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

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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-ofcare 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 origi-

nally 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 medical 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 forms¹ 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-ofcare 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 pointof-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 pointof-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 (publicprivate, 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 effortsvertical disease control programs that are creating competing options.

These insights also go against a prevailing belief in technological determinism. If point-ofcare 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-ofcare, 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.

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References

- Akrich M (1992) The De-Scription of Technical Objects. In: Bijker WE and Law J (eds) *Shaping Technology / Building Society: Studies in Sociotechnical Change.* Cambridge, London: The MIT Press, pp. 205-224.
- Anderson W (2006) *The collectors of lost souls. Turning Kuru Scientists into Whitemen.* Baltimore: Johns Hopkins University Press.
- Angotti N (2010) Working outside of the box: How HIV counselors in Sub-Saharan Africa adapt Western HIV testing norms. *Social Science & Medicine* 71(5): 986-993.
- Armstrong N and Hilton P (2014) Doing diagnosis: Whether and how clinicians use a diagnostic tool of uncertain clinical utility. *Social Science & Medicine* 120: 208-214.
- Attewell G (2016) Alignments? X-ray Diversions, Haptics, Credibility—With a 'Bone-Setting' Clinic in Hyderabad City. *Medical Anthropology* 35(1): 5-16.
- Balarajan Y, Selvaraj S and Subramanian SV (2011) Health care and equity in India. *The Lancet* 377(9764): 505-515.
- Bassett IV, Wang B, Chetty S, et al. (2009) Loss to care and death before antiretroviral therapy in Durban, South Africa. *Journal of Acquired Immune Deficiency Syndromes* 51(2): 135-139.
- Berg M (1997) *Rationalizing medical work: Decision-support techniques and medical practices,* Cambridge, London: MIT Press.
- Bhojani U, Mishra A, Amruthavalli S, et al. (2013) Constraints faced by urban poor in managing diabetes care: patients' perspectives from South India. *Global Health Action*.
- Bourret P, Keating P and Cambrosio A (2011) Regulating diagnosis in post-genomic medicine: re-aligning clinical judgment? *Social Science & Medicine* 73(6): 816-824.
- Brown P, Lyson M and Jenkins T (2011) From diagnosis to social diagnosis. *Social Science & Medicine* 73(6): 939-943.
- Casper MJ and Clarke AE (1998) Making the Pap Smear into the 'Right Tool' for the Job: Cervical Cancer Screening in the USA, circa 1940-95. *Social Studies of Science* 28(2): 255-290.
- Chandler CI, Mangham L, Njei AN, Achonduh O, Mbacham WF and Wiseman V (2012) 'As a clinician, you are not managing lab results, you are managing the patient': How the enactment of malaria at health facilities in Cameroon compares with new WHO guidelines for the use of malaria tests. *Social Science & Medicine* 74(10): 1528-1535.
- Clouse K, Page-Shipp L, Dansey H, et al. (2012) Implementation of Xpert MTB/RIF for routine point-of-care diagnosis of tuberculosis at the primary care level. *South African Medical Journal* 102(10): 805-807.
- Cox H and Webster A (2013) Translating biomedical science into clinical practice: Molecular diagnostics and the determination of malignancy. *Health* 17(4): 391-406.
- Das J, Holla A, Das V, Mohanan M, Tabak D and Chan B (2012) In Urban And Rural India, A Standardized Patient Study Showed Low Levels Of Provider Training And Huge Quality Gaps. *Health Affairs* 31(12): 2774–2784.
- Datye V, Kielmann K, Sheikh K, et al. (2006) Private practitioners' communications with patients around HIV testing in Pune, India. *Health Policy and Planning* 21(5): 343-352.
- De Costa A, Johansson E and Diwan VK (2008) Barriers of Mistrust: Public and Private Health Sectors' Perceptions of Each Other in Madhya Pradesh, India. *Qualitative Health Research* 18(6): 756-766.
- de Laet M and Mol A (2000) The Zimbabwe Bush Pump: Mechanics of a Fluid Technology. *Social Studies of Science* 30(2): 225-263.

- de Swaan A (1977) On the Sociogenesis of the Psychoanalytic Situation. *Human Figurations, Essays for Norbert Elias, Amsterdams Sociologisch Tijdschrift*.
- de Vries G (2008) The 'unknown' practice of genetic testing. In: de Vries G and Horstman K (eds) *Genetics from laboratory to society: Societal learning as an alternative to regulation.* New York: Palgrave Macmillan, pp. 1-16.
- Engel N (2012) New diagnostics for multi-drug resistant Tuberculosis in India: Innovating control and controlling innovation. *BioSocieties* 7(1): 50-71.
- Engel N, Ganesh G, Patil M, et al. (2015) Point-of-care testing in India: missed opportunities to realize the true potential of point-of-care testing programs. *BMC Health Services Research* 15(1): 550.
- Engel N and van Lente H (2014) Organisational innovation and control practices: the case of public–private mix in tuberculosis control in India. *Sociology of Health & Illness* 36(6): 917-931.
- Fochsen G, Deshpande K, Ringsberg KC and Thorson A (2009) Conflicting accountabilities: Doctor's dilemma in TB control in rural India. *Health POlicy* 89(2): 160-167.
- Gardner J, Dew K, Stubbe M, Dowell T and Macdonald L (2011) Patchwork diagnoses: The production of coherence, uncertainty, and manageable bodies. *Social Science & Medicine* 73(6): 843-850.
- George A and Iyer A (2013) Unfree markets: Socially embedded informal health providers in northern Karnataka, India. *Social Science & Medicine* 96(0): 297-304.
- Graham J (2006) Diagnosing Dementia: Epidemiological and clinical data as cultural text. In: Leibing A and Cohen L (eds) *Thinking about dementia: Culture, loss and the anthropology of senility.* New Jersey: Rutgers University Press, pp. 80-105.
- Jensen TE (2012) Intervention by Invitation: New Concerns and New Versions of the User in STS. *Science Studies* 25(1): 13-36.
- Jovanovic M (2014) Creating the 'dis-ease' of high cholesterol: A sociology of diagnosis reception analysis. *Social Science & Medicine* 101(0): 120-128.
- Jutel A (2009) Sociology of diagnosis: a preliminary review. Sociology of Health & Illness 31(2): 278-299.
- Jutel A and Lupton D (2015) Digitizing diagnosis: a review of mobile applications in the diagnostic process. *Diagnosis* 2(2): 89.
- Jutel A and Nettleton S (2011) Towards a sociology of diagnosis: Reflections and opportunities. *Social Science & Medicine* 73(6): 793-800.
- Kielmann K, Datye V, Pradhan A and Rangan S (2014) Balancing authority, deference and trust across the public-private divide in health care: tuberculosis health visitors in western Maharashtra, India. *Global Public Health* 9(8): 975-992.
- Latimer J (1997) Giving patients a future: the constituting of classes in an acute medical unit. *Sociology of Health & Illness* 19(2): 160-185.
- Losina E, Bassett IV, Giddy J, et al. (2010) The "ART" of Linkage: Pre-Treatment Loss to Care after HIV Diagnosis at Two PEPFAR Sites in Durban, South Africa. *PLoS ONE* 5(3): e9538.
- Mol A (2002) The body multiple: Ontology in medical practice, Durham, London: Duke University Press.
- Mueller-Rockstroh B (2007) Ultrasound Travels: The Politics of a Medical Technology in Ghana and Tanzania. Faculty of Arts & Social Sciences, Department of Technology & Society Studies. Maastricht: Doctoral Dissertation, University of Maastricht.
- Mueller-Rockstroh B (2011) Appropriate and Appropriated Technology: Lessons Learned from Ultrasound in Tanzania. *Medical Anthropology* 31(3): 196-212.

- Mykhalovskiy E, McCoy L and Bresalier M (2004) Compliance/Adherence, HIV, and the Critique of Medical Power. *Social Theory & Health* 2(4): 315-340.
- Pant Pai N, Vadnais C, Denkinger C, Engel N and Pai M (2012) Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries. *PLoS Medicine* 9(9): e1001306.
- Pasveer B (1989) Knowledge of shadows: the introduction of X-ray images in medicine. *Sociology of Health & Illness* 11(4): 360-381.
- Peeling RW and Mabey D (2010) Point-of-care tests for diagnosing infections in the developing world. *Clinical Microbiology and Infection* 16: 1062-1069.
- Prasad A (2014) *Imperial Technoscience: Transnational Histories of MRI in the United States, Britain and India:* MIT Press.
- Redfield P (2016) Fluid technologies: The Bush Pump, the LifeStraw® and microworlds of humanitarian design. *Social Studies of Science* 46(2): 159-183.
- Salter CI, Howe A, McDaid L, Blacklock J, Lenaghan E and Shepstone L (2011) Risk, significance and biomedicalisation of a new population: older women's experience of osteoporosis screening. *Social Science & Medicine* 73(6): 808-815.
- Schubert C (2011) Making sure. A comparative micro-analysis of diagnostic instruments in medical practice. *Social Science & Medicine* 73(6): 851-857.
- Scott K and Shanker S (2010) Tying their hands? Institutional obstacles to the success of the ASHA community health worker programme in rural north India. *AIDS Care* 22 Suppl 2: 1606-1612.
- Sengupta A and Nundy S (2005) The private health sector in India. bmj 331(7526): 1157-1158.
- Squire SB, Belaye AK, Kashoti A, et al. (2005) 'Lost' smear-positive pulmonary tuberculosis cases: where are they and why did we lose them? *International Journal of Tuberculosis and Lung Disease* 9(1): 25-31.
- Sreeramareddy CT, Qin ZZ, Satyanarayana S, Subbaraman R and Pai M (2014) Delays in diagnosis and treatment of pulmonary tuberculosis in India: a systematic review. *International Journal of Tuberculosis and Lung Disease* 18(3): 255-266.
- Street A (2011) Artefacts of not-knowing: The medical record, the diagnosis and the production of uncertainty in Papua New Guinean biomedicine. *Social Studies of Science* 41(6): 815-834.
- Suchman L (2002) Located accountabilities in technology production. *Scandinavian Journal of Information Systems* 14(2): 91-105.
- Yellappa V, Battaglioli T, Gurum SK, Narayanan D and Van der Stuyft P (2016) Private practitioners' contributions to the Revised National Tuberculosis Control Programme in a South Indian district. *International Journal of Tuberculosis and Lung Disease* 20(5): 659-665.

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.