

# DIAGNOSTIC DEVICES IN GLOBAL HEALTH

Dr Alice Street of the DIADEV Project provides an anthropological perspective on diagnostic technologies in resource-scarce settings

**I**n low- and middle-income countries health professionals do not always have access to laboratory equipment or expertise with which to identify the pathogenic cause of disease. Until recently, many health workers depended on their clinical experience to empirically diagnose patients and treat them with the drugs that were available. For example, if a child in a remote health facility in Papua New Guinea presented with fever, they'd be treated for malaria. If they were short of breath they'd be treated for pneumonia (Street, 2014). This pragmatic approach to clinical management makes a lot of sense in a resource-scarce context, and for many decades was endorsed by the international community, who provided standard algorithms for syndromic management.

In recent years, however, the humanitarian and economic costs of weak laboratory systems have gained increased attention. There is concern that treatment delays and preventable deaths follow from misdiagnosis; that the unnecessary prescription of antibiotics and other antimicrobials fuels antimicrobial resistance; that the misreporting of diseases undermines the reliability of programme data; and that the rising cost of new, more effective medications is intensifying the need for more targeted treatment.

As the awareness of these costs has grown, hopes have centred on the emergence of a new generation of point of care diagnostic devices that are designed to be portable, quick, and to work in places with no electricity or technical expertise. Devices like rapid diagnostic tests for Malaria, Ebola Virus, and Human African Trypanosomiasis promise to extend laboratory infrastructure to hard-to-reach areas by building reliable and accurate pathogenic diagnosis into a portable kit.

Can such devices strengthen health systems in resource-scarce settings? At the University of Edinburgh, the European Research Council-funded DIADEV team is answering this question with the help of novel conceptual and methodological tools from social anthropology.



## Diagnostic stories

At the heart of this research are the stories of individual diagnostic devices, and what they can tell us about relationships between technical innovation and health systems in resource-scarce settings. Over the course of five years, six researchers will embed themselves in meeting rooms, research laboratories, field-testing sites, rural health centres, hospitals, clinical and reference laboratories in the US, Sierra Leone and India, working alongside the people who create, roll-out or use point-of-care diagnostic devices. They will employ interviews, observational research and qualitative mapping tools to investigate the social, cultural, and technical processes that shape the design of diagnostic devices and their effects on health systems at the point of use.

## Designing for health systems

One of the greatest challenges in the development of diagnostic devices for resource-scarce settings is the sheer number of stakeholders involved (funders, industry, governments, health workers, NGOs, campaign groups), and the diverse interests and values that those stakeholders bring to the table. For example, new rapid diagnostic tests for Ebola virus need to address the economic concerns of industry, the ethical concerns of regulatory authorities, the humanitarian concerns of NGOs and international health organisations, the public health concerns of governments, and the clinical concerns of users.

To understand the social and technical challenges involved in developing devices that meet these different expectations, our team members will interview the stakeholders involved in three prominent diagnostic product development partnerships, and undertake observational research in laboratories and field testing sites in the US, West Africa and India. In a series of collaborative workshops, we will work with developers to explore how research findings from the places where diagnostic devices are used, can be translated into useful tools to guide their design. This anthropological approach promises to provide insight into the everyday relationships and negotiations involved in global health innovation, to help identify the



key factors that govern success in diagnostic development for resource-scarce settings, and to inform processes of multi-stakeholder innovation in global health.

### Integrating devices with health systems

A key challenge in the successful deployment of diagnostic devices outside the laboratory is their integration with existing health systems. For example, research to date shows that rapid diagnostic tests for malaria, which have now become a routine part of healthcare in many low- and middle-income countries, need to be integrated with treatment protocols, medical supply chains, health information systems, training programmes, procurement systems, and medical waste disposal systems, in order to be effective (Street, 2014b; Beisel *et al.* 2016). To investigate what happens to diagnostic devices in practice, and what effect diagnostic devices have on health systems on the ground, team members will carry out 12 months of qualitative fieldwork in communities, rural health facilities, secondary and tertiary care units, and laboratories in Sierra Leone and south India. In collaboration with key stakeholders in those countries, we will develop a qualitative methods toolkit for mapping the flows of resources, personnel, samples, and information between the sites that make up a diagnostic system.

In south India, where rapid diagnostic tests for malaria and dengue have been in circulation for several years, this research will focus on the long-term effects of point-of-care diagnostic devices on the capacity of government to deliver healthcare to hard to reach tribal communities. In Sierra Leone, where the 2014 Ebola outbreak tragically exposed the weakness of existing laboratory systems, we will focus on the role that mobile diagnostic devices play in public health emergencies and their aftermath, and the challenges in innovation, regulation, and integration that need to be addressed in the development of diagnostic infrastructures for emerging diseases.

Point-of-care diagnostic devices are often championed as simple, small, and stable technologies that can work anywhere. Through the crafting of detailed, stories about the travels that specific diagnostic devices take, this project can help us to unpack these assumptions and make visible the fluid, adaptable, and contingent qualities of medical technologies. This is important for establishing a grounded and realistic understanding of the opportunities and challenges that accompany health innovation in resource-scarce settings. It will help governments to identify the strengths and weaknesses of current diagnostic infrastructures, to evaluate the benefits that new diagnostic devices might bring, and to establish the system-strengthening work that is necessary to maximise those benefits.



### Collaboration

The DIADEV Project is hosted in the School of Social and Political Sciences at the University of Edinburgh. It builds on the School's longstanding research into global health innovation, including ESRC-funded research on off-grid health infrastructures, ERC-funded research on the networks of zoonosis innovation, and Wellcome Trust-funded research on the role of diagnostics in global TB control programmes. The team includes researchers in the Department of Global Health and Social Medicine at Kings College London, the King's Sierra Leone Partnership, and the Public Health Foundation India.

Through the telling of diagnostic stories, the mapping of diagnostic infrastructures, and collaborations with stakeholders, DIADEV seeks to identify the lessons that can be drawn from the successes and failures of mobile diagnostic devices in the places where they are developed and deployed. It is hoped that the findings will help inform researchers, funders, policy makers, governments, and users as to whether, and how, these tests can strengthen health systems in resource-scarce settings.

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