

Perspective on HIV Self-testing in North America: A Tale of Two Countries—US and Canada

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ABSTRACT: Long waiting time in clinics, loss of working days to obtain an HIV test result, fear of social visibility, perceived stigma, and discrimination, associated with facility-based HIV testing impede testing efforts. Not surprisingly, therefore, about 25% of Canadians and Americans with HIV continue to live unaware of their positive sero-status, and knowingly or unknowingly contribute to continued HIV transmission in their communities. To such individuals, self-testing for HIV, offers one potential, proactive, de-stigmatizing screening solution. Individuals can screen themselves in the comfort of their home or assisted by a health care professional, and combine it with remote on phone or in person expedited counseling. Self testing has the potential for expanded access, and offers a confidential private testing option, but high costs of currently approved self test, concerns about timely linkages to counseling and care, coupled with a lack of awareness and knowledge about self tests, in communities that desire it the most, stand as obstacles to its expansion. Will self-testing strategy, achieve its destiny of reaching the untested and of expanding access in a people-friendly convenient and affordable manner? Will it succeed in linking people to counseling and care in a timely manner? And, lastly, Will it also bring many more partners to self-test? In this perspective, we explore some of these questions, discusses potential ways in which self testing for HIV could be offered, accessed, expanded, operationalized within Canada and US, to help reach many more individuals that desire a self testing solution.

KEYWORDS: HIV Self testing, North America, Canada, US, perspective

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In 2012, the United States (US) Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) approved the world's first self-test for HIV, an historic decision that turned the tide in favor of normalization of HIV diagnoses.¹ Little did FDA's BPAC know that their approval of the first ever over-the-counter self-test for HIV would catalyze a global momentum in favor of HIV self-testing. HIV self-tests are now on their way to becoming approved in several countries around the world—Britain, France, Denmark, Macau, Hong Kong, Singapore, to name a few.^{2,3} Evidence in favor of self-testing has been published from countries as far as South Africa, Malawi, Uganda, and Kenya.⁴ While in the United States, the FDA is probably in the process of approving other

newer self-tests, Canada is now faced with the need to approve such tests as well, given their explicit demand expressed by communities impacted by the HIV epidemic.

Conventional HIV testing, available since the early 1990s, has clearly failed to reach those who wish to get tested but are unwilling to go to a facility for it.⁵ Although an HIV diagnosis is no longer the “death sentence” as it was 30 years ago,⁶ a diagnosis of HIV even today, in 2014, is stigmatized! It is no surprise therefore that awareness of HIV sero-status continues to be hindered by many sociocultural and contextual barriers. To name a few, stigma, discrimination, long waiting time in clinics, loss of working days to obtain an HIV test result, and social visibility associated with facility-based



testing impede testing efforts.^{7,8} These factors or barriers to testing may sound archaic, but have nonetheless been documented to derail testing even in North America. It is no surprise therefore that about 60% of HIV-positive individuals worldwide^{9,10} and 25% of HIV-positive Canadians¹¹ and Americans continue to live blissfully unaware of their positive sero-status.¹² Many of these individuals transmit the virus unknowingly to their partners and their communities. This potentially impedes our efforts to control HIV infection.

In this context, a self-testing strategy (with tests sold over-the-counter for testing at home and counseling offered on the phone) is pragmatic and bold.^{4,13} It not only offers a destigmatizing alternative to conventional testing but also creates a direct passage to one's knowledge of the HIV sero-status. It not only allows individuals to test themselves in the comfort of their home or assisted by a health care professional, but also offers options to combine it with remote or in person expedited counseling. With this strategy, people can conveniently know their HIV status, while avoiding visibility and long travel and waiting times associated with facility-based testing. The premise is that an offer of convenience along with the time savings could potentially increase the uptake of HIV testing, encourage repeat testing in populations with risky behaviors, and also partner self-testing, while expanding access to HIV testing along the way.¹⁴

However, even though this over-the-counter test-based self-testing strategy has been available in the US since 2012, it is not without some caveats.^{1,10,15} Self-tests kits, as currently available in the US, are expensive (\$40) and assume individuals to be proactive and motivated to buy the test, conduct, and interpret their self-test result, and then call and seek linkages. Linkages for self-test positives entail initiation of post-test counseling, additional confirmatory tests, and referrals for newly diagnosed HIV positives to specialized HIV clinics. Linkages for self-test negatives entail post-test risk-reduction counseling and advice for repeat testing in three to six months. Successful operationalization of linkages will determine the success of this strategy in future.

In this context, it is reasonable to question the following: (a) Will self-testing strategy achieve its destiny of reaching the untested and of expanding access in a people-friendly convenient and affordable manner? (b) Will it succeed in linking people to counseling and care in a timely manner? and (c) Will it also bring many more partners to self-test?

In this perspective, we explore some of these questions and also examine some factors that may work in tandem toward a successful implementation of this strategy.

Self-testing is a Process of Diagnosis and Behavior Change

Self-testing has to be viewed as both a process of diagnosis and an agent for behavior change. Any individual contemplating the purchase of a self-test goes through the process of behavior change that includes a pre-cognition phase and

cognition phase, followed by an action phase (which leads to the purchase of the self-test).¹⁶ Likewise, the process of self-testing toward a diagnosis (with a positive or negative result) is also complex. This process entails accurately understanding the self-test instructions, conducting the self-test correctly, and interpreting the test results accurately. Finally, the process does not stop at obtaining a diagnosis: the self-tester needs to be proactive in seeking linkages by calling a confidential toll-free hotline either for post-test counseling or for confirmatory testing, staging, treatment referrals, treatment initiation, and continued care. Thus, self-testing is only a preliminary attempt to know one's sero-status. Like an over-the-counter pregnancy test, an HIV self-test result will always require a confirmatory test to confirm or refute an initial diagnosis made by a self-test before treatment could be considered. Furthermore, if any of the self-testing steps are done incorrectly, the process of self-testing could be jeopardized and that is always a possibility.

It is therefore reasonable to question whether lay people can indeed correctly self-test or accurately interpret their own result and rapidly seek linkages to post-test counseling and care.^{7,17-19} This is because potential self-testers may vary in literacy, comprehension, motivation, and proactivity levels. Indeed, much is assumed of the lay tester—if the lay tester does not call for linkages or act upon the test result, or if he or she does not have sufficient literacy (grade 6 and above) to confidently conduct and interpret his or her own self-test result, then the process of self-testing will not be considered complete. It will not help him or her and may even be detrimental to him or her and to the community. However, sometimes, such concerns are often ignored in our real-world clinical evaluations where many volunteers self-select when they agree to participate in studies and are motivated, educated, and informed than the lay user.

Self-testing Strategies are Dependent on the Context in Which they are Implemented

As evidenced from our systematic review, two kinds of self-testing strategies, such as supervised self-testing and unsupervised self-testing, have been evaluated in research settings worldwide.⁴ Both supervised self-testing strategies (ie self-testing and counseling aided at any time by a health care professional) and unsupervised self-testing strategies (ie self-testing performed unaided by a self-tester by himself, with counseling and linkages sought confidentially over the phone/internet)⁴ have reported encouraging findings. These include a high acceptability (74–96%), preference (61–91%), and partner self-testing rate (80–97%). Additionally, both strategies reported a high specificity of self-testing (range: 99.8–100%), albeit a lower sensitivity was reported for an unsupervised strategy (range: 92.9–100%; one study) when compared with supervised strategy (range: 97.4–97.9%; three studies).⁴ Variation in literacy and operational errors in conduct could contribute to this discrepancy in accuracy, with the same oral test that was used for both these strategies. Findings explain that



despite an accurate test, conduct of self-tests could be jeopardized at any time. Besides the impact of literacy, comprehension on accuracy has not yet been evaluated.

Although strong findings in terms of linkages were reported for the unsupervised strategy, 96% of preliminary positive individuals who self-tested sought post-test counseling.

Recent trials from Uganda and Malawi have reported sensitivity estimates of 89–90% for an unsupervised strategy vs. 100% for a supervised strategy.^{4,20} Therefore, discrepancy in these estimates merit a scrutiny for future improvement.^{21,22} Overall, an offer of privacy, time savings, convenience, and successful initiation of linkages to treat individuals who tested positive in preliminary self-test facilitated a high acceptability and preference for both self-testing strategies. However, more controlled trials and implementation research from diverse settings have been warranted to confirm these findings.⁴

Delivery and Accuracy of Self-testing Strategies can be Facilitated or Optimized by Innovations

Sensitivity of a self-test and linkages to care could be improved substantially if the process of self-testing is supported by innovative instructions (pictorial, online internet-based applications, or phone-based applications). This was evidenced in our study, where our laboratory-created internet and smartphone applications were evaluated in an unsupervised self-testing strategy by health care professionals in South Africa.²³ These applications not only improved the conduct and interpretation of self-testing but also increased linkage rates (up to 100%). These findings suggested that guiding users with an instructional package may help bump up sensitivity to levels acceptable to many stakeholders (ie at 98.5% in low prevalence vs. 100% in high-prevalence settings).^{4,24} Supported devices with smart instructions or instructions guided by health care professionals will help produce better results, hence the need for a supervised self-testing strategy.

The oral fluid-based point of care test (POCT) is 98.5% sensitive and 99.9% specific in the hands of health care professionals and in research studies.²⁴ However, the accuracy of the oral fluid-based self-test has varied with prevalence, contexts, populations studied, and performance by lay testers versus educated testers. While the study presented to the FDA found the OraQuick self-test to be 93% sensitive among lay testers,¹ a recent study from France reported a sensitivity of 87.2% (81.5–91.3) for OraQuick and 88.3% (82.7–92.2) for DPP test.²⁵ Better tests with high sensitivities are always desired, but it is also important to know that sensitivity and specificity parameters will always vary with the prevalence and the type of patients/clients studied. In high prevalence settings, say >5% or 10%, the positive predictive value of the self-test will be high, but in low prevalence settings (<1%), positive predictive value of the self-test will be low. While a highly sensitive self-test is desirable in low prevalence settings, any antibody-based test will still be limited in detecting

seroconversion within 90 days. So, clear messaging about when to self-test will be extremely important to prevent misguiding customers who happen to self-test after a recent exposure and therefore end up with a false negative result.

Furthermore, reported results from a recent randomized controlled trial in Malawi found a sensitivity of 89%²⁶ amongst lay users. Although, variation in literacy could contribute to the discrepancy between supervised and unsupervised strategies, this factor has not been explored in detail to date. Along with literacy, comes in comprehension of facts and careful conduct. However, baseline literacy was assessed in participants in the FDA trial. Further, in this trial, even after the instructional booklet that comes with the self-test was refined, up to 1.25% (95% CI: 0.95–1.63%) of the subjects failed to obtain a test results due to operational error.¹ These real-life accuracy results point to the need for targeted evidence-based applications that will support the self-tester in using the device, improve knowledge and awareness, and reduce operational errors that improve confidence in test results.

Oral- or Blood-based Self-tests are Limited by the use of an Antibody-based Test

A self-test that is antibody based has an inherent limitation associated with getting an accurate result within 90 days of infection (because of the lack of p24 antigen). This limitation prevents these devices from being an ideal self-test. Therefore, it may be wise to recommend repeat testing after 90 days in case of a recent exposure (unprotected sexual encounter with a suspected partner or unsuspected exposure) to rule out the possibility of being infected or follow up with a clinic-based confirmatory test. Confirmatory tests include new RNA-based tests and combined (antibody and antigen based) blood-based point-of-care tests that can detect HIV in less than 30 (range 7–24) days. Confirmatory tests can also be recommended to anxious testers who do not believe their test result. These additional tests can help pick up infections missed by home self-tests. Thus, in a low-prevalence setting, and in a high-risk population, this is a likely scenario because timing of the self-test may be of essence. In contrast, in a high-prevalence setting, the possibility of a false-negative test result, although likely, is minimized if prevalence levels in subpopulations are at 5–10%. At high-prevalence levels, accuracy of the test improves.²⁴

Regardless of these limitations, all at-risk populations will benefit from knowing their sero-status within a three- to six-month time window vs. not at all, the latter scenario being more likely without the introduction of self-testing.

That being said, it may be wise to prime individuals repeatedly about the limitation of the antibody-based self-tests.²⁴ It may also be wise to prime them to the possibility of taking a repeat self-test, a p24 antigen-based ELISA, or POC test, if they suspect a false-negative result. All these limitations must also be communicated to improve confidence in testing initiatives.



Self-testing Calls for more Implementation Research and Modeling Studies

Currently, there is a lack of global data from mathematical models on the cost-effectiveness, the impact of self-test frequency, and also the public health impact of the introduction of self-tests or strategies on the following outcomes: control of HIV infection or a reduction in transmission. This limits the ability of public health agencies to consider recommending any strategy in their settings.

However, only one modeling study from the US (Seattle) suggests that the replacement of clinic-based tests with home tests in sub-populations such as men who have sex with men (MSM) could potentially increase the detection of HIV, and HIV prevalence as a consequence, to about 28% (if no increase in self-testing frequency is assumed).²⁷ But, if we assume a 2.6 times increase in self-testing frequency, then self-testing could increase detection and subsequent prevalence estimates by 22%. So, in all 22–28% increase in prevalence is to be expected for high-risk populations.²⁷

This statistic suggests that introduction of self-tests will improve uptake of testing, subsequent detection, and estimates of HIV prevalence. It could also encourage an increased frequency of testing and thereby expand access to testing. Therefore, if linkages are conveniently operationalized, it could bring more people into care, thereby bringing about a reduction in transmission. If this happens, then clinics must be prepared to take in new patients, link them into care, and keep them in care.

That being said, better epidemic, economic, or epidemic-economic transmission models are needed to inform policies for both countries, the US and Canada.²⁸ Even more so, more data from sub-populations other than MSMs are needed to better model the trajectories of participants who may seek testing and get linked to care post-testing. Such populations could also include African American and Hispanic Americans for the US, and immigrant minority women, commercial sex workers, aboriginals, and immigrant populations from endemic countries, for Canada. Also, there is an implicit difficulty in obtaining some of the self-testing data, because in part, these tests are novel and data on potential impact can only be guesstimated. One project is currently underway in Quebec to explore the public health impact and cost-effectiveness of self-testing.²⁹

Feasibility of Operationalization

Some caveats in execution of self-testing strategies must be kept in mind. One could also argue that although repeat self-testing has its advantages, it is also associated with increased cost and it could also complicate interpretation of test results in the hands of the lay user. First, a recent sero-convertor in a span of one to three months could find himself reading two self-test results: one with a negative and the other with a positive result. This could lead to some anxiety and confusion, and timely counseling and confirmatory testing will be key to its resolution. Second, test interpretation issues must

be addressed immediately (by counseling participants on the phone or online) so that anxiety associated with weak false-positive or weakly reactive tests, and discordant first and second tests are allayed. Third, timely referrals to the nearest pharmacy-based counselor, or clinic-based provider, will help in resolution of confusion associated with test results. Fourth, but for the other issues, a reduction in unit price of the tests could be balanced by an increase in test frequency. Last, but not the least, in the context of the proposed expansion of self-testing initiatives globally, many more patients will be detected and many more will need treatment. For the strategy to be successful, this possibility has not yet quantified but must be considered.

In the United States, the uptake of these self-tests has been limited by high costs and thereby by low uptake in marginalized communities that are deeply impacted by the epidemic. Supervised self-testing strategies are not yet being offered by any clinic or outreach site, although they have been explored in research studies^{30,31} and evidence has been reported in its favor. An over-the-counter self-test is currently the status quo. In Canada, currently, we have no approved over-the-counter self-tests.

Anecdotally, some sub-populations in Canada have demanded prescription self-tests. These populations are likely to avoid showing up in clinics, for conventional HIV tests. Although self-tests reduce the time taken for the first test, follow-up on linkages will need to be sought by the testers at all times and these are dependent equally on the tester, the test procedure, and the testing facilities.

Self-tests therefore offer the promise of a rapid initial uptake, but a convenient operationalization of confidential and rapid linkages to care will only determine their sustainability. And for that, parallel or integrated systems if set up to expedite linkages will help improve confidence of populations, in this new screening strategy. If this is not done, then patients are likely to face delays in seeking the cascade of care. This reality, which is a possibility in global settings, would not happen in Canada because of the linked systems in place, but delays cannot be ruled out completely.

Global Evidence on Self-testing

Self-testing must therefore be viewed as a conduit or an alternative to seeking rapid care, often at the cost of increased volume of downstream testing done at conventional testing sites but for the goodness of patient populations. It has benefits of rapid early detection and improved numbers of detection. There is an overwhelming amount of global evidence in favor of self-testing (especially in terms of acceptability, preference, uptake, and referrals for partner self-testing). For instance, a recent US study in MSM populations in which options to test were offered to study participants reported that home self-tests and testing in physicians' offices were most preferred by them.³² These studies indicate that because patients prefer home tests, therefore perhaps, improving testing frequency



with provision of many self-tests might help offset some of the limitations of these tests in picking up acute HIV infection (at 90 days vs. 30 days or less). Repeat self-testing could be emphasized and highlighted for some sub-populations or individuals with high-risk profiles.

To date, globally, only two countries have made some progress in the sphere of self-testing—Kenya³³ and the US.³⁴ While US approved HIV self-testing devices, Kenya approved self-testing strategies for its health care professionals.³⁵ Many studies are now being conducted on self-testing globally, and laws are being revised in parallel to facilitate the introduction of these tests, much remains to be done in terms of country-specific policies and strategies and programs to improve their introduction and monitor their performance (post-marketing surveillance).³⁶

Self-tests for HIV have been banned in a few countries, such as India,³⁷ and a few countries in Europe.³⁸ This is because agencies are concerned about a potential misuse of these HIV tests and also worried about sales of inappropriate tests or copy tests in the open market. Likewise, advertising and promotion of poor-quality tests that masquerade as self-tests is also banned. However, in the past two years, a huge demand for self-tests have prompted many big and small diagnostic companies to manufacture both oral and blood-based self-tests. In keeping the global need and demand, last year, the World Health Organization (WHO) raised the necessity of additional global feasibility research to determine the viability of self-testing internationally.^{5,15}

Self-testing in the Canadian Context

In Canada, in the years to come, the Public Health Agencies will need high-quality implementation science data on self-testing to guide their policy decisions. The need for introducing an option to self-test is evident in the light of the epidemic. Equally, the desire to self-test has been expressed by at-risk sub-populations. The operational and integration challenges are different for different sub-populations that have distinct socioeconomic educational profiles, lifestyle, circumstance that dictate needs, and preferences for such strategies. And these need to be kept in mind while developing optimal strategies for them.

According to Public Health Agency of Canada (PHAC), in 2011, there were approximately 71,300 (58,600–84,000) people living with HIV in Canada, an 11.4% increase over 2008 because of new transmissions and improved survival, in which at-risk populations such as MSM were over-represented. MSMs accounted for almost half (46.7%) of the population living with HIV.¹¹ MSMs could consider self-testing, given their historical knowledge of risk levels, educational background, and empowerment and engagement in proactive health behaviors. Particularly, MSMs who engage in high-risk sexual behavior and who might desire frequent testing may opt to perform HIV testing in the convenience of their home. In fact, anecdotal evidence suggests that MSMs would

be interested in accessing self-tests, especially those who are younger, less educated, and living in smaller towns, in a conventional family or with a wife and family.^{39,40}

Other populations who may benefit from self-testing include immigrants from endemic countries, minority women, and aboriginal populations with high incidence and prevalence of HIV. Besides commercial sex workers, and maybe the traditional high-risk populations of injection drug users, women represent a group with substantial proportion of incident infections.^{41,42} Therefore, for the 25% of HIV-positive Canadians who remain unaware of their HIV status, thus continuing to spread HIV to their unsuspecting partners, an offer of self-test may be a potential life saver.¹¹ A timely offer of self-test with linked care may then save costs to the health systems.

In addition to human lives that are lost, HIV infection represents a huge economic burden for Canada. In 2011, the estimated costs of health care, loss of labor productivity, and quality of life generated by HIV infection in Canada amounted to more than \$4 billion.⁴³

In Canada, HIV screening is regulated at the provincial level and offered at primary clinics or mandated testing facilities. Conventional testing at a health facility can be: (a) nominal (ie the name of the person tested appears on test forms, results, and medical records), (b) non-nominal (ie the test is ordered using a code, but the result is recorded in the patient's medical records), or (c) anonymous (ie a code is used instead of the name of the patient). Anonymous testing is available only in seven provinces,^{44,45} while notification of HIV positivity is mandatory in all provinces. If people at high risk adopt self-tests for HIV and seek and get timely linkage to counseling treatment and care, it could realistically impact the Canadian HIV landscape, but again all these hinge on effective operationalization of linkages to counseling, referrals, treatment, and care. Self-testing strategies offered by the establishment of public private partnerships, in communities, outreach settings, pharmacies, emergency departments, STD clinics, could enable early ART initiation by helping to pick up positive cases earlier.

Early initiation of antiretroviral treatment (ART) reduces morbidity and mortality^{46–48} and costly hospitalizations because of comorbidities commonly seen in HIV,^{49–51} but its success is contingent upon early detection of HIV, which requires access to counseling and referral services. Unfortunately, 64.2% of newly diagnosed HIV-positive individuals during 2001–2005 in Canada progressed to AIDS in one year,⁵² and about half (54%) of new HIV patients present with low CD4 levels.⁵³ In southern Alberta, 71% of the newly diagnosed patients in 2009 were immunosuppressed, and 38% had advanced HIV infection.⁵⁴ Finally, surveillance data from the Institut national de santé publique du Québec (INSPQ) showed that 16.3% of the people who tested positive for the first time already had AIDS or advanced HIV infection.⁵⁵ Late presentation creates an enormous economic burden: in



Alberta, the mean cost per patient per month for late presenters was 55% higher than what was spent on early diagnosed patients (\$10,968 ± 5,677 per year).⁵⁴ These high costs and unfavorable outcomes of overdue treatment call for a greater emphasis on early diagnosis of HIV infection for all Canadian provinces.^{56,57}

Self-testing in the US: The Promise of Expanded Access, Early Diagnosis, and Prevention of Onward Transmission

A modeling analysis recently conducted in the US reported that assuming a sensitivity of 93% for self-tests and assuming that 25% of individuals are unaware of their sero-status, the introduction of self-tests would greatly help reduce transmission rates.⁵⁸ It was estimated by the test manufacturers that the projected incremental benefit of the deployment of self-testing was the prevention of 700 onward HIV transmissions per year for every 1,000,000 tests.¹ Currently, there is no industry-independent estimate for the Canadian context. As promising as self-testing sounds, there is a need for estimates and also innovative service delivery models.^{5,15} However, concerns have been expressed against the introduction of self-tests. These include the following: (a) the risk of obtaining false-negative results in the window period,^{14,59} (b) the risk of incomplete counseling and care,⁵⁹ (c) high costs and affordability of self-tests by populations in need,^{59,60} and lastly, (e) concern over effective operationalization of linkages to treatment and care.^{27,59,60} These concerns also apply to Canada.

Evidence for Service Delivery Models and Strategies for Canada

There is clearly no single service delivery model nor strategy that will magically work for all populations around the world.⁴ Likewise, in Canada, we will need to develop and evaluate several different models and strategies for the multicultural and multifaceted Canadian populations across provinces. For example, populations deeply impacted by the HIV epidemic, in particular MSMs, have raised the need to approve these tests in Canada and have demanded prescription of self-tests to frequently monitor their sero-status. Similarly, immigrants from endemic countries typically get tested for HIV once entering the country. If they perceive the need to get tested again, they may prefer to self-test at home. Minority women populations may get tested again if they get pregnant.

Education levels, Internet and Wi-Fi, and smartphone penetration are high in the educated middle-class Canadian population. These populations could be assisted by online software and smartphone or mobile phone applications that can guide them through the process of self-testing and of linkage seeking to care. In this space, our innovations could be adapted for Canadians,²³ They can aid in the operationalization of such e- and m-health-enabled linkages for a sizeable educated population in Canada.

In addition to the high-risk groups, low-risk young adults and youth, who are on social media and very familiar with technology, might also wish to self-test. These groups may also prefer alternative modes of timely counseling on the internet- and smartphone-based facilitated post-test linkages to care. Commercial sex workers who own mobile phones could similarly be reached. This form of online and app-facilitated testing is clearly becoming popular in the world, as proven for a few other sexually transmitted infections.^{30,61-67}

Again, e- and m-health-based innovations can only reach such populations with a certain level of income. But, for aboriginal populations, an assessment of their needs, preferences, community preparedness, and adaptation of the best self-testing strategy (facilitated either with or without a mobile phone in outreach clinics) that suit their lifestyles and circumstances are needed. Further, creative out-of-the-box innovative, community sensitive solutions are required to address their needs and preferences for operationalization of self-testing strategies. Finally, provided continuity of care is maintained for its continued success.

Business Models and Public Health Strategies Will Vary According to The Health Care System in the Countries

To deploy self-testing strategies, there is an imperative need to think outside the box. Several different business models for private developers, and public health strategies for provinces, could be worked at to make it a reality. For example, the prevailing US model (of an over-the-counter sale of self-tests in pharmacies and online, with toll-free counseling provided by trained counselors at call centers) is one of the several possible business models. In the US, self-tests could also be viewed as triage tests or as replacement tests for clinic-based testing. Even more so, a bolder supervised self-testing strategy could be offered in clinical settings as successfully proven in research by the use of tablet-based kiosks in emergency room settings.³¹ This approach could also help expand the reach of self-tests and aid onsite rapid initiation of linkages. These strategies could also be expanded or integrated in mobile van-based test sites or community outreach clinics.

Canada has universal access to health care, and proven evidence of community-based point-of-care rapid testing programs in selected provinces (ie Ontario, British Columbia, Quebec). An offer of self-testing strategies (both, supervised and unsupervised) with linkages to counseling and clinics is a possibility through partnerships. Therefore, both self-testing strategies could be operationalized in various ways: (a) through an over-the-counter sales in pharmacies linked to clinics; (b) by discounted sales in community STD and HIV clinics with established links to counselors and referrals to care, or (c) by offering discounted or free supplies to established outreach mobile point-of-care testing sites with established counseling and treatment referral linkages, and lastly (d) by



offering self-tests in doctors offices, specialized HIV clinics, and dental clinics.

Besides, if the volume of sales is large enough, a reasonable retail price for expanded access in under-resourced communities could be negotiated. A high price point (40–50\$) will deter scale up, and a modest price point (10–20\$) will encourage more people to avail such a strategy.

It is also important to talk about the economics of linkages. This includes linkages with respect to counseling and staging for treatment. For that, a fee for service model could be used as is available for rapid point-of-care testing in many private clinics in different provinces or, it could be synergized with the available counseling linkage models in place in community clinics across provinces. Each province has its own structure of care, and existing infrastructure could be optimized for an offer of self-tests. At all times, however, a reasonable pricing policy of the self-tests will aid expansion, access and facilitate easy availability of tests, and counsel on the phone or internet. For the very poor populations, however, a supervised (on site) self-testing strategy that is perhaps free remains a reasonable option.

In the first self-testing study conducted in a low-risk population of Canadian students,^{13,68} we demonstrated that self-testing in a University-based health clinic was preferred to the current conventional model of rapid testing. Convenience, savings in waiting time, confidentiality, and ease of use were other factors in its favor.

In community clinics, where rapid HIV testing is already being offered, some clients may consider supervised self-testing because of the considerable timesaving it offers in seeking an initial test. Procedures that are set up to avail tests will also need to be modified to accommodate them. Besides, in such clinics with rapid testing in place, adding another option of self-testing for HIV could potentially be cost and time efficient, in that it may increase access and lead to a greater engagement of patients in their own care. Communities may find an offer of supervised self-tests counter-intuitive. In that, it is intended for those test takers who show up repeatedly for testing. In these clinics, prescription of self-tests could be considered. This strategy could also help spread the word to seek testing, encourage more partners to get tested and counseled, and also more that could be easily guided (on phone or via the internet) by counselors available in clinics and thus offer a sustainable 24/7 convenient testing option.

A similar strategy could be operationalized out of our pharmacies. These pharmacies are more conveniently located in the community and have infrastructure (online prescription bookings) in place that could be optimized for such a service.

Better Costs and Affordability

However, the cost of the over-the-counter test is an issue: current cost in the US is 40 USD, and in the open retail and online markets, sometimes the kits are sold for higher price. This could be too high for some individuals with limited disposable

income. With FDA trials for two other self-tests (manufactured by Calypte Biomedical Corporation and Chembio Biodiagnostic Systems) underway in the US, the cost of these tests is expected to fall in the near future. One company alone may not be enough to provide self-tests, so many more companies are likely to enter the market, and perhaps produce even better self-tests, and drive down the price of tests.

Although oral fluids are noninvasive, convenient, and give consistent results, blood-based finger stick self-tests that detect antigen and antibody are also likely in the near future.⁵ Recently, FDA approved a blood-based point-of-care combination test—the Alere Determine HIV-1/2 Ag/Ab Combo Test (Alere™ Inc., Waltham, MA, USA). This test can also pick up p24 antigen as early as within 24 days. Blood-based self-tests, if made minimally invasive and relatively pain-free comparable to the noninvasive oral self-tests, could also be self-tests. They will score high on accuracy and could work for those individuals who will desire a rapid result after an unprotected exposure. Regardless, until that happens, the ability of the antibody-based oral and blood-based tests to pick up infection accurately only after 90 days of exposure must be emphasized.⁶⁹

In the near future, self-tests may become as cheap and affordable as pregnancy tests, and operationalization of linkages through the click of smartphones or computers could become a reality with effective synergy with pharmacies that sell them, or clinics or mobile/outreach sites, which have the infrastructure for them. If community clinic partnerships and collaboration for linkages happens in Canada, then the story of AIDS exceptionalism could potentially become a chapter of note in the history books. If all the stakeholders and players involved in testing coordinate and make it work, then the dream of helping people knowing their sero-status conveniently and in their own preferred ways should not be too far.

Harms Associated with Self-testing Strategies

Partner notification and its sequel, such as the possibility of domestic violence, the possible risk of discrimination in sero-discordant relationships, and the possibility of self-harm, have not been ruled out. They are hard to study in a research context,^{4,14,22} but could be a reality when these tests are rolled out. Likewise, the possibility of coercive testing with self-tests prior to intercourse^{14,59} cannot be ruled out. Similarly, mandatory testing by insurance companies and prospective employers could also happen. But such instances of abuse could occur even with conventional tests as they are related to a diagnosis of HIV and not necessarily to the process of self-testing, although the latter helps uncover the diagnosis. Such situations, as sad as they may be, are beyond the purview of studies, but are a possibility. Mitigation strategies or steps to prevent harm, such as domestic violence help lines or counseling lines, may help prevent possible sequel. This is relevant for communities where stigma and discrimination are rampant.



In Canada, much remains to be done. Along with implementation research into effective strategies, modeling studies that demonstrate the public health impact of self-testing are needed. Rural and peri-urban communities may not be prepared for the introduction of point-of-care tests, let alone self-tests—Aboriginals and other rural and ethnic minority immigrant populations need to be informed about these self-tests and engaged in discussions on methods to introduce them in their preferred way. Such a participatory, end-user centered, patient-preferred approach will help bring about a more refined, nuanced introduction of these tests that will probably be met with success. For the rest of us, for now, this strategy offers a ray of hope of bringing many more into care.

To conclude, HIV self-testing will always be the middle road to enhanced engagement of sub-populations into clinical care.²⁰ But before this strategy can be hailed as a game changer, multiple obstacles stand in its way and a clear concerted plan of action has not yet been realized for any country. Multiple challenges stand in the way of implementation of both unsupervised and supervised strategies, which include the following: (a) public–private partnerships for a seamless connected system of care; (b) engagement of trained counselors; (c) setting up supervised self-testing kiosks in emergency rooms, outreach settings, mobile vans, community clinics, and HIV clinics; (d) payment systems for screening and linkages for both unsupervised and supervised strategies if offered privately; (e) creative payment solutions for mobile phone-based and internet-based counseling that can reach many more populations Canada-wide; (f) effective communications between different stakeholders involved in the testing and counseling process; and, lastly, (g) expedited confirmatory tests available through public and private channels. These challenges if successfully navigated, could help improve the uptake of self-testing. (h) Effective partnerships and collaborations will not only create a framework but also a sustainable platform of care. This platform could also be used for other HIV-related co-infections, in the pipeline, that fancy a futuristic self-testing strategy. Besides, this platform will not only help current generations of testers, some of which have to live in denial, and contend with stigmatization and discrimination today, but also the incoming generations of tomorrow, who will be able to deal with their diagnosis much more confidentially.

An ideal model or strategy of linked care will be a first step toward making an HIV self-testing strategy a real game changer—that vision is yet to be realized, and much remains to be done in pursuit of that destination.

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Author Contributions

NPP conceived and designed the experiments, analyzed the data, wrote the first draft of the manuscript, developed the structure and arguments for the paper, and made critical revisions and approved the final version.

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