visit the public health centre several times, often lose trust and instead access private providers or drop out and self-medicate.

In the private sector, coordination between providers prevents some of these disruptions and

misalignments. Investigation and treatment initiation are often done within one visit or same day, laboratories are next door and opening hours are aligned with patients' needs, such as bus and market schedules (FGD 12 STLS). A patient who is asked to get a test conducted, can go to the laboratory next door and return results to the provider who re-opens the practice in the evening to discuss results. In this way, the point-of-care continuum is ensured. Yet, trust in the provider can be spoiled here as well. Patients are told to get tests done and buy medication at specific labs and medical stores to which the provider refers them. Private providers rarely refer patients to public sector facilities. Many private providers have established kick-backs with other private providers for sending patients to and fro (for instance the laboratories pay 40% of the test fee earned to the private provider for referring the patient). Often patients are aware of the tie-ups between providers and it makes them mistrust these providers for doing unnecessary testing and thus they rather not follow advise to get tested or seek care at all (FGD 13 CHA).

To sum up, in conducting tests efforts have to be made to overcome non-availability of staff, funds, test kits, material or infrastructure. Human resources, money and material (the samples, reagents, registers and forms) as well as the transport, urban/rural and healthcare infrastructure are intimately related and influence whether and how tests are conducted. If misaligned, point-of-care tests cannot be made to work and test and treat cycles break down, with implications for future care seeking and trust into the providers. The site where the testing takes place, often an important consideration for test developers aiming at point of care, including the remoteness of its geography and the size of the population accessing it, determines whether those aspects match and how much time doctors have with patients to do diagnosis and investigations. Not always are these aspects under control of providers and patients. Coordinating these elements is often hampered by limited control over limited resources.

Handling results

The next steps in the diagnostic process outlined in the introduction are "results get reported quickly" and "doctor acts on the results". Our results show that counseling patients when conveying results is part and parcel of the diagnostic test. Absent coordination work in aligning bodily symptoms, test results and providers' opinions/knowledge leaves patients vulnerable to misunderstandings, mistrust and malpractices disrupting the point-of-care continuum.

Community health workers and laboratory technicians emphasize that the process of conveying results is of great importance to patient outcomes and whether and how patients follow-through on the diagnostic process, opt out, adhere to treatment and how they seek diagnostic care the next time they are not well. It matters whether results are given at all, whether given with/without counseling, when they are given, and whether results are given with strings attached (drugs can only be purchased in one medical store, see above). Counseling includes delivering results with care, but also explaining reasons for testing, symptoms and causes of disease (FGDs 13 CHA and 12 STLS).

Counseling is not only relevant for positive diagnostic results (e.g. presence of disease) but also for negative results (e.g. absence of disease). The latter is usually handled without much care and attention: in the public sector negative diagnostic results are often not conveyed at all or without explanation that a negative test result does not always mean absence of disease or cure. Instead patients are told to be 'normal' and the meaning of a follow up test is not clarified. This can have dramatic consequences. The community health workers reiterate one case where the patient died because he stopped taking treatment too early. The positive follow-up test result had been revealed by a laboratory technician without counseling (FGD 13 CHA). A community health worker narrates how some patients switch providers when negative test results are not communicated or explained:

> They would have gone there out of fear, and if they are not told the result, that will create even more panic. (…) If they are just left without any answer…

> "if we go to the government hospital, this is the problem, they will not tell any result, that is why we do not like to go there"…..they will then go and try elsewhere. (P0, FGD 13 CHA)

This lack of trust and counseling in the way results are handled comes particularly to the fore when diagnostic devices create divergent results. For instance, when different doctors interpret the same X-ray differently or when patients with positive results from a private provider need to retest in the public sector in order to access free drugs, yet results turn out negative (FGD 9 labtechs). These instances create confusion, tensions and quarrels between patients and providers. Yet, contrary to Berg (1997) and Mol's (2002) Dutch hospital setting, these different diagnoses across different points of care are not further coordinated. It is up to the patient to decide which one to follow.

Apart from creating tensions due to divergence, test results can be of help with other steps of the diagnostic process, namely convincing a person to seek care in the first place. Some of the community health workers argue that it would help them to test at the doorstep to instill trust in the public healthcare system (FGD 2 ANM). As became clear above, community health workers in India are institutionally limited in their ability to instill trust by limited infrastructure and hierarchical social relationships (Scott and Shanker, 2010). Yet they also expect that strong requests will be made to follow up with treatment at the doorstep (FGD 2 ANM). This highlights the importance of a diagnostic test result as a convincing device to facilitate the process of seeking care.

Handling a result means to be told what to do next, and the way this is done has important consequences for making point-of-care tests work, as well as for patient outcomes, treatment and relationships between patients and providers. The diagnostic devices can challenge these relationships when results are divergent or aide them as a tool to establish trust and a convincing device. It shows that social relations at point of care particularly matter when elements of the diagnostic ensemble are misaligned; when bodily symptoms, test devices and doctors opinions/ knowledge are at odds.

Discussion

The results reveal that making diagnostic tests work at point of care in India and ensuring a point-of-care continuum requires overcoming many frictions through considerable coordination work by providers and patients, as well as alignment of different elements in diagnostic ensembles. These results push STS theory. The fragmented and disjointed nature of the Indian health system requires much more and diverse coordination than in Mol's (2002) Dutch hospital setting or Berg's (1997) oncology ward. At the point of care in India, the coordination across divergent test results, described by Mol (2002), is fragmented and often disrupted, the misalignment and frictions at the point of care encompass more actors and sites (including bodies, diagnostic tools, knowledge, social relations, money, human resources and material) and much more coordination is required than across divergent test results. What is more, the coordination work is not always successful in making multiplicity manageable and ensuring patients end up with one disease and one treatment decision. And lastly, much of this work needs to be done by patients themselves. The fragmented and pluralistic nature of the Indian health system and the particular diagnostic technologies at point of care require patients to embark on potentially costly, lengthy and tiring diagnostic journeys. This also means that the global health promise of circumventing absent infrastructure, poorly coordinated and disjointed health systems with point-of-care diagnostics is flawed. The hope to circumvent national infrastructure through humanitarian design of micro devices ignores considerations of the middle level "between situated actors and far-flung networks (p. 174, Redfield, 2016)". To successfully diagnose at point of care, more investment in health systems is required, otherwise the coordination work becomes unbearable and unsustainable. In what follows, we discuss the alignments that are to be realized through the coordination work that providers and patients have to engage in.

Coordination work

Annemarie Mol (2002) showed that as diseases are multiplied by the enactment of different actors,

coordination ensures that patients end up with one disease and one diagnosis. If test outcomes are divergent, doctors add them up, put them in a hierarchy, or translate them with the help of correlation studies (Mol, 2002). Gardner and colleagues highlight how a clinician patches together two conflicting diagnoses to produce coherence and allow self-governance by the patient (Gardner et al., 2011). At the point-of-care in India *this coordination across divergent test results is fragmented and often disrupted*. Patients do not always leave the point-of-care with one treatment decision and a single disease; with implications for future care seeking and trust into the providers. Providers might order tests that are not able to diagnose a disease (private providers for profit maximization and public doctors due to target orientation). These test results lead to unsuccessful treatment in the private sector and delayed laboratory work in the public sector, both risking that patients opt out and change providers (and tests). Furthermore, divergent test results are not sufficiently explained and coordinated between providers. Public laboratory technicians, for instance, blame private ones for misconducting tests. If the patient wants to access free drugs from the public sector, he/she has to trust the result of the public provider.

Besides coordinating divergent test results, ensuring that patients end up with one disease and a single treatment decision when seeking care in India requires *much more coordination across more actors and sites*. In these diagnostic ensembles (Schubert, 2011), bodies, diagnostic tools, knowledge, social relations, money, human resources and material need to be aligned and mutually configure each other. We showed, for instance, that money, human resources and material necessary to order and conduct tests are intimately related and need to be aligned. Yet, this coordination is dependent on the site the testing takes place (including the remoteness of its geography and the size of the patient population accessing it). In order to make point-of-care tests work and avoid disruption, coordination needs to happen across different steps in the diagnostic process: health-seeking behavior needs to be coordinated with how tests are conducted and results are handled (availability of staff, trust and counseling). Practices need to be coordinated across different sites that are geographically far away or are difficult to reach due to absent referral and transportation infrastructure or cost involved in making those links. Coordination needs to happen between different providers (public-private, community-primary-secondary care level) and between providers and communities, who all have divergent practices of care or healthcare seeking, interests and expectations that shape their relationships in these diagnostic encounters. Community health workers for instance need to mediate across different knowledges, healthcare seeking practices and social relations, while patients need to coordinate perceived symptoms with ability to pay, available tests, transportation and healthcare infrastructure and eligibility for accessing care. This also means that the presumed test and treat cycle is often not circular and linear, but messy, intricate, with overlaps, detours, bypasses, frictions, frustrations and competitions in-between the different steps. Our focus on multiple diseases showed how point-of-care tests for different diseases compete and interfere with each other, on the level of the workload in laboratories (unnecessary malaria testing), incentives for doctors to order tests for one disease over another (low incentives for ordering sputum microscopy for tuberculosis), the sample characteristics required to conduct tests (blood vs sputum samples that need to be coughed up), and the dynamics of seeking care and diagnostic services for stigmatized vs non-stigmatized diseases (delay vs affordability). Overall, the patient's trajectory is not a step-wise sequence of conscious decisions, but involves distributed work entailing different moments, spaces, materials and actors (Berg, 1997). Conducting a test at the doorstep in communities, for instance, can help support efforts of seeking care. In a similar way, infrastructure, users, knowledge and tests all hang together and cannot be separated. While these connections and overlaps are not in itself a problem, in fact they are necessary to make point-of-care tests work, they require a lot of coordination. This coordination is particularly important since neither infrastructure, users, knowledge nor tests are stable. At the point of care in India, patients need to do a lot of the coordination work themselves.

Being sent to and fro

In the oncology wards that Berg (1997) studied, medical personnel was engaged in ad-hoc maintenance work to ensure patients stay on track. This involved continuous re-articulations of their tasks and of the patients' pathways based on the available data, material or constraints they encountered. In the case of atherosclerosis that Mol (2002) studied there is flow of an itinerary (that is held together with forms, appointments, conversations) along which the patient travels from one site and situation to another. In both of these accounts, patients are not particularly active agents in the process. The patient itinerary at the point-of-care in India is much less characterized by flow than by fragmentation, delays and disruptions and patients in India are and need to be more active participants in these dynamics. Contrary to adherence to medication or medical screening programmes (where an asymptomatic population is tested to classify people into those likely to have/have not a disease), there is not such a clear adherence discourse (even if heterogeneous or from multiple sources, (Mykhalovskiy et al., 2004)) for adhering to diagnostic journeys in India. Because of the many sites and providers involved, patients can re-enter at many different sites and steps. What holds the itinerary together is the patient's will to move on, shaped by his/her ability to pay or persistent symptoms and supported at times by community health workers repeated home visits and doctors' referral slips or directions indicating where to go next. When doctors collect specimen, these need to be transformed to become mobile objects. They then travel to distant places, turning the people, those who gave the samples, into medical objects and bodies (Anderson, 2006). In India, patients themselves, as carriers of specimen, travel to different sites and need to return results in the form of reports and communication to the original doctor.

Patients thus need to be knowledgeable actors, equipped with discipline, determination and socio-economic resources to engage in the necessary coordination work. Yet, patients are powerful actors as well, pushing back these expectations. They change providers, delay, back-off, opt out or re-enter elsewhere when there are frictions, when symptoms, expectations, healthcare seeking practices, sample requirements, test results, doctor's advice and services at the healthcare centre do not align. This is contrary to where power in diagnosing is usually located. In the sociology of diagnosis, the social power of diagnosis (Jutel and Nettleton, 2011) is often seen as the exercise of power by the clinician over the patient, the way the patient is labelled and subsequently has access to treatment options (Latimer, 1997). The dynamics of point-of-care testing in India produce and enact certain kinds of patients that are at the same time turned into bodies vulnerable to the many frictions along the way and powerful actors shaping diagnostic technologies, practices and actor dynamics.

Implications for global health innovation practices

Besides the diagnostic technology, many other aspects need to align and be coordinated in order to ensure functioning point-of-care testing. The concepts of medical work, enactment and diagnostic ensembles have been helpful to show the coordination work that is necessary to keep diagnostic ensembles aligned. In India, these diagnostic ensembles often go beyond the actual testing site. Currently, this coordination work by providers and patients is not sufficiently supported and acknowledged. The diagnostic devices also seem to assume patients that have discipline, determination and resources and functioning social relations at point-of-care. Diagnostic devices can further challenge these coordination efforts and relationships or aide them as a tool to instill trust and a convincing device.

The particular diagnostic landscape and infrastructure in India allow insights into the coordination work required in a country where patients are expected to do more to make point-of-care tests work, as carriers of their own samples, reports, results and medical history in-between providers and laboratories. In countries with more centralized testing infrastructures, such as South Africa, most testing is conducted in centralized laboratories and samples and results are transported by couriers between clinics and laboratories. The results discussed here are thus also relevant to more general debates on task-shifting of health-related work onto patients. Focusing on point-of-

care diagnostics and related practices as a method helped to draw out how diagnostic technologies interact with, are molded by and shape health system issues, often presented and researched separately in global health (policy). If we had only focused on health system issues without examining technologies we would have missed, for instance, how sample requirements of sputum microscopy interact with incentive structures for private doctors; how price of glucometer testing interacts with care-seeking, questions of access, and affordability; how ordering rapid tests or biopsy of lymph nodes interact with social hierarchies and relationships between providers and patients; and how making diagnostics work at point of care is threatened by other global efforts-vertical disease control programs that are creating competing options.

These insights also go against a prevailing belief in technological determinism. If point-of-care tests are not designed with the coordination work and elements of diagnostic ensembles in mind -be they in India or elsewhere-, they will fail to function. Furthermore, if test developers, researchers, donors and decision-makers do not pay attention to the coordination work by providers and patients in ensuring diagnosis at point-of-care, current practices of global health sciences risk replicating established power structures. Amit Prasad's work on the transnational histories of MRI shows how dualist distinctions, such as north-south, east-west, naturalize exclusions and hierarchies and reinforce the Eurocentric structure of modern science (Prasad, 2014). In the case of point-of-care testing, exclusions and hierarchies can be reinforced if, for instance, assumptions that patients can be expected to queue, wait or travel between providers are not questioned and thus built into point-of-care testing programs or if relationships between patients and providers are not addressed. Newer tests used at point-of-care, such as the HIV rapid tests, have not necessarily changed entrenched power structures or democratized relationships between providers and patients. More research into diagnostic practices and health systems is thus needed as part of research, development and evaluation processes for point-of-care diagnostics. This will require multi-disciplinary research approaches, for instance combining basic science, engineering, public health and ethnography, that can involve different forms of expertise (of providers, patients, suppliers, lab technicians, policymakers, etc.) early on and throughout these research processes to capture the coordination work and elements of diagnostic ensembles at play.

According to Suchman (2002), developers should locate themselves in the socio-material networks and forms of work that characterize technical systems, such as point-of-care testing settings, and not aim to control these networks or the design process as such. This would imply to explicitly locate design work, because everyone's perspective is bound to a certain locality (a perspective from somewhere) and designers need to take responsibility for that. Objects, then, can only be designed when everyone participates "through collective knowledge of the particular and multiple locations of their production and use." (Suchman, 2002: 96). Such considerations are especially important when designing diagnostics that need to work in very different, potentially resource-constrained settings. Such settings along with weak healthcare systems and stigmatized diseases have forced policymakers and test developers to take those uncertainties more into account. Yet, the way questions of intended use and capacities of settings are asked, and the way demonstration or evaluation studies are designed can still be ignorant about the work involved in making diagnostics work (Engel, 2012). It is thus central to make heterogeneous practices visible (Jensen, 2012). STS inspired studies such as this one, thus have an important role to play in complementing, confronting and troubling global innovation practices of diagnostic test development for the point of care.

Acknowledgements

We are grateful for the time and insights provided by all the study participants. We are particularly thankful for support in data collection and analysis by Mamata Patil. We also would like to thank Agnes Meershoek, Anja Krumeich, the editorial team and the anonymous reviewers for useful comments on earlier drafts.

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Notes

1 The study was approved by the institutional ethics committee of the Institute of Public Health (IPH), Bangalore, India and the ethics review board of the McGill University Health Centre (MUHC), Montreal, Canada.

Fabian Muniesa, Liliana Doganova, Horacio Ortiz, Álvaro Pina-Stranger, Florence Paterson, Alaric Bourgoin, Véra Ehrenstein, Pierre-André Juven, David Pontille, Başak Saraç-Lesavre and Guillaume Yon (2017) Capitalization: A Cultural Guide. Paris: Presses des Mines. 167 pages. ISBN: 9782356714220

Alexander B. Kinney
abk5074@email.arizona.edu
Nicholas J. Rowland
njr12@psu.edu

"What is capital?" and "How does something achieve such a distinction?" These are without doubt important questions. *Capitalization: A Cultural Guide* attempts to delineate under what circumstances the mundane is transmogrified into the economic. This book is a hectic, albeit guided tour through sites of ethnographic study of capitalization as a process, both historic and contemporary. As with many tours, it does as much to clarify the issues as it does confuse and challenge the reader. Still, taken as the product of brainstorming sessions in the basement of Ecoles des Mines de Paris, such intensified ambiguity is forgivable: the read is thrilling and frustrating; timely but a bit too clever for its own good. It is, as they say, a "mixed bag." However, so is capitalization, so perhaps it is fitting; form fits function in the brief tour that is this book.

At core, the reader learns that capitalization is a set of relational operations; not a thing, per se, but a particular mode for linking things together. The introduction and the concluding chapter are a proper point of departure for future studies remarking on the sites, perspectives, actors, and settings under which capitalization occurs. The preamble invites the reader into Muniesa et. al's intellectual think tank, and the book that follows is a compendium of individual answers to the "strange assignment" that elicited their composition. Initially participants were set this task: "describe an act of capitalization (one page)." Readers learn that this task at first rendered participants "disoriented and clueless" (p. 7). And in response, the "book is ... a collective attempt to reconcile these feelings" (p. 7). By the concluding chapter though, there is no reconciliation to speak of. The final chapter, much like the rest of the book, dispenses with any expectation that a scholarly demonstration of what defines capitalization can be conclusive. In part this arises in the approach the group of authors collectively adopts, committing to very little in an intellectual sense, being clear about their preference for an anthropologically-oriented, pragmatic approach to capitalization by becoming sensitized to performativity. The book effects a concluding of the project, which gave rise to it, rather than providing anything conclusive. So, it achieves the authors' aim of "formulating a problem and examining the terms in which it can be properly dealt with" (p. 8).

The seemingly authorless chapters between the preamble and conclusion are cumbersome to read, but not on account of length. Contributions range from 3 to 13 pages. At the beginning of the final chapter we finally meet the constructs that orient these chapters and make their continuity accessible to the reader. The "semiotic complex" of "[i]nvestment gaze, valuation scenario, [and]

asset condition" (p. 127) certainly has interpretive potential, although the authors did not burden themselves by specifying meanings, other than to position them as staunch alternatives to concepts assessing the substantive components of capitalization (e.g. the capitalist, capital, or capitalism) (p. 127). The authors leave readers aware that they are fully responsible for sense-making in this supposedly uncharted environment, and that maybe is the true purpose of this collection: it is an effort to guide readers into collaborating in this challenge.

From a scholarly standpoint, attention given to prior literature is underwhelming. "It is striking (not to mention frustrating) to observe, however, how the immense continent of valuation which is capitalization has been neglected in anthropological and sociological research" the authors pointedly note (p. 13). Yet even the casual reader will detect the obvious paucity of engagement with the economic sociological or anthropological service that *has* dealt with facets of capitalization establishing the economic value of non-economic goods or services (see e.g. Espelend and Stevens, 1998) or classic work from cultural studies documenting the social underpinnings of economic life (see e.g. Bourdieu, 2005). Less forgivable, general concepts such as "gaze" and "scenario" are deployed without fodder or recognition of their use anywhere else in scholarly literature.

In the end, this potpourri-style manual provides snippets of ethnographic insight that, at best, point at capitalization in ways that are based on a few stated rather than tested methodological preferences. It is difficult to see its value, economic or otherwise, as a textbook given its treatment of concepts. As a supplemental resource, it also has limitations. It remains unclear, for example, how the process of "capitalization" differs from other more well known concepts such as commensuration or even commodification. Yet it was from this annoying, uneasy haze that clarity about the significance of the book emerged. We kept going back to the book; we kept opening the book. We learned that *Capitalization* is a text that leaves the reader with unanswered questions begging for answers, and, surely, some of those readers will pursue those answers in future inquiry.

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Merete Lie and Nina Lykke (eds.) (2017) Assisted Reproduction Across Borders. Feminist Perspectives on Normalizations, Disruptions and Transmissions. London and New York: Routledge. 315 pages. ISBN: 978-1-138-67464-6

Nelly Oudshoorn
n.e.j.oudshoorn@utwente.nl

Whatever happened to New Reproductive Technologies? Whereas the birth of the first 'test-tube baby' in the UK in 1978 was the topic of heated debates it now has become part of medical history books. Once in a while we may meet friends or family who tell us about their experiences with in vitro fertilization or other technologies for the treatment of infertility, or we may undergo these procedures ourselves, which suggests that these once new technologies have been integrated into routine medical practices and are no longer considered as controversial. Interestingly, these technologies are no longer referred to as New Reproductive Technologies but as Assistive Reproductive Technologies (ARTs). What does it actually mean when technologies are no longer described as new? Does it imply that they have developed into standard medical procedures that are accessible worldwide and integrated into the general perceptions of human reproduction? Does it imply that they are no longer contested? Have ARTs reached a phase of normalization? In *Assisted Reproduction Across Borders* the authors argue against the idea that ARTs can be considered as normalized technologies.

Compared to most other edited volumes on reproductive technologies, the major strength of this edited volume is that it extends the scope of research to the Global South, most notably India, Iran, and South Africa and includes countries in the Global North that were largely invisible in previous feminist studies, including Israel and Palestine, Ukraine and Russia. The adoption of a global North-South perspective has resulted in a very important and rich book on the many faces of ARTs in different cultural contexts, revealing geopolitical inequalities in access, controversial practices of surrogacy, fierce political debates, disruptions of legal frameworks, and changing cultural norms of reproduction, gender and the family. *Assisted Reproduction Across Borders* is a must read for scholars interested in social, cultural and economic processes of the integration and normalization of reproductive technologies. But, as I will elaborate at the end of my review, some critique of the notion of normalization mobilized here is needed if analyses pointing to disruptions and transmissions are to be generative.

The book consists of 5 parts and 21 chapters. In Part I, *ARTs in a Neoliberal World of Transnational Reproflows*, the contributors describe the transnational movements of what Marcia Inhorn (2010) called 'reproductive exiles': people who cross borders to get access to assistive reproductive technologies. Indeed, ARTs have no borders. The chapters describe the transnational traffic in embryos, human gametes and related gestational labor in which India and South Africa have become global hotspots for respectively surrogacy arrangements and egg donation (chapter 1 and 5).

These transnational 'reproflows' introduce novel geopolitical inequalities and paradoxes in which people from the US and Europe benefit from ARTs at the expense of women in India and South Africa who have become providers of gametes and are doing the gestational labor.

In Part II *Perplexed State Regulations, Legal Inconsistencies and Cultural Tricksters*, the authors describe how ARTs introduce legal inconsistencies and contradictions because these technologies enable alternative family-building practices thus disrupting existing legal frameworks. I particularly liked chapter 7 by Kristin Spilker in which she theorizes the paradoxes and tensions in ART policies in Norway by using Donna Haraway's notion of the 'trickster'. Whereas Haraway introduced this concept to capture the surprises and ironies of knowledge production, Spilker demonstrates how the trickster figure is extremely useful to understand that processes of adaptation and normalization of technologies are not linear or predictable. In Part III, *Religious Fundamentalism, Humanist Values, and State Dilemmas in an Era of Technological Monsters*, the focus of the book shifts from studying ARTs in more secular states to national contexts in which state policies are shaped by fundamentalist religions, including Catholicism and the Islam, which resist 'unnatural' conception and restrict access to ARTs. Interestingly, more restrictive regulations do not necessarily imply that people will adhere to the morality imposed on them by the state. In Italy, for example, where the Catholic Church has a strong impact on the framing of ARTs regulation, many people escape the restrictive regulations by travelling to other countries to get infertility treatment (chapter 10).

In part IV, *ARTs as Entangled in Demographic Agendas and Biopolitics*, the authors address the different ways in which demographic policies are intertwined with nationalisms. The most intriguing chapter in this part of the volume is chapter 15 by Sigrid Vertommen in which she describes how ARTs have become part of political conflicts between Israel and Palestine. To promote Jewish-Israeli births, Israeli citizens receive full economic support for an unlimited number of IVF treatments. In contrast, Israel tries to prevent Palestinian births by denying political prisoners conjugal visits in Israeli prisons, although women and men resist these suppressive regulations by smuggling sperm. Finally, Part V *"New Normals" and their Discontents* discusses cultural contexts in which ARTs have become accepted as uncontroversial methods to have children. Intriguingly, the 'new normals' described in these chapters, such as lesbian families, create new troubles and discontents again.

In sum, the editors and contributors of this fascinating book have succeeded in demonstrating the wide variety in regulations, controversies and in/exclusion processes in many different cultural contexts. However, the question that remains unanswered is whether ARTs will ever cease to be controversial. At the end of the introductory chapter, the editors conclude that "normalization is not an apt term" (p.17) because there are many contexts in which ARTs are not accepted and made accessible as normal ways to have children. I expected to find a further discussion of what concepts would be better to capture the dynamics of the implementation of ARTs.

The way in which the editors frame normalization reminds me of earlier debates within STS on the concept of closure. This key notion of the SCOT approach has been criticized because it reifies a linear approach to technology thus neglecting the role of users in appropriating technologies. This criticism has resulted in a re-conceptualization of closure from a static approach in which technologies stabilize during the design process to an open, ongoing process in which users are engaged in (re)defining and (re)designing the meanings and functional purposes of a technology in all stages of technological development (Tosoni and Pinch, 2017: 91; Oudshoorn and Pinch, 2003). As the early approach to closure, the perspective on technology developed in this book considers normalization as a process that happens during a specific stage of technological development, in this case the integration into standard, routine practices in healthcare and legislation. However, the chapters of the book illustrate that normalization may better be understood as an ongoing process in which controversies that have disappeared in one specific cultural context may emerge again in other contexts. To avoid an approach to normalization as a fixed, final phase of the integration of

technologies in society, it may be useful as well to refrain from applying ARTs as an overall term because it suggests a misplaced coherence and unity to theorize infertility treatments. As many chapters illustrate, embryo transfer, egg-freezing, gamete donation, and surrogacy each have their own dynamics of reifying or disrupting regulations, values and practices at the intersection of reproduction, family and gender. So, as Kristin Spilker has argued in chapter 7, it is not necessarily the novelty of technologies that triggers controversies but new combinations of infertility treatments, regulations, value systems and people that may destabilize established alliances and introduce controversies again. The concept of trickster is a useful first step in developing an alternative approach to normalization that accounts for the unpredictable ways in which technologies become integrated in society.

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Andrew Pickering (ed.) (1992) Science as Practice and Culture. Chicago: University of Chicago Press. 474 pages. ISBN: 9780226668017

Helen Verran

Helen.Verran@cdu.edu.au

Why does *Science as Practice and Culture* warrant review twenty-five years on from its publication when most STS books published that year have already sunk, unremarked, into obscurity? I propose that in 2017 *Science as Practice and Culture* is a useful diffraction grating by which to examine contemporary STS. I re-read the book attempting to identify both the major currents, and the 'back-channels' of STS collective life twenty-five years ago with the aim of illuminating the present.

In 1993, Malcolm Ashmore, began his review of the book this way: "This volume… has a mission encapsulated in the following slogan or rallying cry: sociology of knowledge (SSK) is dead; long live sociology of scientific practice!" (Ashmore, 1993: 489). One way to understand this review then is as an answer to the question 'What have we made of sociology of scientific practice twenty-five years on?' I am doing the reflexive work urged on us back then by scholars like Ashmore. One story of what we have made of it began to emerge for me as impressions gleaned in working with groups of graduate students in Holland, Denmark and California earlier this year. The groups seemed to share a working imaginary of what STS is nowadays, including a particular story of its pasts. I later found it explicitly articulated (Puig de la Bellacasa, 2017: 31).

The story goes like this: in STS epistemics first we had the contest between objectivism and constructivism. This was an STS version of the very old, but still hot contest otherwise known as realism versus relativism, or rationalism against scepticism. STS came of age with the triumph of 'social constructivism' in the forms of SSK, ethnomethodology, EPOR and symbolic interactionism. And then along came 'ontological constitutionalism', in the form of ANT, material semiotics (which allowed among other things, feminist and postcolonialist issues to emerge as ethical concerns), and later for inquiring into modes of existence (and immodestly proposing redesign of modernity's institutions). In some versions, this latest chapter of the STS story also included non-representational theory. In this working imaginary, objectivism, social constructivism, and ontological constitutionalism all now thrive as variant STS epistemic practices in their own niches. No single methodology dominates, and each adopts a civil demeanour with respect to the others, each insisting on staying distinct, but also prepared to work with the others.

The story envisages the politico-epistemics of the modern state as a sort of cosmopolitics, where governance inevitably involves working with those who think otherwise. To some degree this reality of governance shapes and is perhaps also influenced by, STS. I find the story both useful and entertaining; I can go along with it as a working imaginary. But immediately, I wonder if there is evidence that would support such a story of multiple STS pasts working together. And, further, what might be left out of the story? What lines of STS inquiry might have been silenced in

that story of the co-constituting of the politico-epistemic landscape of the modern state and STS? These are the questions I attend to in offering a reading of *Science as Practice and Culture* a quarter of a century after its publication.

In 1992 I was co-ordinating and teaching a Master of Science in Society, the first masters coursework program established in the Arts Faculty at University of Melbourne. Its establishment had been funded in a partnership arrangement with the state government, also a first of its kind. Under this program, mature age students recently made redundant in Australia's first wave of privatisation of state enterprises were eligible for free tuition. A new global order was in the making and STS too was changing.

I had hoped to find material I could use in teaching in this volume, so it appeared on my bookshelves soon after publication. I no longer remember if I did use any of the articles, but I do remember being a bit put off by the collection as a whole. Back then the section headings used to group the articles made little sense, and when in 2017 I go back to reconsider the book, they still seem less than useful. A cursory glance at the chapters has them falling into two groups: those that provoke and are provocatively responded to, and those that more quietly argue on the basis of empirical evidence, that if you wish to understand the roles and place of science in society, science is usefully read as practice and culture instead of theory and methodology. In offering a reading of the book in 2017, I will apply this grouping. I separate off those articles which speak directly to each other, from those that in various ways, argue and evidence the claim that the concepts of practice and culture are analytically useful when it comes to understanding the sciences.

The idea of analysing science as an expression of organisational practice and culture, rather than as a means of generating epistemically valid objective facts to support the functioning of the state, was still controversial in the early 1990s. Accordingly, in Britain the book was reviewed (negatively) in *The Times Literary Supplement*, and (positively) in the *Times Higher Education Supplement*. In France the prestigious *L'Année sociologique* offered a long review from a rather puzzled sociologist. From the reviews I have found, it seems that while historians of science, and sociologists took the opportunity to catch up on what was happening in STS, the 'new kid on the block', predictably the book was ignored by philosophers of science. It seems not to have been reviewed in the STS journals, however, in meetings of science studies scholars it was a hot topic. As I remember the 1994 4S meeting in New Orleans, where I first came across Andy Pickering the editor of the collection, the provocative articles collected together in the book were still hotly debated.

Yet hot exchanges do not age well, so in 2017 these papers read as a rather bad tempered exchange amongst seven protagonists, all identifying as sociologists. To use the Australian idiom, this group of articles could be summed up as 'a verbal punch-up between seven blokes, most of them Brits, but with a couple of French guys in there, who came out swinging.' The radical consequences of the epistemic practices of social constructivism was the bone of contention. A practice-focussed variant of strong social constructivism (the empirical program of relativism) promoted by Harry Collins and Steven Yearley opposed other variants in the form of ethnomethodology (Mike Lynch) and sociology of scientific knowledge (David Bloor). Establishing dividing lines seemed to be the aim. The issue that caused most heat was what was read as two recent developments to manage the radical epistemic consequences of social constructivism. The first was the shift of some British sociologists of science towards reflexivity (Steve Woolgar is the representative included in the collection), and the second was actor-network theory as developed by 'the French school'—Michel Callon and Bruno Latour. These two groups were seen as pushing things too far, and as likely to generate counter-productive outrage amongst the likes of the readers of *The Times Literary Supplement*, and *L'Année sociologique*. These groups were accused of playing "epistemological chicken".

This set of papers was often raked over in the years that followed the publication of the collection, and I can add nothing new. Let me acknowledge the passionate arguments for what they are, and note that in the moment of the coming together of the collection, the insistence of 'the French school' that they wanted to invent a new

game in STS, to leave aside the conversation over epistemology that is an outcome of the particular ontologies embedded in the contest between social constructivism and objectivism, was largely ignored. Perhaps we should be thankful that only a few years later it would be widely accepted that in order to account for the many ways scientists bring in nonhumans, STS analysts must learn to occupy many ontological positions, and to entertain a whole range of ontological possibilities. Philosophical insights from Stengers and Whitehead began to enrich the analytic capacities of actor-network theory, to develop 'ontological constitutionalism.' As knowledge making practice this approach opens up possibilities for critical discussion of the ontological constitution of entities known in science; they parochialize or provincialize the ontological practices of both social constructivism and objectivism, having abandoned claims to be concerned with truth.

In the papers collected together in this book then, while social constructivism is much in evidence, and shows no sign of comity, we see clearly that by the early 1990s ontological constitutionalism was more than holding its own. But what about objectivism? Do we see a civil STS objectivism that might be said to have settled comfortably into a niche in a landscape accepting of differentiated (distinct and connected) STS epistemic practices, which articulate—albeit not too loudly, incommensurable metaphysical commitments? Here I turn to the group of less controversial papers. Is there evidence in the collection that by the 1990s some modest forms of objectivism had emerged? The epistemic practices of such objectivisms would be robust enough to offer possibilities for effecting objective truth mobilizing a notion of truth as corresponding, when necessary. Yet while insistently distinct, such a truth form would have a (limited) capacity to connect to other truth forms, such as the coherence truth form of social constructivism.

In their different ways the papers by Ian Hacking and Steve Fuller which more or less book-end the collection, articulate viable versions of objectivisms that could be worked in that way. Hacking is keen to engage with what he calls the motley of science, proposing what might be named as a form of objectivism subject to socio-materialist limits. He is *not* arguing that what laboratories sciences generate "are mental or social constructs, but rather for down-to-earth materialism" (Hacking, 1992: 30). Acknowledging the moderating effects of the socio-material actualities of laboratories allows for an objectivism that recognizes its limits. Steve Fuller's objectivism by contrast recognizes psycho-social limits by focusing on the actualities of scientists' behaviours. In 1992, the epistemic practices of 'other' STS scholars may still have been experienced as alien (or wrong), but STS as a landscape of multiple methodologies, many sets of truth practices, both distinct and connected in various ways, is certainly discernable in *Science as Practice and Culture*. The STS recognition that science *is* organizational practice, with the corollary that it expresses many particular institutional cultures that effect various specific epistemic standards and ontological strategies, was perhaps prescient in 1992, but its salience for developing possibilities for critique of the politico-epistemics emerging in the versions of the modern (neo)liberal democratic state that were already then in evidence, is not in doubt.

As a collection of papers then, *Science as Practice and Culture* seems to express (and record) some of the moments by which today's complex STS analytic terrain came into being. This tentative conclusion brings me to my second question. Are further analytic currents discernable in the collection; streams of analysis that have so far remained unremarked? Here I turn to the very final paper in the collection, by anthropologist of science, Sharon Traweek. Beginning in the 1980s her ethnographic empirical studies were carried out in a Japanese high energy physics laboratory. There, as a tall, red-haired woman engaging the epistemic practices of American cultural anthropology, of course she stood out as distinct, but she was also multiply connected. She stayed there in-place, committed to going on collectively, doing many differentiations with the Japanese men who were her knowledge making colleagues, she went on, simultaneously separated from and connected to those who thought otherwise.

In this final paper (it has the feel of an afterword) I detect a further –ism that I suggest should be added to the line up of –isms that emerged unbidden in graduate student seminars I

participated in earlier this year, a version of which I came across later, in a recently published book—a story of what contemporary STS *is*. Traweek's paper enacts a truth form we might name as situationism. I suggest it is a truth form, a figure animating epistemic practices, that is widely enacted in STS. While situationism has been present in science studies since ethnographies of science began in the 1980s, as truth practice, it has remained more or less unnoticed. Yet I suggest it is this very truth form that mediated the emergence of complexity in contemporary STS epistemic practices, covertly enabling the actual doings of its various empirical objectivisms, social constructivisms and ontological constitutionalism together and separately.

A situationist methodology articulates a truth form that is not representationist (like those of objectivism and social constructivism) but which does offer possibility for accounting 'how we know we know'. While not fully fledged, not admitting (to itself?) that it is a truth form, a set of epistemic practices, it is exemplified in at least some of the "string of stories" (Traweek, 1992: 461) that constitute Traweek's paper. The ethnographic stories of Japanese physicists' naming practices comparatively embedded in the paper's extended elaboration of American cultural anthropological naming practices, exemplifies this pragmatic and situated truth form, enacted in particular deeds, peculiar to ethnography yet not owned-to by any school of anthropology.

I suggest that nothing stands in the way of STS ethnographies owning-to that situationist truth form enacted in ethnography. Less subject to the Hermes complex which in anthropology often takes the paralytic form of not belonging anywhere (and of which Traweeks's paper is a stellar example), STS ethnography in my experience openly, even promiscuously, expresses both and neither belonging and not belonging—like all its fellow STS methodologies and their truth forms. In concluding my re-reading of *Science as Practice and Culture*, this is the truth form I point to and celebrate as a constituent truth form in contemporary STS, and as there flourishing in 1990s science studies as an unnoticed back-channel.

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Science & Technology Studies

Volume 30, Issue 3, 2017

Guest editorial

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