# Point-of-care assays for early infant diagnosis in Zimbabwe

*Lancet HIV* 2019
Published Online
February 5, 2019
http://dx.doi.org/10.1016/S2352-3018(18)30335-7
See Online/Articles
http://dx.doi.org/10.1016/S2352-3018(18)30328-X

Delays in diagnosis of HIV and initiation of antiretroviral therapy (ART) for infants significantly increase early infant morbidity and mortality.[1] By contrast, innovations in early infant HIV diagnostics and improvements in turnaround times could reduce infant morbidity and mortality.

In *The Lancet HIV*, Simone C Frank and colleagues modelled the cost-effectiveness of point-of-care (POC) assays for early infant diagnosis compared with conventional centralised laboratory-based testing in Zimbabwe.[2] Although several studies[3-6] have shown that HIV-related POC testing technologies are cost-effective, Frank and colleagues' is the first cost-effectiveness modelling study in which POC and conventional testing for early infant diagnosis were compared. The model suggests that survival would improve among infants with HIV if POC testing was used, largely because of timely return of results and early ART initiation. The authors thus recommend that policy makers incorporate POC assays into their early infant testing programmes.

Frank and colleagues calculated that POC assays for early infant diagnosis were no longer cost-effective if the cost per test increased from the base case of $28 (in 2016 US$) to more than $60 per test. The increase to $60 or greater is expected when throughput is reduced to less than 0·5 tests per day. This low throughput might be expected in low-prevalence settings but could also be possible in many HIV-treating facilities in high-prevalence settings. For example, if POC testing equipment were placed in all HIV-treating facilities in Zambia, which has a similar HIV prevalence to that in Zimbabwe, approximately 95% of facilities would have an average daily platform utilisation of less than 0·5 early infant HIV tests.[7,8] Only facilities with more than 3000 patients taking ART could be expected to reach more than 0·5 daily early infant HIV tests. In circumstances where test utilisation is likely to be low, the authors point out that the use of polyvalent platforms could increase use of POC testing instruments. Polyvalent platforms not only provide access to a range of tests (such as measurement of HIV viral load and diagnosis of tuberculosis, among others) via one machine, but also reduce the cost per test by sharing excess capacity with other tests.

Frank and colleagues acknowledge that the most efficient way to distribute POC instruments is not yet known, which could affect the cost-effectiveness of POC testing for early infant diagnosis. Despite potentially low instrument utilisation, a clear possible use-case for POC instruments is to increase access to early infant testing in remote areas, which can face substantial sample transport costs and unacceptably long turnaround times for results with conventional HIV testing. For instance, sample transport costs in Zambia are projected to account for up to 64% of the cost of a test for the most remote 5% of patients.[9,10] Facilities in such hard-to-reach areas could thus be prime candidates for placement of POC instruments, which would eliminate the cost of sample transportation and improve the cost-effectiveness of POC compared with conventional testing because of a decrease in turnaround time for results. Both polyvalent platforms and optimal placement of POC instruments will be key to ensure cost-effectiveness and long-term sustainability in these remote, often-low-volume settings.

Alternatively, policy makers might consider innovations and investment in timely result delivery and sample transport, which might help to reduce the turnaround time for results of conventional early infant testing. As Frank and colleagues note, the timely return of HIV test results is one of the predominant mechanisms by which early infant diagnosis programmes avert early infant mortality. Although they do not model the possibility of time to return of results of conventional assays being less than 1 month, if turnaround times for conventional testing improved substantially, then POC testing for early infant diagnosis might no longer be cost-effective. One study[11] showed that the use of mobile phones and text messaging to deliver results decreased turnaround times for return of conventional early infant testing from 53 days to 36 days. Investment in the conventional system would benefit not only early infant testing, but also an expanded basket of tests.

The results of Frank and colleagues' study provides good evidence for the cost-effectiveness of POC early infant testing compared with conventional laboratory-based testing, and also evidence for the broader cost-effectiveness of investment in reducing turnaround times for the results of early infant HIV tests specifically.

However, before adoption and operationalisation of POC early infant testing, efficient placement of POC testing equipment needs to be considered such that turnaround times, access, and instrument utilisation are optimised within an integrated tiered laboratory network.

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BEN reports grants from Gilead, MSD, ViiV Healthcare, and Janssen. SJG declares no competing interests.

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