

OPEN

Barriers to Implementation of Rapid and Point-of-Care Tests for Human Immunodeficiency Virus Infection

Findings From a Systematic Review (1996–2014)

Nitika Pant Pai, MD, MPH, PhD,* Samantha Wilkinson, MSc,† Roni Deli-Houssein, BSc,† Rohit Vijh, BSc,† Caroline Vadnais, BEng,† Tarannum Behlim, MD,† Marc Steben, MD, CCMF, FCMF, DESS,‡ Nora Engel, PhD,§ and Tom Wong, MD, MPH, FRCPC||

Background: Implementation of human immunodeficiency virus rapid and point-of-care tests (RDT/POCT) is understood to be impeded by many different factors that operate at 4 main levels—test devices, patients, providers, and health systems—yet a knowledge gap exists of how they act and interact to impede implementation. To fill this gap, and with a view to improving the quality of implementation, we conducted a systematic review.

Methods: Five databases were searched, 16,672 citations were retrieved, and data were abstracted on 132 studies by 2 reviewers.

Findings: Across 3 levels (ie, patients, providers, and health systems), a majority (59%, 112/190) of the 190 barriers were related to the integration of RDT/POCT, followed by test-device-related concern (ie, accuracy) at 41% (78/190). At the patient level, a lack of awareness about tests (15/54, 28%) and time taken to test (12/54, 22%) dominated. At the provider and health system levels, integration of RDT/POCT in clinical workflows (7/24, 29%) and within hospitals (21/34, 62%) prevailed. Accuracy (57/78, 73%) was dominant only at the device level.

Interpretation: Integration barriers dominated the findings followed by test accuracy. Although accuracy has improved during the years, an ideal implementation could be achieved by improving the integration of RDT/POCT within clinics, hospitals, and health systems, with clear protocols, training on quality assurance and control, clear communication, and linkage plans to improve health outcomes of patients. This finding is pertinent for a future envisioned implementation and global scale-up of RDT/POCT-based initiatives.

Key Words: barriers, implementation research, HIV, point-of-care tests, rapid

(*Point of Care* 2015;14: 81–87)

BACKGROUND

For the past 15 years, since early 1990s, rapid human immunodeficiency virus (HIV) tests (RDTs) have enabled to decrease

From the *Department of Medicine, McGill University; †Division of Clinical Epidemiology, Department of Medicine, McGill University Health Centre; ‡INSPQ, Montreal, Quebec, Canada; §Department of Health, Ethics & Society, Research School for Public Health and Primary Care, Maastricht University, Maastricht, The Netherlands; and ||Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada.

Reprints: Nitika Pant Pai, MD, MPH, PhD, Division of Clinical Epidemiology, Department of Medicine, McGill University and Health Centre, V Building (V2.19), 687 Pine Ave, West Montreal, Quebec, Canada. E-mail: nitika.pai@mcgill.ca.

The authors declare no conflict of interest.

Supported by Bill and Melinda Gates Foundation OPP1061487.

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Website (www.pocjournal.com).

References for the Supplemental Digital Content is available at <http://links.lww.com/POC/A8>.

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

ISSN: 1533-029X

the time between testing and receipt of initial screening test results, thus facilitating a decentralization of HIV testing services.^{1,2} Since 2000s, point-of-care tests (POCTs) enabled testing in many settings without access to formal laboratory services that are located primarily in low- and middle-income settings and have dominated this diagnostics space. Both RDTs/POCTs have been at the core of many screening strategies, including voluntary testing and counseling, provider-initiated testing and counseling, home-based clinics, or community outreach-based testing and counseling. Recently, POCT-based self-tests have promised a private anonymous solution that will expand access to communities, which avoid conventional facility testing. However, with the swift and widespread implementation of POCT globally, many barriers and impediments have been reported, which have prevented an ideal implementation.^{3,4} Understanding these barriers and factors impeding implementation is key to improving their future envisioned performance. In this context, therefore, a synthesis of barriers across levels of health care systems is long overdue.

In the RDT/POCT diagnostics space, a considerable attention is given to product development and market needs and size. Scientifically, improvements in test accuracy predominate for Food and Drug Administration and European Union approvals, whereas implementation and uptake issues remain secondary. With a lax implementation, even the most accurate tests, if not implemented correctly, end up with poor quality results. Factors contributing to failure are several but operate at 4 levels of health care systems (ie, device, patients, providers, and health care systems). The following factors fall in various categories: infrastructural, attitudinal, and contextual. Furthermore, sometimes, an introduction of technology alone in a workspace or health system is not enough. Understanding the disruption that RDT/POCT will bring into their workspaces is essential to improve their implementation. Engagement of key stakeholders including at-risk patient populations and their communities, policy makers, and providers alike along with sensitization to the potential of a new technology to improve health care is essential.

Implementation of RDT/POCT in the context of research and in programmatic suboptimal implementation could be attributed to many factors, namely, (1) a lack of resources and infrastructure (ie, personnel, distribution channels, and supply chain), (2) a lack of quality control (QC) and assurance program, (3) a delay in receipt of test results, and (4) a failure in communication of test/treatment plans to the patient, which translates to an incomplete establishment of linkages to follow-up care. When all these happen, the advantage of the point of testing at the point of clinical care is totally lost. At that point, it is reasonable to question whether POCT does more harm than good.

Some other factors operate at macro health system level and are harder to address because they vary with different health systems. These include a lack of adequate oversight, a deficient groundwork preparation of different components of health ecosystem, and an incomplete engagement of providers and

communities with RDT/POCT initiatives. Oftentimes, providers are insensitive to the fundamental factors that impair a successful deployment of RDT/POCT.⁵⁻⁷

In an earlier policy article, we shortlisted several barriers that impeded implementation of POCTs.⁸ In this systematic review, we aim to methodically document, explore, and classify all the barriers reported at different levels of the health system. These have been reported in the context of implementation/operational research surveys or evaluations with HIV POCTs. Knowledge about them is key to informed action plans and evidence-based policies and programs. As newer, advanced, and synergized RDT/POC technologies are in development, a critical informative synthesis that plugs a global knowledge gap at different levels is long overdue.

METHODS

Objective

The aims of this study were to identify barriers noted in the implementation of screening interventions with RDT and POCT for HIV in populations around the world and to classify them in 4 levels—device, patient, providers, and health systems.

Search Strategy, Selection Criteria, and Data Abstraction

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines,⁹ we undertook a systematic review to identify all the prevailing barriers faced by HIV RDT/POC programs in real-world settings.

We searched 5 worldwide online databases (ie, CINAHL, EMBASE, PsycINFO, BIOSIS, and MEDLINE [via PubMed]) for the period of January 1, 1996, to February 28, 2014. For searching MEDLINE, we used the search string detailed in Supplemental Digital Content 1 (<http://links.lww.com/POC/A2>).

Our search strategy was comprehensive in compliance with the guidelines of Cochrane Collaboration. The search was designed by a librarian (B.N.) to identify all studies that evaluated an aspect of RDT/POCT and performed by 2 independent reviewers (R.V. and S.W.). Studies were examined for direct exploration of barriers/challenges relating to RDT/POCT documented as primary or secondary findings. Barriers examined included at the device level, at the patient level, at the provider level, and at the health care systems levels.

Two reviewers (T.B. and R.D.) identified preliminary citations and independently abstracted the data. Data were abstracted if a potential barrier to RDT/POCT implementation was identified as a primary or secondary finding and reported in the results and in the discussion section of each included study. A third reviewer (S.W.) updated citations and collated and analyzed all the data. Discrepancies were resolved in consultation with senior author N.P.P. at all stages of the review.

Because the aim of our review was to identify all of the barriers at different levels, we included any study that used an HIV RDT/POCT in human populations and that reported evidence of barriers to RDT/POCT. Both English-language and non-English-language articles were included.

Excluded studies such as news reports, modeling studies, case reports, reviews, opinions, and articles that reported counseling and qualitative barriers to implementation. Qualitative barriers will be synthesized in another review.

A prepiloted data abstraction form was created in Excel in consultation (N.P.P., T.B., and R.D.). Data collected included the study location, design, sample size, test used, and the barriers and the level at which it was reported.

Statistical Analysis

Barriers were classified into 4 categories as follows: test device, patients, providers, and health system related. To simplify reporting, we counted the number of barriers reported within each category and later summarized the data as proportions. The data were collected and analyzed using Excel. Given the scope of our work, we did not apply a study quality checklist to the included studies.

RESULTS

Figure 1 details the study selection process. A total of 16,672 citations were identified by the initial search. After applying our inclusion and exclusion criteria as detailed previously, 132 studies were included in our final subset for analysis.

A summary table detailing each study is provided in the Supplemental Digital Contents 2 to 5 (<http://links.lww.com/POC/A3>, <http://links.lww.com/POC/A4>, <http://links.lww.com/POC/A5>, <http://links.lww.com/POC/A6>). Across the 132 studies, a total of 190 barriers were reported. The barriers were identified from a range of study types, predominantly diagnostic evaluations (65/132, 49%) and surveys (27/132, 20%).

A vast majority of studies reported only 1 barrier (89/132, 67%), 31 studies reported 2 barriers (31/132, 23%), 10 reported 3 barriers (10/132, 8%), and 2 studies reported 4 and 5 barriers, respectively (2/132, 2%). We included each barrier in our analysis as an independent data point.

At the device level, reported barriers (78/190, 41%) were primarily related to diagnostic accuracy (57/78, 73%), followed closely by implementation of barriers such as (1) difficulties in test conduct (15/78, 19%), with complicated testing protocols as in performing multiple steps,¹⁰ and (2) difficulties in reading the test results¹¹ or following protocols.¹² These results are summarized in Figure 2.

At the patient levels, main barriers (54/190, 28%) that were identified were (1) a lack of awareness and misconceptions relating to RDT/POCT (15/54, 28%), such as patient belief that RDT/POCT devices were not accurate¹³⁻¹⁵; (2) patient time constraints (12/54, 22%) that included the turnaround time it took to perform RDT/POCT including the time to test, counsel, and receive results and linkages; (3) privacy and fear associated with receiving results with RDT/POCT (9/54, 17%), such as feeling too overwhelmed to receive a result in a clinic setting¹⁶ or concerns relating to their

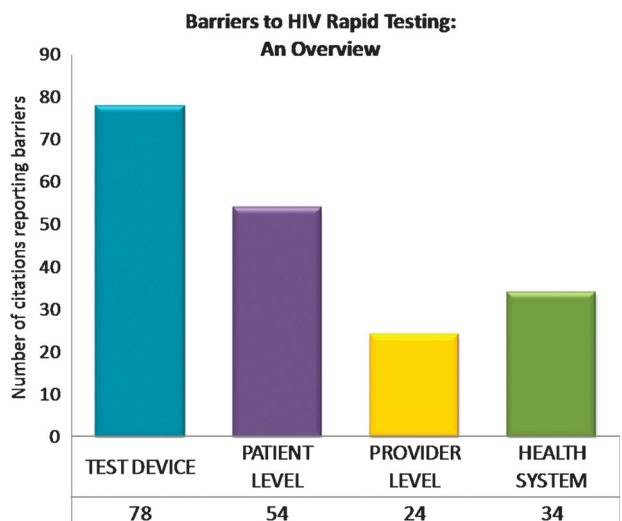


FIGURE 1. Barriers to RDT/POCTs.

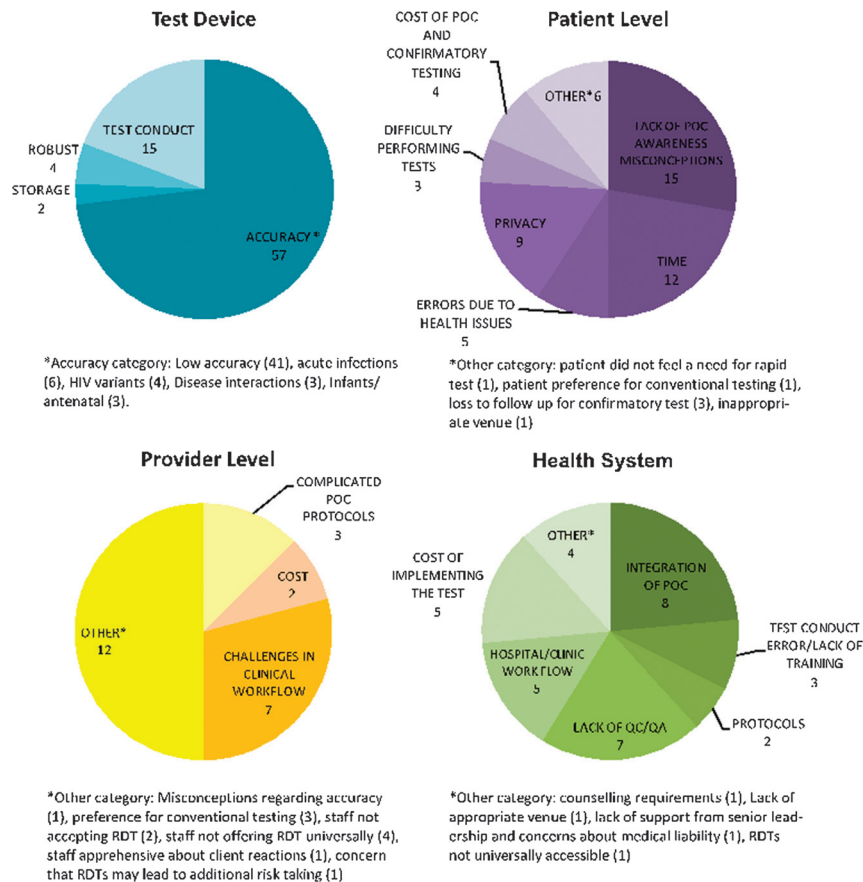


FIGURE 2. A breakdown of barriers to RDT/POCTs testing at different levels.

privacy¹⁷; and finally, (4) operational errors (5/54, 9%), such as dry mouth, making it difficult for patients to provide a saliva/oral sample,^{18,19} and costs associated with obtaining a confirmatory test. So, to report them in order, accuracy, followed by patient concerns such as misinformation, beliefs, fear, anxiety, and time-consuming testing protocols and costs, predominated findings at the patient level.

At the provider level, barriers (24/190, 13%) were predominantly related to challenges in integrating them in their clinical workflow (11/24, 46%). Other challenges were related to time, costs, and attitudes and reluctance of staff to conduct POCTs. For example, clinics were not able to find the time to adequately train staff, or patients were often met with negative attitudes from staff regarding RDT/POCT, and clinics did not offer RDTs regularly (7/24, 33%).²⁰⁻²³ A number of studies reported staff reluctance to use RDT/POCT, citing reasons such as distrust of their results and apprehension about the reaction of clients to a rapid test result, as well as staff not being aware of RDT/POCT availability or not having the time to attend training for them.²⁴⁻²⁹ In summary, a lack of interest, poor investment in training, negative perceptions regarding its benefits, reluctance due to change posed in their workflow, and resultant attitudes impeded their implementation. Other barriers were high costs, preference, and mistrust in accuracy.

At the health system level, reported barriers (34/190, 18%) were predominantly related to integration, for example, (1) difficulties integrating the tests within the health care systems (8/34, 24%) or within the hospitals' clinical workflows (13/34, 38%),

(2) a lack of QC and assurance of POCT/RDT (7/34, 21%), and finally, (3) high costs associated with implementing these tests within the existing health care systems (5/34, 15%).

In summary, across all the main levels of the health care system, implementation barriers (Fig. 3) such as difficulties within clinical workflows, health systems, lack of quality in implementation, turnaround time taken to offer rapid tests, difficult protocols, and complications in execution impeded delivery and staff reluctance in offering rapid testing. These barriers (59%, 112/19) were documented statistically (ie, device level, 19%; patient level, 28%; provider level, 13%; and health system level, 18%). They were followed closely by concerns regarding accuracy of test devices and patient level concerns (ie, apprehension, anxiety, knowledge, and information). High cost was also a deterrent and appeared at all levels of the health system. These have been illustrated in Figure 2.

Secondarily, at all levels, a dissatisfaction with the accuracy of RDT/POCT was observed (57/190, 30%). This fact was further analyzed. Accuracy concerns were subdivided into (1) dissatisfaction with the general accuracy of the test device (ie, sensitivity or specificity) (41/57, 72%) and (2) a lack of accuracy in detecting an acute HIV infection (6/57, 11%), for HIV variants (4/57, 7%) and HIV in infants (3/57, 5%) (please refer to Fig. 2).

To establish whether the economic status of the country impacted barriers experienced when implementing RDTs, we subgrouped our analysis according to the country the study was completed in using World Bank Income classifications. Results are detailed in Figure 4. Economic status seems to affect the use

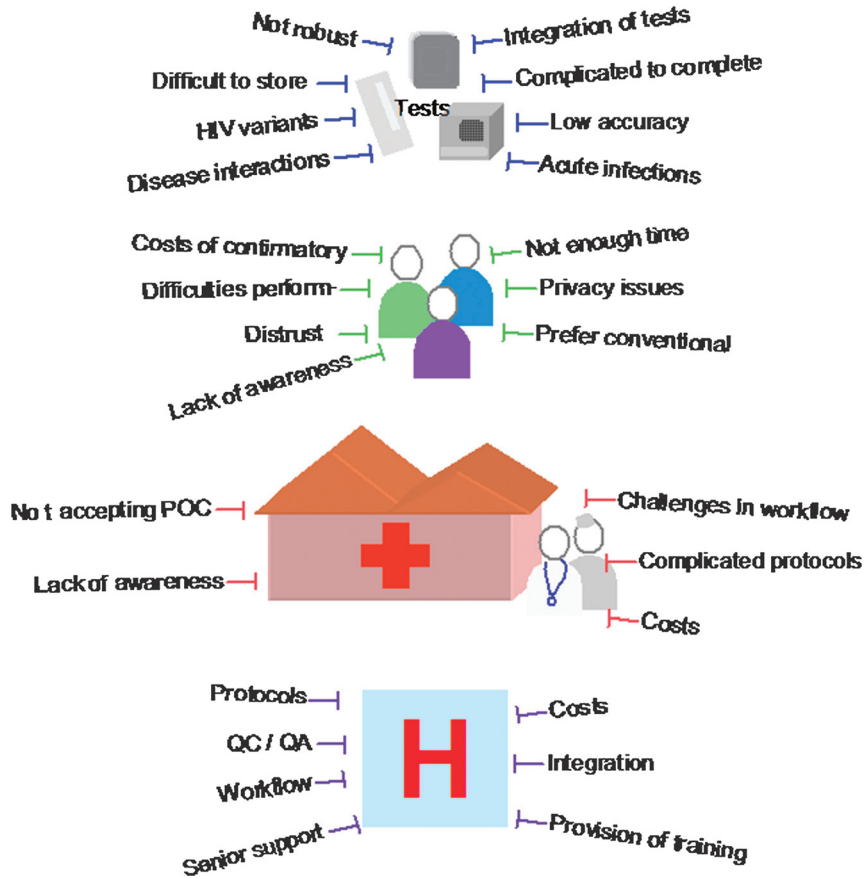


FIGURE 3. A visual representation of the major barriers at device, patient, provider, and health system levels.

of RDTs/POCTs in practice. For high-income countries, health care system level, provider level, and device barriers seem to be more equally represented. Surprisingly, the most common barrier reported for upper middle, lower middle, and lower income countries referred to the test device.

DISCUSSION

Our review highlights implementation barriers that impeded successful implementation of HIV RDT/POCT. The prominent health system barrier was integration of RDT/POCT into the clinical workflows at the provider and health systems levels, followed by inadequate knowledge of test protocols, lack of quality assessment or quality control (QC), additionally posed challenges in test execution, and action plans for integration. Across all levels of the health care system (ie, device, patient, provider, and health systems), we found evidence of misinformation more so at the patient level. Misconceptions, beliefs, lack of awareness, staff reluctance, and attitudes also added to the imperfect implementation. All these collectively impede an optimum integration of RDT/POCT. Across high- and low-income settings, it emerged as an issue. This finding is powerful because it confirms that, although technologies could be accurate, a poor orientation of patients, with poorly thought out integration plans, can backfire implementation. It seemed that setting up quality assurance improving turnaround time taken to test protocols, reducing costs, and setting up clear screening, diagnostic clinical pathways protocols, and clinical management action plans with RDT/POCT was pertinent to their successful implementation.

Programs based on RDT/POCT require a considerable investment in equipment, infrastructure, QC, certification of health care professionals, linkages to care, and clinical and diagnostic pathway plans. A POCT continuum of care is key to the success of POCT initiative.⁸ This continuum of care includes setting up clear plans embedded in health care systems with the buy-ins of health care providers and will help improve trust and faith of patients in tests and in the ability of health care professionals to embrace, improve quality, and act on the results for their patients. Clinics with good QC and quality assurance programs; efficient,

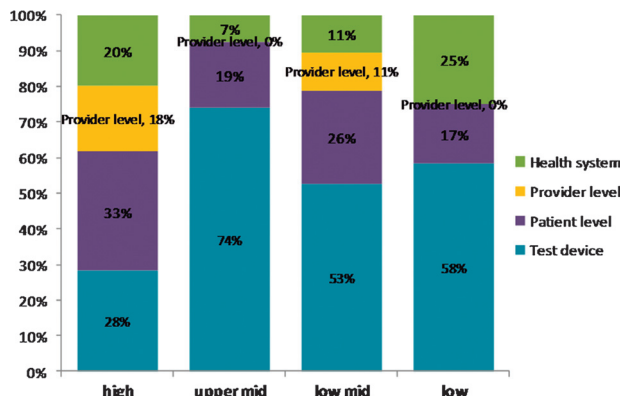


FIGURE 4. Barriers to RDT/POCTs, according to World Bank Income classifications.

accurate, and smart protocols for testing; and communication plans can engage patients better for clinical management. Communication of test results and action on the test result and improvement of clinical management are paramount to the success of RDT/POCT programs. Such investments will go a long way to improve a successful implementation of decentralized RDT/POCT and in preventing losses to follow-up of patients after rapid testing and follow-up on confirmatory testing.

Concern regarding accuracy of RDT/POCT test result emerged as the second most important barrier to uptake. If RDT/POCTs are not perceived to be accurate, their integration becomes a key issue. However, because an overwhelming number of the included studies were diagnostic evaluations, with the evaluation of accuracy as the primary objective, accuracy concern seems overrepresented. Conversely, studies that investigated the impact of RDT/POCTs on the health care system were rare.

Our review highlights gaps and underscores challenges that need to be addressed before decentralized models of testing with POCT could take center stage in many global settings. To improve quality and efficiency of testing, health care workers need to be supported before, during RDT/POCT implementation, and after introduction. Therefore, to improve integration in clinical workflow, certain conditions are a prerequisite. Proficiency testing, certification of professionals, and provision of training set the standards that improve the quality of testing.³⁰ A reporting system and a tracking system for test results, with linked patient profiles, always help improve communication plans between test counselors, patients, and their providers. This improves the turnaround time to action and clinical management plan. However, because strip-based flow through assays and lateral flow assays (POCT) seem to be simple to execute, appropriate training, certifications, and quality assurance and QC procedures have often been ignored in global settings. Quality control and quality assurance procedures such as maintaining a log of running controls at regular intervals, sensitizing everyone in the workplace to the standard operating procedures, and maintaining a log of temperature and storage conditions, a log of test kits, and the serial number of batches help improve conduct and facilitate the process of giving feedback to the test manufacturers and providers in case of erroneous results. With a clear record and plan of action on tests performed, interpreted, and acted upon, health care workers improve their performance in the workplace.

Sometimes, relatively simple tests can fall short of performance if confirmatory testing and linked test result communication systems are not in place. For example, tests can be performed without communicating the results to the physicians, or records of completion may not be well kept, and as a consequence, action plans are not maintained, and then, patients are never tracked into care and are lost to follow-up. It is at these key action points that the whole point of POCT/RDT of improving the quality, communication, and action plans with efficient, accurate testing is lost. These relatively minor issues impede a successful implementation.

At the patient level, in addition to accuracy, a lack of awareness or misconceptions regarding the role of RDT/POCT for their conditions was reported. These called for a better patient preparedness, better health literacy information, and perhaps, an improved community sensitization and awareness campaigns. We found that, despite the “rapid” nature of these tests, in some studies, patients still did not create time for such a testing method.¹⁵ They were unable to wait around for many test results (which, for some devices, could be a few hours). In some instances, they did not value a fast RDT/POCT result when they needed to wait for a confirmatory test result, which was subject to delay.^{15,31–33} In some other settings, patients preferred taking more time to reflect and prepare for an HIV result and feared receiving a test

result instantly.^{16,34} However, good quality pretest and posttest counseling, information, and mass media campaigns should go some way to allay this fear especially in the context of HIV. Because an HIV diagnosis can still be laden with stigma and shame, misconceptions are still apparent in the patient population, which can be countered with community awareness programs. Further research may be needed to identify the misconceptions that are most prominent and how these are best addressed.

At the device level, our findings indicate that, since their introduction, a challenge in the implementation of RDT/POCT has been dissatisfaction with the accuracy of the devices. This is perhaps unsurprising given that, for the span of our review, improvements in accuracy of HIV tests did take place. In fact, in 2012, Food and Drug Administration approved an over-the-counter self-test for HIV.³⁵ For 20 years, several new tests were introduced, and the accuracy of RDT/POCT inevitably improved with updated test devices, improved testing technologies, refinements to buffer solutions, better capture agents, and enhanced platforms. Furthermore, test-device-related barriers have reported decrease over time. Detailed time trends in our data have been difficult to identify given that tests have entered the market at different points and many studies reported on multiple tests. Moreover, despite progress, concerns regarding test accuracy could linger in the provider and patient mindset. Steps therefore need to be taken to clearly communicate to the patient and provider communities which devices that are setting appropriate and give assurances as to the accuracy of RDT/POCT. Accuracy is one of the ways in which providers who are vested in the conventional laboratory systems introduce doubt in the minds of patients and policy makers to prevent the use of RDT/POCT. Although, anecdotally, it has been reported that maximum sale of these RDT/POCT occurs in the conventional laboratories, accuracy is often used as a diagnostic test yardstick and, sometimes, acts as a barrier. In a high prevalence setting, although accuracy of an oral or finger stick POCT for HIV at 98% to 99% is good enough, it becomes an issue in a low prevalence setting because of false positivity concerns. To offset this issue, education and awareness of patients about the possible occurrence of false negatives or positives are necessary.³⁶

Strength

The following strengths of our review remain in our thorough search: independent and updated data abstraction and following a rigid protocol.

Limitations

Our review may be subject to language and reporting biases. Included studies reported the results of cross-sectional diagnostic evaluations in implementation research contexts, rather than reporting on real-world perspectives. The barriers met by specialist research teams and willing research participants are likely to be fewer and different compared with a real-world implementation of the RDT/POCT. Given this, it seems likely that our systematic review only hints at the real-world barriers that exist and inevitably missed some of the barriers faced when implementing a new technology into practice. For this reason, we assume that our analysis represents a “tip of the iceberg” scenario.

Implications

Our results could help inform RDT/POCT health service delivery standards and improve optimization of RDTs across global settings. Our findings could potentially be of interest to all stakeholders (ie, researchers, funders, and policy makers) who are seeking to understand the conceptual underpinnings of integration of

RDT/POCT in various health settings. Furthermore, to some extent, it may benefit patients (the central stakeholders) who can be unaware of the process of RDT/POCT-based testing and, with awareness and knowledge, can help develop strategies that could facilitate a smoother integrated introduction.

Overall, understanding the landscape of barriers and mapping them in the context of the implementation of RDT/POCT are timely. It could influence the implementation of current singleton test, whereas it will also inform the implementation of duplexed, multiplexed, or platform-based RDTs/POCTs that are being approved or are in development.

The review will be informative for all stakeholders, from policy makers, providers, to researchers, who are involved in planning the integration of all RDTs/POCTs, as well as manufacturers who develop new tests and technologies. Each stakeholder group is likely to benefit from anticipating issues that may hinder the integration and the adoption of a new technology. A deeper understanding of the issues can improve the quality of testing and integration and reduce health system-level bottlenecks with clear implementation and communication action plans. This will help complete the POCT continuum (of test, treat, link, prevent, and retain in care).⁸ Improved quality assessment/QC procedure, internal control run at regular intervals, data storage, data communication to the providers and patients, and improved data connectivity will all help improve the implementation. Some of the barriers that are beyond the purview of the technology but lie within the domain of implementation can only be resolved by communication with the professionals involved in establishing these systems in the hospital laboratories or outreach sites.

CONCLUSIONS

In the sexually transmitted and blood-borne infections' (STBBIs)' POCT diagnostics space, HIV RDTs/POCTs were the first to enter the market. Therefore, lessons learnt from their implementation will help provide information about other STBBIs. It is clear that overcoming these challenges to RDT/POCT integration will require a paradigm shift in understanding and embracing their potential that will help improve their use and impact patient care. Addressing these barriers today is paramount to the future success of RDT/POCT initiatives for STBBIs in the times to come.

REFERENCES

- Mortimer J. An alternative approach to confirming anti-HIV reactivity: a multi-country collaborative study. *Bull World Health Organ.* 1992;70(6):751–756.
- Reid SD, Fidler SJ, Cooke GS. Tracking the progress of HIV: the impact of point-of-care tests on antiretroviral therapy. *J Clin Epidemiol.* 2013;5:387–396.
- Johnson C, Baggaley R, Forsythe S, et al. Realizing the potential for HIV self-testing. *AIDS Behav.* 2014;18(suppl 4):S391–S395.
- WHO. *Global Update on the Health Sector Response to HIV.* 2014.
- Pant Pai N, Joshi R, Dogra S, et al. Evaluation of diagnostic accuracy, feasibility and client preference for rapid oral fluid-based diagnosis of HIV infection in rural India. *PLoS One.* 2007;2(4):e367.
- Plate DK, Rapid HIV Test Evaluation Working Group. Evaluation and implementation of rapid HIV tests: the experience in 11 African countries. *AIDS Res Hum Retroviruses.* 2007;23(12):1491–1498.
- Schito ML, D'Souza MP, Owen SM, et al. Challenges for rapid molecular HIV diagnostics. *J Infect Dis.* 2010;201(suppl 1):S1–S6.
- Pai NP, Vadnais C, Denking C, et al. Point-of-care testing for infectious diseases: diversity, complexity, and barriers in low- and middle-income countries. *PLoS Med.* 2012;9(9):e1001306.
- Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med.* 2009;151(4):264–269.
- Ferreira Junior OC, Ferreira C, Riedel M, et al. Evaluation of rapid tests for anti-HIV detection in Brazil. *AIDS.* 2005;19(suppl 4):S70–S75.
- Forsyth BW, Barringer SR, Walls TA, et al. Rapid HIV testing of women in labor: too long a delay. *J Acquir Immune Defic Syndr.* 2004;35(2):151–154.
- Granade TC, Parekh BS, Phillips SK, et al. Performance of the OraQuick and Hema-Strip rapid HIV antibody detection assays by non-laboratorians. *J Clin Virol.* 2004;30(3):229–232.
- Liu A, Kilmarx PH, Supawitkul S, et al. Rapid whole-blood finger-stick test for HIV antibody: performance and acceptability among women in northern Thailand. *J Acquir Immune Defic Syndr.* 2003;33(2):194–198.
- Greensides DR, Berkelman R, Lansky A, et al. Alternative HIV testing methods among populations at high risk for HIV infection. *Public Health Rep.* 2003;118(6):531–539.
- Hutchinson AB, Corbie-Smith G, Thomas SB, et al. Understanding the patient's perspective on rapid and routine HIV testing in an inner-city urgent care center. *AIDS Educ Prev.* 2004;16(2):101–114.
- Malonza IM, Richardson BA, Kreiss JK, et al. The effect of rapid HIV-1 testing on uptake of perinatal HIV-1 interventions: a randomized clinical trial. *AIDS.* 2003;17(1):113–118.
- Dietz CA, Ablah E, Reznik D, et al. Patients' attitudes about rapid oral HIV screening in an urban, free dental clinic. *AIDS Patient Care STDS.* 2008;22(3):205–212.
- Bhore AV, Sastry J, Patke D, et al. Sensitivity and specificity of rapid HIV testing of pregnant women in India. *Int J STD AIDS.* 2003;14(1):37–41.
- Saville RD, Constantine NT, Holm-Hansen C, et al. Evaluation of two novel immunoassays designed to detect HIV antibodies in oral fluids. *J Clin Lab Anal.* 1997;11(1):63–68.
- Yao K, Wafula W, Bile EC, et al. Ensuring the quality of HIV rapid testing in resource-poor countries using a systematic approach to training. *Am J Clin Pathol.* 2010;134(4):568–572.
- Anaya HD, Bokhour B, Feld J, et al. Implementation of routine rapid HIV testing within the U.S. Department of Veterans Affairs Healthcare System. *J Healthc Qual.* 2012;34(5):7–14.
- Levison J, Williams LT, Moore A, et al. Increasing use of rapid HIV testing in labor and delivery among women with no prenatal care: a local initiative. *Matern Child Health J.* 2011;15(6):822–826.
- Hsieh YH, Jung JJ, Shahan JB, et al. Emergency medicine resident attitudes and perceptions of HIV testing before and after a focused training program and testing implementation. *Acad Emerg Med.* 2009;16(11):1165–1173.
- Choudhury LP, Kutty VR. Obstetric practices related to HIV in Kerala. *Indian J Med Ethics.* 2007;4(1):12–15.
- Genet P, Legall C, Peudepiece P, et al. Difficulties of routine rapid HIV screening in emergency department. *Retrovirology.* 2010;7(suppl 1):49.
- Sohoni A, Gordon DM, Vahidnia F, et al. Emergency department staff satisfaction with rapid human immunodeficiency virus testing. *Acad Emerg Med.* 2010;17(5):561–565.
- Bogart LM, Howerton D, Lange J, et al. Provider-related barriers to rapid HIV testing in U.S. urban non-profit community clinics, community-based organizations (CBOs) and hospitals. *AIDS Behav.* 2010;14(3):697–707.
- Carballo-Díéguez A, Frasca T, Dolezal C, et al. Will gay and bisexually active men at high risk of infection use over-the-counter rapid HIV tests to screen sexual partners? *J Sex Res.* 2012;49(4):379–387.
- Hsieh YH, Gaydos CA, Hogan MT, et al. What qualities are most important to making a point of care test desirable for clinicians and others offering sexually transmitted infection testing? *PLoS One.* 2011;6(4):e19263.

30. Centers for Disease Control and Prevention. Quality assurance guidelines for testing using rapid HIV antibody tests waived under the Clinical Laboratory Improvement Amendments of 1988. 2007.
31. Beckwith CG. Letter to the editor—response to: “Feasibility and acceptability of rapid HIV testing in jail”. *AIDS Patient Care STDS*. 2007; 21(10):717.
32. Mkwanazi NB, Patel D, Newell ML, et al. Rapid testing may not improve uptake of HIV testing and same day results in a rural South African community: a cohort study of 12,000 women. *PLoS One*. 2008;3(10):e3501.
33. Darling KE, Diserens EA, N'garambe C, et al. A cross-sectional survey of attitudes to HIV risk and rapid HIV testing among clients of sex workers in Switzerland. *Sex Transm Infect*. 2012;88(6):462–464.
34. Cohall A, Dini S, Nye A, et al. HIV testing preferences among young men of color who have sex with men. *Am J Public Health*. 2010;100(10):1961–1966.
35. FDA. *First Rapid Home-Use HIV Kit Approved for Self-Testing*. Silver Spring, MD; 2012.
36. Pant Pai N, Balram B, Shivkumar S, et al. Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis. *Lancet Infect Dis*. 2012;12(5):373–380.