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The Testing Revolution: Investigating Diagnostic Devices in Global Health

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By Alice Street


Image by Alice Street in collaboration with Jennifer Littlejohn.

The origins of laboratory medicine are often traced to the establishment of a small clinical laboratory in Guy's Hospital, London, in 1828. Here, in a small side-room, medical students used sterilisers, incubators and microscopes to identify bacteriological organisms in biological samples taken from the patients in the ward next door. In this simple removal of bodily fluid from the patient's body and its transfer to a laboratory bench a few metres away, it is possible to see the 'laboratory revolution' that transformed European medicine in the mid-nineteenth century (Cunningham and Wiliams, 1992). With the rise of the laboratory, the site of production of medical knowledge and authority shifted from the hospital bed to the laboratory bench. Medical scientists and students identified diseases within disinterred organs, tissues and fluids, rather than the patient body, laboratory technology came to dominate medical practice, and the biological and experimental sciences exerted a new supremacy over clinical medicine.

Yet, in 2003 when I was a PhD student in social anthropology setting off to study the practice of biomedicine in Papua New Guinea's public hospitals

and clinics, the story of laboratory medicine told by European medical historians provided little insight to the everyday clinical work of doctors, nurses, or indeed laboratory technicians. As the Acting CEO of a provincial hospital explained to me on my first day of fieldwork there, ‘we don’t have all the resources to make diagnoses on hand… final diagnoses are only made when the patient leaves’. The hospital did have a small pathology unit but chronic failings in the supply of reagents, an unreliable electricity supply, and a lack of appropriate equipment meant doctors rarely trusted its test results, preferring to rely on their clinical experience in a pragmatic ethic of ‘doing what we can’ for patients who they often referred to as ‘generally sick’. Doctors had been trained in clinical pathology, and the medical textbooks they studied consistently referred them to laboratory tests as the gold standard of medical knowledge. Equipped with a robust training in laboratory medicine, they were nonetheless forced to practice it without a functioning laboratory, leading to widespread frustration and poor morale (Street, 2014).

In the rural clinics where I carried out additional research, the contrast with archetypal accounts of laboratory medicine by European medical historians was even more stark. Here patients were not so much diagnosed as bureaucratically processed (see also Harper, 2014). Community health workers used ‘standard treatment books’ to align patients’ symptoms with the medicines available. Most patients who presented with fever-based symptoms or a persistent cough were given antibiotics and antimalarials. Patients were rarely ‘given’ a diagnosis, instead health workers handed out drugs and recorded a tally of disease incidence on the daily record sheet.

At the time there was a lot of excitement about ARVs being made available in Papua New Guinea, and a push by international donors to improve access to tuberculosis drugs through the WHO’s approved DOTS programme. But there was little policy discussion of the country’s limited laboratory capacity. The laboratory in the hospital where I worked was the source of much disparagement among the growing number of international medical researchers carrying out clinical trials in the hospital wards. But when I suggested to one medical researcher from Australia that improvements in the hospital’s clinical pathology infrastructure could potentially assuage emerging tensions with the hospital staff, the response was disdain: ‘They will never have a working laboratory here. It is impossible because of the climate and lack of power infrastructure’.

For much of the 2000s, the practice of laboratory medicine without a laboratory was accepted by the international community in Papua New Guinea and elsewhere as simply the way care is delivered in a resource-limited hospital. The lack of rural laboratory services and the persistence of treatment-focused empirical diagnosis at a primary care

level barely registered a response from national policy makers or international donors and organisations.

But by the end of the decade, when I returned to Papua New Guinea to begin new fieldwork with a provincial health management team, much had changed. The Global Fund was providing support for the establishment of sputum microscopy for tuberculosis at a district level and had awarded funding for the deployment of 6 million malaria rapid diagnostic tests to accompany a new malaria treatment protocol in the country. The consultancy arm of a local university had been given the Global Fund contract to roll out training in the use of malaria rapid diagnostic tests across the national health workforce. The same university had built a new training laboratory next door to the hospital where I had previously worked, and was offering to host its laboratory services. In 2015, when I returned again for a short follow-up trip, I was able to observe village health volunteers using malaria RDTs to diagnose and treat local patients in their homes.

Somewhere between my first trip to PNG in 2003 and my last one in 2015, normative assumptions about what constituted basic care in resource-limited settings had shifted. It was no longer deemed acceptable by international observers that patients in lower income countries be treated solely based on symptoms. In hospitals and urban centres, where it was previously an accepted inevitability that laboratories do not work, there was now international assistance for laboratory strengthening. In primary healthcare, the over-prescription of antimalarials and antibiotics that followed from presumptive diagnosis was abhorred as economically inefficient and fueling antimicrobial resistance. Access to laboratory quality testing that could provide unmediated access to the pathogens and microorganisms causing treatable diseases had become a global health priority.

This shift in ideas about what is necessary and what is possible in resource-limited settings was enabled, in part, by the emergence of a new generation of diagnostic tests and devices. These included point of care tests, like rapid bench-top PCR devices that could be deployed in hospital or district laboratories and portable, easy-to-use antigen-based rapid diagnostic tests for use in rural clinics, such as those incorporated into the new malaria treatment protocol in Papua New Guinea.

The attention that organisations like the WHO now give to diagnostic capacity and the mobilization of resources for diagnostic innovation by philanthropic foundations like the Bill and Melinda Gates Foundation has vastly improved the availability of testing technologies in countries like Papua New Guinea, from bench-top GeneXpert and CD4 machines donated to hospital laboratories, to rapid diagnostic tests for malaria and

dengue deployed in rural clinics. But these are individual testing devices, not laboratories. The construction of a rural laboratory infrastructure is still widely conceived as impossible in lower income countries that lack a universal road network, communication systems or electrification infrastructure. The laboratory revolution in 19th century Europe was characterized by the establishment of laboratory spaces for training, research and clinical testing, and by the development of new laboratory techniques, protocols and assays that were made publicly available through academic publication (of course it also reproduced class inequalities, introduced disciplinary hierarchies and participated in racialized medicine). In contrast, the testing revolution in 21st century global health involves the development of closed devices that are protected by intellectual property, circulate as commodities, and feature sample-in-result-out systems that are designed to by-pass untrusted local expertise (Street, 2018).

What has changed with the arrival of a device-focused testing revolution in global health? How are a new generation of diagnostic tests transforming health systems? And what can the rise of diagnostics tell us about changing priorities, values, and relationships in global health? These are the key questions that inspired us to start DiaDev, an European Research Council funded research project investigating the design and use of diagnostic devices in global health. Drawing on novel conceptual and methodological tools from social anthropology, it investigates the social, cultural and technical processes involved in developing, deploying and using diagnostic devices in resource-limited settings. Through the telling of diagnostic stories, the mapping of diagnostic infrastructures, and collaborations with stakeholders, DiaDev seeks to identity the lessons that can be drawn from the successes and failures of diagnostic devices in the places where they are developed and deployed.

In January 2018, the DiaDev team convened an interdisciplinary workshop to explore initial ideas and conceptual frameworks for tackling these questions across the social sciences and humanities. Below I outline three ideas that emerged in part from these discussions for what the critical study of global health diagnostics might look like.

1.From diagnosis to diagnostics

At the heart of the DiaDev project are stories of individual diagnostic devices, such as those for Ebola virus disease, malaria, onchocerciasis, or antimicrobial resistance, and what they tell us about the opportunities and challenges that accompany technological innovation in resource-limited health settings. Anthropologists are frequently brought into operational research on technology-focused interventions at the point of implementation and are expected to translate the experiences of

end-users for policy audiences. But device biographies neither begin nor end in the clinic. In fact, implementation is often prefigured in the market research and imaginings of end-use scenarios that developers build into device design, whether in terms of assumptions about the best way to extract a sample, what temperature a device needs to be stored at, or how it will be repaired or disposed of. What people do with diagnostic devices, including the adaptations needed to make machines work in a particular site, and what people do with the information provided by a device, also demand to be understood as forms of design work or hidden innovation.

Diagnostic devices often have aesthetic and material qualities that give them the appearance of finished, self-contained, stable objects (e.g. see the pieces by Lee and Bevan in this series). DiaDev seeks to disrupt this process of closure and reification by focusing on the device as a steadfastly unstable assemblage of material components, relationships, and practices. Diagnostic devices are not simply developed in one site and then used in another: they travel through research laboratories, manufacturing plants, investment company board rooms, regulatory bodies, clinics, and ministries of health in open-ended and unpredictable biographical trajectories of speculation, development, transformation and re-design. It is these uncertain biographies that DiaDev seeks to follow.

2.Diagnostic value

When a health worker employs a diagnostic device to test a patient for a specific disease, they are no longer (if they ever were) the only two actors with a stake in the result. The diagnostic revolution has galvanized a new collective of stakeholders: large-scale biotech firms already established in the diagnostics industry in Europe and North America; academic research groups and their spin-offs, small for-profit start-ups, product-development partnerships, regulatory bodies, development agencies, philanthropic donors, angel investors, ministries of health, and medical and public health researchers. The latent presence of these multiple actors raises the question: who and what is diagnosis for?

Drawing on perspectives and questions in social anthropology, DiaDev explores the multiple values that underpin investments in the testing revolution. What kind of humanitarian, scientific, medical and economic value does diagnosis generate and for whom? How do people know what a good diagnostic device is and what modes of measurement and evidentiary thresholds do they employ to decide this? How are different values negotiated and transformed in the course of device development, design, deployment and use? What kinds of mechanisms are international organisations introducing to manage multi-stakeholder endeavours, and whose voices do they amplify or suppress? For the DiaDev team, diagnostic devices offer an unparalleled opportunity for insight into the

changing power dynamics and cultural values that shape global health interventions and partnerships.

3.Diagnostic data

What kind of information do diagnostic devices generate and to what purposes? Some of the loudest voices calling for improved access to diagnosis have emphasized the need for improved care in places without access to reliable laboratory infrastructure. Treating patients solely based on their symptoms risks both misdiagnosis and unnecessary treatment-associated harm. Many of the academic groups, small start-up companies and not-for-profits developing new diagnostic devices for use in resource-limited settings employ a humanitarian discourse to appeal for support and funding for their activities. The DiaDev team will explore how diagnostic devices are transforming clinical encounters, relationships between patients and health workers, and the nature of medical care in the places where they are deployed. But the field of global health diagnostics is emerging rapidly, and the public health, medical, and economic opportunities that accompany diagnostic development and deployment are swiftly proliferating beyond the context of care.

The value and purpose of diagnosis are changing alongside technological developments. Advances in data connectivity mean that diagnostic devices now offer opportunities for the generation of large population level data-sets, with potential applications in public health surveillance, planning, programme evaluation, and emergent disease surveillance and tracking. In the context of emerging disease outbreaks, for example, diagnostics are as significant for the data they can yield about transmission dynamics as they are for the management of individual patients. In elimination campaigns and areas of low transmission, public health experts and funders are increasingly calling for diagnostic devices that can establish whether elimination has been achieved or to monitor the effectiveness of donor-supported disease control programmes. In such situations, diagnostic devices test populations rather than individuals and diagnosis is decoupled from treatment, with potentially significant implications for the fragile social contracts that often embed health technologies in local health systems. Following these developments and the changing meanings and expectations of diagnosis means looking beyond the context of care, to the multiple ways in which diagnostic devices are deployed as data devices and how diagnostic data is reshaping the priorities and relationships of global public health.

Diagnostic Stories

Most of the entries in the “Diagnostic stories” series were originally presented at the DiaDev launch workshop in January 2018. They go some

way to addressing DiaDev's founding questions about how diagnostic devices are transforming health systems and what they reveal of changes in global health values and priorities. They also demonstrate the sheer diversity of diagnostic devices that are being developed and deployed in global settings. Some of the issues the pieces raise, such as the challenges of integration, or the redistribution of expertise, trust and authority, draw attention to commonalities between the devices. In other cases, individual stories draw attention to device-specific technical or ethical dilemmas and promise to open up new avenues for critical enquiry, such as the problems of locating diagnostic devices for zoonotic disease across human and non-human bodies (Thompson), the implementation problems generated when less-accurate rapid diagnostic tests require further confirmatory testing (Bevan; Lee), the role of diagnostics in epidemiology (Harding-Esch); issues of laboratory procurement, repair and maintenance (Bezuidenhout), and the ethics of diagnosis when a test does not lead automatically to medical intervention (Sturdy; Lowy). The range of devices explored in the catalogue demonstrates that the full range of possibilities for the critical study of diagnostic devices in global health are only just becoming apparent, and many fruitful interdisciplinary conversations that cut across history, anthropology, science and technology studies, epidemiology and geography are yet to come.

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Diagnostic stories *follows the emerging world of devices, instruments, protocols and machines that make up the world of global health diagnostics. Through the telling of stories about specific technological artefacts it traces the rise of diagnosis as a global health concern and offers a critical perspective on the device-focused approach of many attempts to improve diagnostic infrastructure in the Global South. The series is edited by Alice Street.*

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