THE FINAL FRONTIER

Breaking Down Barriers to Community Engagement in Diagnostics Research

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Throughout this *TAGline* edition, we've seen the power of community engagement to positively influence prevention and treatment research, and how the HIV and TB research fields have evolved–albeit at different paces–from a default policy of exclusion of communities from decision-making to an acceptance, appreciation, and normalization of community engagement and even leadership in research. Yet these advances have largely been absent from diagnostics research.

We're seeing progress toward engaging communities in the development of diagnostics. For example, developers of TB diagnostic products in late-stage development have consulted with the Global TB Community Advisory Board (TB CAB, see Sound Off) on pathways to developing their tests and on getting them recommended and supported through donor funding mechanisms. Manufacturers who have inappropriately marketed TB tests in India have had to respond to TB CAB concerns.[1, 2] The Stop TB Partnership's New Diagnostics Working Group, housed at FIND, includes community representation and thoughtfully liaises with civil society organizations such as TAG in many of their efforts. A TB survivor participated in the World Health Organization's process to develop target product profiles for new TB diagnostics.[3] A Unitaid grant to FIND for hepatitis C diagnostics scale-up includes a community engagement component.

But the little community engagement in diagnostics development so far has often been tokenized, or has come rather late in the process. This exclusion is likely in part due to: (i) lack of awareness of the need to involve communities and the mechanisms for doing so, (ii) presumptions around communities' ability to engage in the more technical nature of diagnostic development, and (iii) the fact that diagnostic research does not follow the same clinical development pathway with human participants as development for drugs, vaccines, and other prevention interventions.

Increasing the involvement of communities, from concept development to the post-implementation review stage, would help ensure that tests are responding to patient needs and are acceptably designed (e.g., with regard to the type of sample collected and the route of collection, and with affordability and simplicity in mind). This could include organizing community surveys or consultations, interviewing community leaders during the design stage about applicability, and having developers meet with community advisory boards or community steering committees before approving or launching a diagnostics development or implementation project. At later stages of the development lifecycle, engaging communities in planning in-country validation studies–which are often required for national use–would ensure selection of sites that are appropriate, geared to key populations, and community-friendly. This includes potentially involving members of key populations as screening/testing peer educators, to ultimately inform national guidance.

These communities can include people who are at risk for or have the disease, as well as those who care for them, including community health workers and clinicians. For example, for hepatitis C diagnostic research, including community representatives who use drugs or engage in sex work might be critically important to ensure that tests meet their needs and are being implemented in places where they seek care. For TB, key community members to engage might include parents of children with TB, and people with HIV, for whom sensitive diagnostics with easy sample collection are still lacking.

Empowering communities to engage in diagnostics research is essential. Investing in expanded opportunities to increase diagnostics literacy would sensitize communities to new tools coming down the pipeline, building their technical capacity to advocate for sound research and uptake of appropriate tools. Such advocacy could include calls to streamline regulatory processes and normative guidance development at the national and global levels.

Given that existing community engagement principles have largely been developed for a distinct scope–clinical trials that involve putting an intervention directly into bodies–a targeted effort to guide community engagement in diagnostics research would be useful for community members, developers, and donors alike. Key recommendations and tools for Good

Participatory Practice Guidelines–which were originally developed for biomedical HIV prevention trials, and have since been adapted to TB drug, TB vaccine, and emerging pathogens trials[4]–should be developed to guide engagement in diagnostics development across diseases. The GPP guidelines provide a systematic framework that could be adapted to the processes, stakeholders, and decision points critical to diagnostic research. Over a decades' worth of GPP implementation and lessons learned will provide a solid foundation for making ethical and appropriate community engagement a cornerstone of diagnostic research and development.

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Endnotes

1. Global TB Community Advisory Board. TAG, TB CAB, India CAB open letter to Qiagen re: Marketing and use of QuantiFERON-TB Gold for active TB in India and high TB burden countries. 2013 May 14. Available from: http://www.tbonline.info/media/uploads/documents/qiagen_open_letter_final.pdf.
2. Global TB Community Advisory Board. Activists call for withdrawal of substandard TB test from India. 2016 July 6. Available from: http://www.tbonline.info/media/uploads/documents/dcgi_genedrive_letter_draft_final.pdf.
3. World Health Organization. High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting. Geneva: World Health Organization; 2014. Available from: https://www.who.int/tb/publications/tpp_report/en/.
4. Global Advocacy for HIV Prevention. Good Participatory Practice (GPP) Guidelines [Internet]. n.d. Available from: https://www.avac.org/good-participatory-practice.