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EDITORIAL

Tuberculosis diagnostics: Why we need more qualitative research

After decades of neglect, the field of tuberculosis (TB) diagnostics is advancing. New tests have been developed and evaluated, existing ones are being adapted for new contexts, and decision-makers have a rich pipeline to choose from and invest in [1]. Yet, some important gaps remain, including the need for a simple, point-of-care (POC) test [2].

In order to be able to develop, validate, and scale-up diagnostics, a thorough assessment of the context and settings of use at the different points of care is necessary. This requires research approaches that are able to take into account processes and reveal complex relationships and patterns involved in making diagnostics work in the real world. Qualitative research approaches are ideally suited for this. They offer a range of methodologies, such as in-depth interviews, focus group discussions, participant observations and discourse analysis, that can make sense of processes and meanings in their natural settings, and answer the how and why questions [3].

Yet, qualitative research on TB diagnostics is scarce. The few published studies have mainly focused on how stigma and disease perceptions influence healthcare seeking and diagnosis [4,5], reasons for delay in healthcare seeking [5–7] and what it means to live with TB diagnosis [8]. Such studies generate important insights for test developers, and more research is needed into patient needs and pathways to diagnosis. Yet, it does not make use of the full potential of qualitative research for answering the most pressing questions of the TB diagnostics community.

1. How to take into account complex diagnostic ecosystems?

New diagnostic tests need to function in a complex ecosystem of different users (patients, healthcare providers, laboratory technicians, communities, manufacturers, suppliers, and policymakers) at different levels of healthcare systems. In developing new tests, we might need a variety of different target product profiles and business models to do justice to different settings of use, i.e. hospital, clinic, peripheral laboratory, community and home [9]. This can be further complicated in settings that have a multiplicity of providers, incentive mechanisms and the absence of clear regulations (e.g. India) [10]. It is unclear how to shorten time delay in the diagnosis of TB, ensure links to rapid and correct treatment regimens and make tools fit to different user needs and settings. Qualitative research can generate a thorough understanding of these systemic issues and how regulatory, economic, epidemiological, behavioral, socio-cultural, technical, clinical, and political aspects interrelate in existing diagnostic processes.

2. How to scale-up and combine new and existing diagnostic tests in routine programs?

As new TB diagnostics become available, it can be challenging to ensure a successful scale-up at the country level and combine new tests with existing algorithms [11]. How do governments and TB control programs make choices about new tools? Why do some tests get scaled-up while others do not?

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Even if simple POC TB tests were developed, will health providers actually use them to make rapid decisions about TB treatment? Such questions will require, among others, understanding the role diagnostic tests play in patient—practitioner interactions, as part of comprehensive care and in combination with other diagnostic technologies and clinical decision-making. Qualitative research can examine underlying processes and meanings involved in diagnosing TB, and render visible the varied aspects involved in making a diagnostic technology work.

3. How to actively manage and foster innovation for TB diagnostics at the country level?

It is unclear what different policymakers and actors along the value chain need, what evidence is required, and how decisions are being made [12]. Qualitative research can examine the needs of different stakeholders in decision-making and evaluation processes. For example, test developers need to understand what the unmet needs are, as well as potential barriers for scale-up of tests [13] and qualitative research can provide the answers.

4. How to assess tests and evaluate their impact?

There is an increasing recognition that test accuracy studies and expert opinions are insufficient for policy and scale-up decisions [14]. We need data on the impact of the test on important outcomes of patients, on diagnostic decision-making, and on public health outcomes (e.g. reduction in TB incidence). Calls have been made for more implementation, operational and health systems research [2,15]. Several frameworks, such as the impact assessment framework by Mann et al. [16], or the technical and programmatic recommendations required for policy recommendations on new TB diagnostics [17] are emerging that can support collecting this kind of evidence. These frameworks have in common the fact that they account for the contexts in which diagnostic tests have to function in and employ a range of methods, including qualitative research.

Our own work in India shows the potential of qualitative research to study the processes of adapting and testing a new TB diagnostic device in its intended setting of use [18], and why inaccurate blood antibody tests are so popular in the private health sector [10]. Further inspirations for qualitative research in TB diagnostics can also be drawn from experiences with qualitative methods in medical device design (design ethnographies) with emerging frameworks specifically for diagnostic tests [19,20], in health technology assessment [21] and alongside clinical trials [22].

5. Why is qualitative research underused in the field of TB?

Qualitative research often involves fieldwork which can vary in its duration and extent (from months to years). Data collection techniques can be organized cost-effectively, but involve dedicated human resources with (substantial) time and capacity for data collection and analysis. Another hesitation stems from the concern to reach statistical generalizations. Contrary to quantitative methods, qualitative methods aim at analytical not statistical generalization. Lastly, publication barriers might discourage researchers. Medical journals, editors and reviewers may undervalue publications with qualitative results. Instead of focusing on a false dichotomy between quantitative and qualitative methods, they should focus on which approach and methodologies are required to solve a particular problem [3].

Overall, the challenges that the TB community faces are too urgent and complex to exclude potentially valuable research methodologies. We need more qualitative research to support innovators of TB diagnostics in developing better products, and TB controllers and policy-makers to translate products into showing an impact on health.

Conflicts of interest

None of the authors have any industry or financial conflicts to declare. MP serves as a consultant to the Bill & Melinda Gates Foundation.

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