Blind spots in the implementation of point-of-care diagnostics for underserved communities

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Standfirst

Point-of-care (POC) diagnostics are particularly important in resource-limited settings. However, to ensure their sustainability, deployment and uptake by underserved communities, systemic, infrastructural, bevioural, operational and logistical limitations need to be addressed.

Point-of-care diagnostics

Point-of-care (POC) technologies, also called near-patient testing or bedside testing, can guide clinical decisions at the time and place a patient is tested. POC diagnostic tools are particularly important in resource-limited settings and for underserved populations, who may not have easy access to healthcare facilities. To ensure uptake and effective, sustainable use, diagnostic tools need to be context-specific. In addition, the World Health Organisation (WHO) introduced the REASSURED (Real-time connectivity, Ease of sample collection, Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free, Delivered) criteria to guide the development and implementation of POC diagnostics in resource-limited settings. However, although much effort is invested in optimising diagnostic performance during development, comparartively less attention is paid to factors contributing to their sustainable implementation. As a result, approximately 47 percent of the global population has little to no access to diagnostics. Importantly, in low- and middle-income countries (LMICs), only 19 percent of patients have access to appropriate diagnostics at the primary health care level [1].

Supply chain management

The COVID-19 pandemic did not only expose the crucial role of POC diagnostics in health care, but also weaknesses in supply chain management systems for diagnostics and therapeutics in resource-limited settings. Our evaluation of COVID-19 POC tests supply chain management in one of the most affected regions of South Africa showed that inventory management, test distribution and human resource capacity posed the greatest barriers to test accessibility [2]. Therefore, the supply chain should be shortened through local production and digitization and automation of procurement systems should be established [3]. Moreover, supply chain management systems could be improved by increasing procurement, inventory management, storage, distribution, quality assurance and human resource capacity. Weak supply chain management systems may lead to significant stockouts of POC diagnostic tests, compromising the potential and promise of POC diagnostics and negatively impacting health

outcomes. Therefore, the local development of high-quality POC diagnostics should be promoted through collaborations between the global South and global North to address supply chain limitations in resource-limited settings.

Diagnostic literacy

The availability of diagnostics does not necessarily lead to their uptake and improved health outcomes. Health literacy influences the uptake of health services and is a major determinant of health outcomes, imperative to global health. Health literacy is defined as a set of skills that allows patients to control their own well-being, make smart healthcare choices, improve their communication with healthcare workers and advocate for themselves in healthcare settings. In the context of POC diagnostics, health literacy is referred to as diagnostics literacy [4]. Importantly, diagnostics literacy interventions in resource-limited settings should follow the REASSURED criteria.

Diagnostics literacy encompasses a range of factors that are closely related to health promotion: social accountability, culture; individual empowerment; community development; media and numeracy. At the population level, diagnostic literacy further involves knowledge and awareness of accessing and using health technologies for disease screening, diagnosis and point-of-care treatment. In the case of digital-linked diagnostics, numeracy also needs to be encorporated in the diagnostic literacy program.

Misconceptions and systemic biases

A critical phase in the implementation of health tools for diagnosis, prevention and treatment is deliverability to end users, including the logistics of getting the tool to the affected population and the buy-in, uptake, correct interpretation and follow-on actions by the end user. However, misconceptions and socially constructed impediments with regards to the delivery of diagnostics and therapeutics to remote or rural settings may discourage the investment in such technologies; for example, the baseless beliefs, encountered during the early preparations for rolling out HIV antiretrovirals in Africa in 2001, that the lack of roads, shortages of doctors and hospitals and wars may prevent the delivery of HIV treatment. Even worse, misconceptions, such as Africans "don't know what Western time is and therefore would not reliably take their medicines at the right time" are hugely damaging, perpetuating and exacerbating health inequalities.

In the wake of the COVID-19 pandemic, several publications reported the challenges of at-home self testing for SARS-CoV-2 infection, some without supporting evidence[5,6] . We evaluated the willingness, ability and follow-through of self-testing by villagers in Zimbabwe. Preliminary results of our evaluation demonstrate that the villagers understand the need to test, are willing to self-test, can conduct the test correctly and are willing to follow the self isolation guidelines if tested positive for the virus.

Moreover, challenges, such as the lack of trained personnel, reliable electricity, clean water, remoteness and cold chain requirements may be addressed if there is political, national and/or scientific will.

Precision biomarkers for disease detection

Biases can drive health ineaqualities rooted in different molecular or genetic attributes. Therefore, identifying adequate disease biomarkers is key to addressing health disparities, but requires the mitigation of biases in biomarker research[7]. Biases can emerge at various stages of biomarker

discovery, development, validation and implementation. In particular, the lack of population diversity and representation in biomarker studies undermines the generalizability and applicability of findings to broader populations. Such studies do often not account for population heterogeneity in terms of genetic, environmental, disease prevalence, aetiology and socioeconomic factors, threby contributing to disparities in biomarker adoption, utilisation and detection rates.

Addressing these biases is imperative for successfully integrating biomarker-based diagnostics in underserved communities. It is critical to recognise that underserved is often synonymous with being excluded. The exclusion starts at the initial development of diagnostic tools and biomarkers, which first requires the identification of the disease and test subject. However, the design of diagnostic tools based on biomarkers that are analysed, tested and optimised for only a narrow cohort of the population do not serve all people equally. For example, oximeters designed to determine levels of blood oxygen in several conditions, including pneumonia and COVID-19, perform less well in dark-skinned people[8], failing to accurately diagnose dangerously-low blood oxygen levels in these patients. Therefore, it is important to evaluate the performance and utility of diagnostic devices in underserved populations, considering factors such as ethnicity, age and comorbidities. Recommendations for clinical trials testing therapeutics in a way to be inclusive of underserved populations should also be extended to diagnostics[9].

Diagnostic gaps

A glaring health ineaqulity compromising progress towards the health sustainable development goal (SDG3) is the lack of POC diagnostics for neglected tropical diseases, which affect 1.7 billion people globally. This group of 20 mostly infectious dieases primarily affect the poorest and most marginalised populations. Importantly, these diseases could be treated if diagnosed early, emphasising the importance of accurate diagnostic tools for timely treatment and intervention [10]. Challenges include the lack of a reliable market, demanding and unpredictable customers, poor limited research in relevant populations , and poor diagnostic literacy [4,10]. Indeed, diagnosis of neglected tropical diseases has not been prioritized by local policy makers and the affected communities may not have driven demand for such diagnostics, as opposed to other diseases, for which there is greater awareness, such as COVID19.

To overcome these multifaceted challenges, innovative and context-specific solutions are needed that consider population variations, the intricacies of the disease profile, affordability, sample collection and transportation logistics, as well as infrastructure and resource availability. For example, diagnostic devices can be designed to operate on mobile battery power, mitigating the reliance on unreliable electricity. Nonetheless, translating such innovations from the laboratory to real-world applications in low-resource settings remains challenging primarily owing to their high cost and limited usability. In addition, the development of diagnostics for neglected tropical diseases may be perceived as economically nonviable, thereby limiting investment in their design and optimization. Furthermore, diagnostics developers and policy makers should be cognizant of the negative environmental impact of POC diagnostics made from unrecyclable material. In addition, target contexts should be considered, including different cultures as well as genetic and social variations in a population.

Neglected tropical diseases tend to cluster in the same geographical regions, and therefore, multiplexed POC diagnostics may be developed, for example for malaria and Human African trypanosomiasis (HAT). Developing such tests may be challenging and costly; however, the overall cost-benefit ratio of multiplexing diagnostics may be favourable in the long term, reducing expenses associated with multiple tests and treatment delays [10].

Overcoming these challenges necessitates collaborative efforts among diagnostics developers, researchers and healthcare professionals in resource-limited settings as well as industry partners and public health organisations. Initiatives such as the Global Health Innovative Technology Fund (GHIT Fund), the Foundation for Innovative New Diagnostics (FIND), PATH and the WHO (World Health Organization) TDR (Tropical Disease Research) program demonstrate the importance of collective efforts in advancing diagnostic solutions.

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Which affect 1.7 billion people globally: https://southafrica.un.org/en/sdgs/3
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