



## The routine offer of HIV testing in primary care settings: A review of the evidence

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The routine offer of an HIV test (routine testing) is the practice of systematically approaching patients with an offer of an HIV test when seeking healthcare, regardless of known risk factors or symptoms of HIV infection. The aim of routine HIV testing is to increase the number of people screened for HIV; support the diagnosis of HIV; and link people who are diagnosed with HIV to clinical services.

Routine testing can be implemented in any healthcare setting. This review details routine testing programs in primary care settings such as community health centres (CHCs) and sexual health clinics.

### A note on the language used in this review

We use the terms *routine offer of testing* and *routine testing* interchangeably, acknowledging that patients should only be tested with their explicit, informed and voluntary consent.

We use the term *offer* for both opt-in and opt-out programs when patients are approached for testing.

We use the term *accept* when patients in opt-in programs agree to testing, and patients in opt-out programs do not decline testing.

### What are the findings of this review?

We reviewed the available scientific evidence to determine if routine HIV testing in primary care settings improves HIV testing outcomes. The evidence was:

1. **Moderate that patients are offered HIV testing within routine testing programs.** While the majority of studies found offer rates of 75% or greater in various primary care settings, offer rates ranged from 9% to 96%. Generally, higher offer rates occurred with the use of an opt-out approach to routine testing.
2. **Moderate that HIV tests are accepted when offered within routine testing programs.** HIV test acceptance rates varied between 35% and 89%.
3. **Moderate that routine testing programs result in patients receiving an HIV test and that it results in an increase in the absolute number of tests performed.** Patient testing rates ranged from 11% to 90%. All studies that investigated if there was an increase in the absolute number of tests performed found an increase compared to a time period before the implementation of routine testing.
4. **Strong that routine testing programs identify people living with HIV at rates above the cost-effectiveness threshold of 0.1%.** Seropositivity rates in primary care settings ranged from 0% to 2%, with the vast majority of studies finding rates above 0.1%.
5. **Moderate on whether people diagnosed with HIV are linked to care in routine testing programs.** Between 77% and 100% of people diagnosed with HIV were linked to HIV care.

## Summary Table: Evidence to support routine offer of HIV testing outcomes

	Strong	Moderate	Limited	Mixed
<b>HIV test offer</b>		X		
<b>HIV test acceptance</b>		X		
<b>HIV test completed</b>		X		
<b>HIV seropositivity at rates above cost-effectiveness threshold</b>	X			
<b>Linkage to care</b>		X		

We also identified from the evidence the factors that facilitate establishing a routine HIV testing program in primary care. These factors, which will be discussed later in the article, are:

1. identify a champion to lead and support HIV testing practice change
2. make supportive organizational policy change related to HIV testing
3. adapt clinic flow to facilitate HIV testing
4. adapt the electronic medical record (EMR) system to prompt staff to offer HIV testing
5. train staff on how to offer, conduct and talk about HIV testing
6. develop tools to support staff to offer, conduct and talk to patients about HIV testing
7. monitor and evaluate the HIV testing program
8. establish strong links to HIV-specific clinical services

### What is this review about?

This review defines routine testing and distinguishes between opt-in and opt-out approaches. It also reviews whether in primary care settings that have routine testing programs:

- patients are routinely approached for HIV testing
- patients accept testing when approached
- HIV tests are performed
- HIV diagnoses are made (above the cost-effectiveness threshold)
- patients diagnosed with HIV are linked to care

This review also identifies from the available literature the factors that facilitate the development and delivery of routine HIV testing programs in primary care settings.

### Why should people be tested for HIV?

HIV diagnosis at the earliest possible opportunity is crucial to maximize the health benefits of HIV care and treatment for a person living with HIV. We know there are substantial health benefits to starting HIV treatment early.<sup>1,2</sup> We also have strong evidence that when people living with HIV are engaged in care, adhere to their treatment, and maintain an undetectable viral load, their chance of transmitting HIV to others is significantly reduced.<sup>3,4,5,6,7,8,9,10,11</sup> In fact, for sexual transmission, the [risk is negligible](#). However, people living with HIV can only benefit from treatment if they know their HIV status and are engaged in care.

In Canada, we are not doing well at diagnosing HIV.<sup>12,13,14</sup> According to 2014 estimates from the Public Health Agency of Canada (PHAC), just over 16,000 people living with HIV are unaware they have HIV.<sup>15</sup> This represents

about 21% of all people with HIV but this proportion varies by population: 18% for men who have sex with men (MSM); 20% for people who use injection drugs; and 28% for heterosexual men and women.<sup>16</sup>

In addition, many people are being diagnosed late in the course of their HIV infection,<sup>17,18</sup> often having had multiple missed opportunities for earlier diagnosis in acute, community and primary care settings.<sup>19</sup> Timely diagnosis increases opportunities to link and engage people living with HIV to care and treatment, which maximizes the health and prevention benefits of early treatment.

Despite the importance of HIV testing, many people have never been tested for HIV<sup>20,21,22</sup> or don't test as frequently as they should.<sup>20,21</sup> This may be due to individual, healthcare provider, and structural barriers to testing. Individual-level barriers may include a lack of perceived risk of HIV infection<sup>20,23</sup> discomfort in discussing and lack of knowledge of HIV,<sup>20</sup> fear of stigma and discrimination,<sup>20,24,25</sup> and fear that the test results will not be confidential.<sup>24,26</sup> Healthcare providers may also pose a barrier to testing - some healthcare providers don't have the necessary knowledge and skill to properly assess patient risk,<sup>27</sup> and some may be uncomfortable offering testing.<sup>24,26,28,29</sup> Finally, structural barriers to HIV testing may include poor access to testing services;<sup>20</sup> time constraints and competing priorities during healthcare appointments;<sup>27,30</sup> and lack of human and financial resources to offer testing in hospitals and clinics.<sup>26,30</sup>

## What is routine HIV testing?

Routine testing is the practice of systematically approaching patients for HIV testing when they seek healthcare, regardless of known risk factors or symptoms of HIV infection.

There are two general types of routine HIV testing:

- **Opt-in testing:** patients are offered an HIV test and must *actively accept* testing before the test can occur.
- **Opt-out testing:** patients are notified that HIV testing is a part of normal care for everyone but they can decline. If they don't *actively decline* a test, consent to testing is assumed.

## The routine offer of HIV testing is already part of healthcare practices in some settings in Canada

The PHAC *HIV testing and screening guide* makes a recommendation for the normalization of HIV testing in the general population by making the offer of HIV testing a component of routine medical care.<sup>31</sup> The guide does not provide specific recommendations on how often the discussion about HIV testing between patient and provider should happen.<sup>31</sup> In terms of provincial guidelines, British Columbia and Saskatchewan recommend the routine offer of HIV testing for the general population at least every five years, and more frequently for people who may be exposed to HIV in an ongoing way.<sup>19,32</sup>

The PHAC guide also recommends that all pregnant people be routinely offered an HIV test during their first prenatal visit.<sup>31</sup> The routine offer of HIV testing for pregnant people is also recommended by the Society of Obstetricians and Gynaecologists of Canada and many of the provinces have made similar recommendations, including Nova Scotia, Quebec, Ontario, Saskatchewan, Alberta, British Columbia and Yukon Territory.<sup>19,33,34,35,36,37</sup>

## Does routine HIV testing in primary care work?

We reviewed the available scientific literature to determine if routine testing in primary care improves outcomes related to testing. [Details on our methodology](#) are at the end of this article. Evidence presented in this review comes from Canada and from regions with HIV epidemics similar to our own, such as the United States, Europe and Australia.

We assessed the available scientific evidence to support each outcome and assigned it an evidence rating. Although the evidence rating is flexible (to a certain degree), ratings were based on the following criteria:

1. **Strong Evidence:** At least one systematic review or a large body of randomized controlled trials and quasi-experimental studies (and observational research) supports the ability of the intervention to impact the

outcome.

2. **Moderate Evidence:** Limited randomized controlled trials and/or quasi-experimental studies (with the support of observational research) support the ability of the intervention to impact the outcome.
3. **Limited Evidence:** Observational research supports the ability of the intervention to impact the outcome.
4. **Mixed Evidence:** There is both research that supports and does not support the ability of the intervention to impact the outcome.
5. **No Evidence:** No published research exists to support the ability of the intervention to impact the outcome.

## What percentage of patients are offered routine HIV testing in primary care?

A policy to offer routine HIV testing to patients does not guarantee that all patients will be offered an HIV test. Imperfect offer rates may occur because healthcare providers and allied professionals may be uncomfortable talking about HIV testing.<sup>24,26,28,29</sup> They may also feel they do not have enough time to offer HIV tests when there are competing clinical priorities during patient visits.<sup>27,30</sup>

### Overview

There was moderate evidence that HIV tests are routinely offered in primary care settings with a routine testing policy. Offer rates in these settings ranged from 9% to 96% across one quasi-experimental study<sup>38</sup> and seven observational studies.<sup>23,39,40,41,42,43,44</sup> There were seven studies with an offer rate of 50% or greater<sup>23,38,39,40,41,42,43</sup> and three studies with an offer rate of less than 50%.<sup>42,44,45</sup>

Although the evidence was mixed, the majority of studies found offer rates of 75% or greater in various primary care settings with routine testing policies. Generally, higher offer rates occurred when there was an opt-out approach to routine testing.

### Evidence

#### Offer rates of 50% or greater

An observational study<sup>39</sup> conducted between July 2007 and March 2008 in a community health centre (CHC) in the Bronx borough of New York City examined a pilot program that routinely offered opt-out laboratory testing to patients of five general internists. These doctors were chosen because their patients were most likely to fit program criteria (18 years or older, English speaking, not pregnant and not known to be HIV positive). Tests were offered by both designated HIV testers and healthcare providers. Over eight months, 94% of patients were offered an HIV test.

A quasi-experimental study<sup>38</sup> collected data from nine CHCs in New York City that were part of a network of CHCs in the boroughs of Queens and the Bronx. The study compared baseline data from 2010 to data collected after the introduction of routine testing between 2011 and 2013. Routine opt-out laboratory and rapid HIV tests were offered by healthcare providers. From 2011 to 2013, 79% of patients were offered an HIV test. Baseline data on HIV testing offer rates were not given.

An observational study<sup>40</sup> examined routine HIV test offer rates before and after a policy change from routine opt-in HIV testing to routine opt-out HIV testing at a sexual health clinic in London, UK. The study reported on outcomes for patients who were assessed as low risk for HIV infection. Opt-out testing was introduced in the clinic in December 2003. The study does not mention if laboratory or rapid testing was used. Of the last 300 patients seen in the clinic under the opt-in testing program 83% were offered testing. When opt-out HIV testing was introduced, a significantly greater percentage (94%) of the first 300 patients seen were offered an HIV test.

An observational study<sup>41</sup> was conducted in a South Carolina CHC after the clinic started offering routine opt-out rapid HIV tests in December 2006. The clinic cares for both urban and rural patients in an area with low HIV prevalence. Triage nurses offered the test to patients. Over eight months, 96% of patients were offered an HIV test.

An observational study<sup>43</sup> reported data from an audit of a sexual health clinic in Portsmouth, UK, that used a routine opt-out laboratory testing approach. The HIV testing program was assessed at two time points, in 2003 and 2004. Patient charts were reviewed over a six-week period during each audit. Using an opt-out approach at both time

points, 94% of patients were offered an HIV test in 2003 and 95% in 2004.

An observational study<sup>42</sup> reviewed data from two CHCs offering routine laboratory-based HIV testing. Medical assistants were responsible for offering the HIV test in both CHCs. The first CHC, in Houston, Texas, started offering routine opt-in HIV testing in July 2012; the second CHC, in Atlanta, Georgia, started offering routine opt-out HIV testing in June 2012. In the Houston CHC, 48% of patients were offered an HIV test between July 2012 and April 2014, compared to 80% in the Atlanta CHC between June 2012 and April 2014. The study authors suggest that electronic medical record (EMR) prompts were responsible for the disparity between sites. In the Atlanta CHC, staff had to choose whether an HIV test was accepted or declined when prompted before they could access a patient's chart. In the Houston CHC, the EMR prompted staff to offer a test but did not prevent them from accessing the patient's chart. Compared to the 12-month period before implementation (when both risk-based and routine testing were used, depending on the location and clinic), the CHC in Houston saw a 733% increase in the number of tests offered and the CHC in Atlanta saw a 617% increase in the number of tests offered.

An observational study<sup>23</sup> reported on the implementation of a routine HIV screening program in a CHC that serves a neighbourhood of Philadelphia where HIV rates are high (between 2% and 3% of residents are HIV positive) and where residents have limited access to healthcare. The study was conducted between January 2012 and August 2014. During the pilot program, medical assistants offered both routine opt-out laboratory and rapid testing. Over 30 months, 59% of patients were offered an HIV test, an increase from the estimated 5% at baseline (risk-based assessment).

### **Offer rates less than 50%**

As already reviewed above, an observational study<sup>42</sup> investigated data from two CHCs offering routine laboratory HIV testing. In the first CHC, in Houston, Texas, 48% of patients were offered an HIV test compared to 80% in the Atlanta, Georgia, CHC.

An observational study<sup>44</sup> conducted in North Carolina, South Carolina and Mississippi included data from six CHCs that introduced routine opt-out rapid HIV testing to their services. The CHCs served patients disproportionately impacted by HIV. Program roll-out started in December 2006 and all CHCs submitted final data in March 2008. Overall, 28% (range between 7% and 50%) of patients were offered an HIV test during the study period. Compared to the number of people tested prior to the implementation of routine testing, there was a 438% increase in the number of people offered a test.

An observational study<sup>45</sup> was conducted in two primary care clinics – an internal medical clinic and an internal medical specialty clinic – in the United States in 2007. This study reported results from the implementation of an opt-in approach to routine HIV testing, using a rapid test. Nurses, doctors and medical assistants offered HIV testing to patients. Using an opt-in rapid test approach, only 9% of patients were offered an HIV test as part of the four-month pilot program.

### **What percentage of patients accept testing when offered a test?**

Not all patients accept (or do not refuse) HIV tests when offered. Patients may decline a test because they don't perceive themselves to be at risk for infection;<sup>20,23</sup> fear stigma and discrimination if they test positive;<sup>20,24,25</sup> and fear that the test results will not be confidential.<sup>24,26</sup> Patients may also refuse HIV tests because they have recently been tested.<sup>20,39,46</sup>

### **Overview**

There is moderate evidence that people accept an HIV test during routine testing. HIV test acceptance rates varied between 35% and 89% across one randomized controlled trial<sup>47</sup> and seven observational studies.<sup>23,29,39,40,43,45,48</sup> There were five studies with acceptance rates of 50% or greater<sup>29,40,43,45,48</sup> and three studies with acceptance rates lower than 50%.<sup>23,39,47</sup>

### **Evidence**

## Acceptance rates 50% or greater

An observational study<sup>29</sup> reported on outcomes related to the integration of a routine opt-in rapid HIV testing program into standard care at a family planning clinic located in a diverse, low-income neighbourhood of Philadelphia. During the study period, between April 2007 and May 2009, clinic staff offered patients HIV testing. Before the study, routine HIV testing was offered by a dedicated HIV counsellor whose only task was to offer and perform HIV tests. Acceptance rates increased from 76% when offers were made by the dedicated HIV counsellor to 89% when clinic staff routinely offered tests.

An observational study<sup>40</sup> examined HIV test acceptance before and after a policy change from routine opt-in HIV testing to opt-out HIV testing at a sexual health clinic in London, UK. The study reported on outcomes for patients who were assessed as low risk for HIV infection. Opt-out testing was introduced in the clinic in December 2003. The study does not mention if laboratory or rapid testing was used. The acceptance rate remained stable (77% before the policy change, and 78% after).

An observational study<sup>45</sup> was conducted in two primary care clinics – an internal medical clinic and an internal medical specialty clinic – in the United States in 2007. This study reported results from the implementation of routine opt-in rapid testing. Nurses, doctors and medical assistants offered HIV testing to patients. The acceptance rate of the test when offered was 69%.

An observational study<sup>48</sup> examined data from a sexually transmitted infections (STI) clinic in Phoenix, Arizona, where opt-in laboratory HIV testing was added to an array of tests routinely offered to all clinic patients by a healthcare provider. Over 18 months (from July 2003 to December 2004), 68% of patients accepted a test when it was offered.

An observational study<sup>43</sup> reported data from an audit of a sexual health clinic in Portsmouth, UK, that used a routine opt-out laboratory testing approach. The HIV testing program was assessed at two time points, in 2003 and 2004. Patient charts were reviewed over a six-week period during each audit. At both time points, 64% and 65% of patients, respectively, accepted testing when it was offered.

## Acceptance rates lower than 50%

A randomized controlled trial<sup>47</sup> was conducted in an area of London with the ninth highest HIV prevalence in the UK. The intervention looked at routine opt-out rapid testing at 20 primary care clinics where tests were offered by either a medical assistant or a nurse. The study found that 45% of patients in the intervention group accepted a test when offered. The study also looked at a control group at 20 other primary care clinics where testing was offered by healthcare providers as part of usual care (risk-based testing), but did not report the percent of patients that accepted testing in this group.

An observational study<sup>39</sup> conducted between July 2007 and March 2008 in a CHC in the Bronx borough of New York City examined a pilot program that routinely offered opt-out laboratory testing to patients of five general internists. These doctors were chosen because they were most likely to have patients that fit program criteria (18 years or older, English-speaking, not pregnant, and not known to be HIV positive). Tests were offered by both designated HIV testers and healthcare providers. Over eight months, 35% of patients accepted an HIV test when it was offered.

An observational study<sup>23</sup> reported on the implementation of a routine HIV screening program in a CHC that serves a neighbourhood of Philadelphia where HIV rates are high (between 2% and 3% of residents are HIV positive) and where residents have limited access to healthcare. The study was conducted between January 2012 and August 2014. During the pilot program, medical assistants offered both routine opt-out laboratory and rapid testing. Over 30 months, 43% of patients accepted an HIV test when it was offered.

## Testing rates in routine HIV testing programs

Testing rates can be calculated in two different ways:

- the number of tests performed divided by all patients
- the number of tests performed divided by all patients who were offered testing



For consistency, reported below is the percentage of all patients who were tested, except in one instance where this calculation could not be performed. In this case, the percentage of patients who were tested after being offered the test was used.

## Overview

There is moderate evidence that people who attended sites with routine testing were actually tested for HIV. Testing rates of patients ranged from 11% to 90% across two quasi-experimental studies<sup>49,50</sup> and eight observational studies.<sup>23,40,41,42,44,51,52,53</sup> There were four studies with testing rates of 50% or greater<sup>40,41,51,52</sup> and six studies with testing rates lower than 50%.<sup>23,42,44,49,50,53</sup>

There was moderate evidence that routine testing programs result in an increase in the absolute number of tests performed compared to a time period before the implementation of routine testing. The increase ranged from 26% to 249%.<sup>29,42,44,49,52,53,54,55</sup>

## Evidence

### Testing rates 50% or greater

An observational study<sup>51</sup> in an STI clinic in Denver, Colorado, examined data from a routine opt-out HIV testing program over four time periods from 2003 to 2005. HIV testing was offered by a medical assistant. Laboratory testing was phased out in favour of rapid testing over the course of the study. During the first period, rapid testing was optional. By the fourth period, laboratory testing had been phased out. Over the course of the study, 90% of *all patients* were tested. The percentage of patients tested within each time period was not provided.

An observational study<sup>52</sup> reviewed data from 10 family planning clinics with documented high rates of teen pregnancy and STIs in Houston, Texas, between 2011 and 2014. Clinics were located in hospitals, schools and community settings. Healthcare providers routinely offered routine opt-out rapid testing to patients. Overall, 86% of *all patients* who visited the clinics were tested. The absolute number of HIV tests increased by 133% when compared to a comparable time period before the implementation of routine testing.

An observational study<sup>41</sup> was conducted in a South Carolina CHC after the clinic started offering routine opt-out rapid HIV tests in December 2006. The clinic cares for both urban and rural patients in an area with low HIV prevalence. Triage nurses offered the test. Over eight months, 58% of *all patients* were tested for HIV.

An observational study<sup>40</sup> examined HIV testing outcomes before and after a policy change from routine opt-in HIV testing to opt-out HIV testing at a sexual health clinic in London, UK. The study reported on outcomes for patients who were assessed as low risk for HIV infection. Opt-out routine testing was introduced in the clinic in December 2003. The study does not mention if laboratory or rapid testing was used. The percentage of *all patients* who were tested for HIV increased significantly from 68% to 77% after routine opt-out testing was implemented.

### Testing rates below 50%

An observational study<sup>23</sup> reported on the implementation of a routine HIV screening program in a CHC that serves a neighbourhood of Philadelphia where HIV rates are high (between 2% and 3% of residents are HIV positive) and where residents have limited access to healthcare. The study was conducted between January 2012 and August 2014. During the pilot program, medical assistants offered both routine opt-out laboratory and rapid testing. Over 30 months, 43% of the *patients offered* an HIV test were tested.

An observational study<sup>42</sup> reviewed data from two CHCs offering routine laboratory HIV testing. Medical assistants were responsible for offering the HIV test in both CHCs. The first CHC, in Houston, Texas, started offering routine opt-in HIV testing in July 2012; the second CHC, in Atlanta, Georgia, started offering routine opt-out HIV testing in June 2012. Overall, 21% of *all patients* were tested for HIV. Compared to the 12 months prior to the implementation of routine testing, the number of patients tested increased 116%.

In a quasi-experimental study,<sup>49</sup> healthcare providers in 10 CHCs in the Bronx borough of New York City offered routine opt-out laboratory testing for HIV to their patient population. When the new approach was introduced in 2003, 8% of *all patients* were tested for HIV. By the end of the pilot phase of the study in 2007, 20% of *all patients* were tested for HIV. Comparing the absolute numbers of people tested in 2003 to 2007, the number of patients tested increased 184%.

An observational study<sup>44</sup> conducted in North Carolina, South Carolina and Mississippi included data from six CHCs that introduced routine opt-out rapid HIV testing to their services. The CHCs served patients disproportionately impacted by HIV. Program roll-out started in December 2006 and all CHCs submitted final data in March 2008. Of *all patients*, 18% were tested for HIV. Compared to the year prior to routine testing implementation, the number of patients tested increased 249%.

A quasi-experimental study<sup>50</sup> reported on findings from a routine testing program in a healthcare network in Cleveland, Ohio, that provides services to a patient population with limited healthcare options in seven hospital-based primary care clinics and CHCs. Healthcare providers offered routine opt-in laboratory HIV testing. The study compared the percentage of all patients tested before and after the July 2010 introduction of an electronic medical record reminder, which prompted healthcare providers to offer a test. Overall, the percentage of *all patients* receiving first time HIV testing increased significantly from 4% to 17%.

An observational study<sup>53</sup> reported on outcomes from a routine HIV testing program in a primary care clinic in Dayton, Ohio, in 2010. Most of the clinic's patients are heavily impacted by the social determinants of health. Over a three-month period, medical assistants offered routine opt-in laboratory HIV testing to patients for a fee. Overall, 11% of *all patients* were tested for HIV. There was a 207% increase in the absolute number of tests conducted, compared to a similar period before routine testing was implemented.

## **Increase in HIV testing after the introduction of routine testing**

In the previous studies, the increase in the absolute number of tests performed ranged from 116% to 249%.<sup>42,44,49,52,53</sup> In addition to these studies, there are two other quasi-experimental studies<sup>54,55</sup> and one observational study<sup>29</sup> that did not report on their testing rates after introducing routine testing into their primary care settings. Instead, they only reported on the percent increase in the absolute number of tests performed. These studies found the increase in the absolute number of tests performed ranged from 26% to 125%

A quasi-experimental study<sup>54</sup> examined four CHCs that moved from routine opt-in to routine opt-out laboratory HIV testing in Philadelphia in September 2013. All four CHCs serve patients that are significantly impacted by the social determinants of health. The routine opt-out tests were offered by a medical assistant. Over nine months, the four sites reported the absolute number of HIV tests performed increased 125%.

A quasi-experimental study<sup>55</sup> examined routine opt-out laboratory testing in Vancouver's primary care clinics as part of a city-wide reorganization of HIV services. During the first year, the study reported the absolute number of HIV tests performed increased 62% after routine opt-out testing was introduced.

An observational study<sup>29</sup> reported on outcomes related to the integration of a routine opt-in rapid HIV testing program into standard care at a family planning clinic located in a diverse, low-income neighbourhood of Philadelphia. During the study period, between April 2007 and May 2009, clinic staff offered patients HIV testing. Before the study, routine HIV testing was offered by a dedicated HIV counsellor whose only task was to offer and perform HIV tests. The clinic reported the absolute number of tests performed by clinic staff increased 26% compared to the number performed by the designated HIV counsellor.

## **HIV seropositivity rates in routine HIV testing programs**

The routine offer of an HIV test gives patients an opportunity to learn their HIV status.

One way to measure whether routine HIV testing programs are reaching people with HIV is through positivity rates. The positivity rate of a testing program is determined by the number of people who are diagnosed with HIV divided by the overall number of people tested by the program. The Centers for Disease Control and Prevention (CDC) has



determined that a positivity rate equal to or greater than 0.1% is cost-effective.<sup>56</sup>

## Overview

There is strong evidence that routine testing programs identify people living with HIV at rates above the 0.1% cost-effectiveness threshold. Seropositivity rates ranged between 0% and 2% in primary care settings in one randomized controlled trial,<sup>47</sup> four quasi-experimental studies<sup>38,49,50,54</sup> and 13 observational studies.<sup>23,29,38,40,42,43,44,45,48,51,52,53,57</sup> There were 15 studies with seropositivity rates above the cost-effectiveness threshold<sup>23,29,38,40,42,44,45,47,48,49,50,51,52,54,56</sup> and three studies below the cost-effectiveness threshold.<sup>38,53,43</sup>

All studies that compared the positivity rate from a time period before the implementation of the routine offer of HIV testing found either a comparable positivity rate or a lower positivity rate with routine testing.<sup>58,51,29,42,55,38,47,52,50</sup> This is not unexpected because a risk-based testing approach was used before routine testing was introduced. It is not surprising that testing people known to be at high risk for HIV would result in higher positivity rates compared to testing people using a general population-based approach.

## Evidence

### Positivity rates above the cost-effectiveness threshold

An observational study<sup>40</sup> examined HIV testing outcomes before and after a policy change from routine opt-in HIV testing to opt-out HIV testing at a sexual health clinic in London, UK. The study reported on outcomes for patients assessed as low risk for HIV infection, and the seropositivity rate of patients assessed to be high risk for HIV infection, based on a discussion with a physician. Opt-out testing was introduced in the clinic in December 2003. The study does not mention if laboratory or rapid testing was used. No “low-risk” patient was diagnosed with HIV. Six of 146 “high-risk” patients were diagnosed with HIV, giving a seropositivity rate of 4.1%. Overall, the seropositivity rate was 1.6%.

A quasi-experimental study<sup>57</sup> offered routine HIV testing in a CHC in New Haven, Connecticut. The study did not specify the type of test, who offered it, or whether an opt-in or opt-out approach was used. Before the introduction of routine testing, 30 of 2,526 tests (1.2%) were positive. After the introduction of routine testing, the positivity rate decreased, and 12 of 1,684 tests (0.7%) were positive.

An observational study<sup>51</sup> in an STI clinic in Denver, Colorado, examined data from a routine opt-out HIV testing program over four time periods from 2003 to 2005. HIV testing was offered by a medical assistant. Laboratory testing was phased out in favour of rapid testing over the course of the study. During the first period, rapid testing was optional. By the fourth period, laboratory testing had been phased out. Overall, 192 of 30,405 tests (0.63%) were positive (ranging from 0.5% to 0.8% over the four periods of the study).

An observational study<sup>29</sup> reported on outcomes related to the integration of a routine opt-in rapid HIV testing program into standard care at a family planning clinic located in a diverse, low-income neighbourhood of Philadelphia. The study was conducted between April 2007 and May 2009. Clinic staff offered patients HIV testing during this time period. Before the study, routine HIV testing was offered by a dedicated HIV counsellor whose only task was to offer and perform HIV tests. Overall, 16 of 2198 tests (0.7%) were positive. Three of 30 tests (10%) in men and 13 of 2,155 tests (0.6%) in women were positive. Prior to the implementation of routine opt-in rapid testing, the positivity rate was less than 0.5%.

An observational study<sup>42</sup> reviewed data from two CHCs offering routine laboratory HIV testing. Medical assistants were responsible for offering the HIV test in both CHCs. The first CHC, in Houston, Texas, started offering routine opt-in HIV testing in July 2012; the second CHC, in Atlanta, Georgia, started offering routine opt-out HIV testing in June 2012. In the Houston CHC, 52 of 9,909 tests (0.5%) were positive (compared to 0.8% in the year before routine testing). At the Atlanta CHC, 75 of 11,920 tests (0.7%) were positive (compared to 1.6% in the year before routine testing).

An observational study<sup>48</sup> examined data from an STI clinic in Phoenix, Arizona, where opt-in laboratory HIV testing was added to an array of tests routinely offered to all clinic patients by a healthcare provider. Over 18 months (from July 2003 to December 2004), 68 of 12,176 tests (0.56%) were positive (0.86% in men and 0.12% in women). Of the 58 patients notified of their HIV-positive test result, 90% reported they had not previously been diagnosed.

A quasi-experimental study<sup>54</sup> examined four CHCs that moved from routine opt-in to opt-out HIV testing in Philadelphia in September 2013. All four CHCs serve patients that are significantly impacted by the social determinants of health. The routine opt-out tests were offered by a medical assistant. Over nine months during the opt-in period, four of 1,731 tests (0.23%) were positive. Over nine months during the opt-out period, 13 of 3,890 tests (0.3%) were positive.

A quasi-experimental study<sup>38</sup> collected data from nine CHCs in New York City that were part of a network of CHCs in the Queens and Bronx boroughs. The study compared baseline data from 2010 to data collected between 2011 and 2013. Routine opt-out laboratory and rapid HIV tests were offered by healthcare providers between 2011 and 2013. At baseline in 2010, 19 of 2,079 tests (0.9%) were positive. Between 2011 and 2013, 166 of 49,646 tests (0.3%) were positive. Although the positivity rate went down between 2011 and 2013, the absolute number of positive tests increased by 2,288%. At baseline in 2010, three of 19 diagnosed patients (16%) were newly diagnosed. Between 2011 and 2013, 55 of the 166 diagnosed patients (33%) were newly diagnosed.

An observational study<sup>45</sup> was conducted in two primary care clinics – an internal medical clinic and an internal medical specialty clinic – in the United States in 2007. This study reported results from the implementation of a routine opt-in rapid HIV testing. Nurses, doctors and medical assistants offered HIV testing to patients. One of 367 tests (0.27%) was positive.

An observational study<sup>23</sup> reported on the implementation of a routine HIV screening program in a CHC that serves a neighbourhood of Philadelphia where HIV rates are high (between 2% and 3% of residents are HIV positive) and where residents have limited access to healthcare. The study was conducted between January 2012 and August 2014. During the pilot program, routine opt-out laboratory and rapid testing was offered by medical assistants. Over 30 months, 17 of 5,878 tests (0.3%) were positive, of which 13 (76%) were new diagnoses.

An observational study<sup>52</sup> reviewed data from 10 family planning clinics in Houston, Texas, between 2011 and 2014. Clinics were located in hospitals, schools and community settings and had documented high rates of teen pregnancy and STIs. Healthcare providers offered routine opt-out rapid testing to patients. Overall, 88 of 34,299 tests (0.3%) were positive (0.8% for men and 0.1% for women). This positivity rate was unchanged from the time period before the implementation of routine testing.

A randomized controlled trial<sup>47</sup> was conducted in an area of London with the ninth highest HIV prevalence in the UK. The intervention compared routine opt-out rapid testing at 20 primary care clinics where tests were offered by either a medical assistant or a nurse to a control group of usual care (risk-based testing) at 20 other primary care clinics where tests were offered by healthcare providers. In the intervention group (routine testing), 43 of 4,978 people (0.9%) tested positive, of which 32 (74%) were new diagnoses. This compared to 21 of 2,465 people (0.09%) who tested positive in the control group (risk-based testing), of which 14 of 21 (66%) were new diagnoses.

An observational study<sup>44</sup> conducted in North Carolina, South Carolina and Mississippi included data from six CHCs that introduced routine opt-out rapid HIV testing to their services. The CHCs served patients disproportionately impacted by HIV. Program roll-out started in December 2006 and all CHCs submitted final data in March 2008. Of the 10,769 people tested, 39 (0.3%) were diagnosed with HIV, of which 17 (43%) were new diagnoses.

A quasi-experimental study<sup>50</sup> reported on findings from a routine testing program in a healthcare network in Cleveland, Ohio, that provides services to a patient population with limited healthcare options in seven hospital-based primary care clinics and CHCs. Healthcare providers offered routine opt-in laboratory HIV tests. The study compared the percentage of all patients tested before and after the July 2010 introduction of an electronic medical record reminder, which prompted healthcare providers to offer a test. Overall, the seropositivity rate stayed at 0.2% before and after the implementation of routine testing.

In a quasi-experimental study,<sup>49</sup> healthcare providers in 10 CHCs in the Bronx borough of New York City offered

routine opt-out laboratory testing for HIV to their patient population. There were 433 people diagnosed with HIV (annual seropositivity ranged from 0.2% to 0.6%), of which 420 (97%) were new diagnoses.

### **Positivity rates that did not meet the cost-effectiveness threshold**

An observational study<sup>39</sup> conducted between July 2007 and March 2008 in a CHC in the Bronx borough of New York City examined a pilot program that routinely offered opt-out laboratory testing to patients of five general internists. These doctors were chosen because their patients were most likely to fit program criteria (18 years or older, English-speaking, not pregnant, and not known to be HIV positive). Tests were offered both by designated HIV testers and healthcare providers. There were no HIV-positive results among the 105 tests performed.

An observational study<sup>53</sup> reported on outcomes from a routine HIV testing program in a primary care clinic in Dayton, Ohio. Most of the clinic's patients are heavily impacted by the social determinants of health. Medical assistants offered routine opt-in laboratory HIV testing over three months to patients for a fee. There were no HIV-positive results among the 31 tests performed.

An observational study<sup>43</sup> reported data from an audit of a sexual health clinic in Portsmouth, UK, that used a routine opt-out testing approach. The HIV testing program was assessed at two time points, in 2003 and 2004. Patient charts were reviewed over a six-week period during each audit. Using an opt-out approach and a laboratory test at both time points, there were no positive test results in either time period among 777 patients who accepted testing.

### **Percentage of patients linked to HIV care**

Once diagnosed, a person living with HIV should be referred to an HIV primary care provider so that their health can be monitored and they can be offered treatment. Early entry into care and treatment can have significant positive health outcomes for people living with HIV.<sup>1,2</sup>

There are a number of ways successful linkage to care is defined. Definitions can include client acceptance of a referral, attendance at a first HIV-specific appointment, and attending a visit with a specialist in the last year.

### **Overview**

There is moderate evidence from three quasi-experimental studies<sup>38,49,54</sup> and four observational studies<sup>23,29,42,44</sup> that patients are linked to HIV care from primary care settings after a positive HIV test result. Between 77% and 100% of patients diagnosed with HIV were linked to HIV care.

### **Evidence**

In a quasi-experimental study,<sup>49</sup> healthcare providers in 10 CHCs in the Bronx borough of New York City offered routine opt-out laboratory HIV testing to their patient population. Between 2006 and 2013, 96% of patients with HIV were linked to care. The study authors noted that this was higher than previously reported Bronx linkage-to-care rates of 59% and 69%.

A quasi-experimental study<sup>38</sup> collected data from nine CHCs in New York City that were part of a network of CHCs in the Queens and Bronx boroughs. The study compared baseline data from 2010 to data collected between 2011 and 2013. Routine opt-out laboratory and rapid HIV tests were offered by healthcare providers between 2011 and 2013. At baseline, in 2010, all of the 19 patients diagnosed with HIV (100%) were linked to care. Between 2011 and 2013, 127 of 166 patients with HIV (77%) were linked to care.

A quasi-experimental study<sup>54</sup> examined four CHCs that moved from routine opt-in to routine opt-out HIV testing in Philadelphia in September 2013. All four CHCs serve patients that are significantly impacted by the social determinants of health. The routine opt-out tests were offered by a medical assistant. During the last nine months of opt-in testing, one of four patients with HIV (25%) was linked to care. Over the first nine months of opt-out testing, nine of 13 patients with HIV (69%) were linked to care.

An observational study<sup>23</sup> reported on the implementation of a routine HIV screening program in a CHC that serves a neighbourhood of Philadelphia where HIV rates are high (between 2% and 3% of residents are HIV positive) and

where residents have limited access to healthcare. The study was conducted between January 2012 and August 2014. During the pilot program, routine opt-out laboratory and rapid testing was offered by medical assistants. Over 30 months, all of the 17 patients who were diagnosed with HIV (100%) were linked to care.

An observational study<sup>29</sup> reported on outcomes related to the integration of a routine opt-in rapid HIV testing program into standard care at a family planning clinic located in a diverse, low-income neighbourhood of Philadelphia. The study was conducted between April 2007 and May 2009. Clinic staff offered patients HIV testing during this time period. Before the study, routine HIV testing was offered by a dedicated HIV counsellor whose only task was to offer and perform HIV tests. All of the 16 patients diagnosed with HIV (100%) were linked to care.

An observational study<sup>42</sup> reviewed data from two CHCs offering routine laboratory HIV testing. Medical assistants were responsible for offering the HIV test in both CHCs. The first CHC, in Houston, Texas, started offering opt-in routine HIV testing in July 2012; the second CHC, in Atlanta, Georgia, started offering opt-out routine HIV testing in June 2012. At the Houston clinic, 41 of 52 patients diagnosed with HIV (79%) were linked to care, while 74 of 75 patients diagnosed with HIV (99%) were linked to care at the Atlanta clinic.

An observational study<sup>44</sup> conducted in North Carolina, South Carolina and Mississippi included data from six CHCs that introduced opt-out rapid HIV testing to their services. The CHCs served patients disproportionately impacted by HIV. Program roll-out started in December 2006 and all CHCs submitted final data in March 2008. Fourteen of 17 patients diagnosed with HIV (86%) were linked to care.

## **What factors facilitate establishing a routine HIV testing program in primary care?**

We identified eight facilitators of routine HIV testing programs in the literature. They are:

1. identify a champion to lead and support HIV testing practice change
2. make supportive organizational policy change related to HIV testing
3. adapt clinic flow to facilitate HIV testing
4. adapt the electronic medical record (EMR) system to prompt staff to offer HIV testing
5. train staff on how to offer, conduct and talk about HIV testing
6. develop tools to support staff to offer, conduct and talk to patients about HIV testing
7. monitor and evaluate the HIV testing program
8. establish strong links to HIV-specific clinical services

### **Identify a champion to lead and support HIV testing practice change**

Agencies wanting to establish a routine HIV testing program in their primary care settings should identify a site champion.<sup>29,52</sup> A champion can help ensure that practice change related to routine HIV testing becomes established practice by:

- ensuring changes that facilitate routine HIV testing are effective,<sup>29</sup>
- organizing training for staff,<sup>29</sup>
- providing mentorship and support,<sup>29,52</sup> and
- motivating staff members to continue to routinely offer HIV testing to patients.<sup>29</sup>

### **Make supportive organizational policy change related to HIV testing**

Agency policy should support any routine HIV testing program.<sup>23,38,42,49,51,58</sup> This includes a policy that clearly endorses routine HIV testing.<sup>23,38,42,57</sup> In addition, agency consent policies should be streamlined.<sup>23,51</sup> This can be done by moving from written to verbal consent, or consolidating consent for all medical tests into one consent form.

### **Adapt clinic flow to facilitate HIV testing**

Agencies adopting a routine HIV testing program should consider adapting their clinic processes to best integrate routine HIV testing into clinic procedures.<sup>29,44,51,52,54</sup> They should seek input from staff during the transition

process to understand what process is easiest for them.<sup>52</sup> Agencies intending to use a rapid HIV test in their setting may want to consider whether laboratory processes need to be adapted.<sup>29</sup>

### **Adapt the electronic medical record system (EMR) to prompt staff to offer HIV testing**

Agencies that use an EMR should consider modifying it to maximize staff support for routine HIV testing.<sup>23,38,42,49,54</sup> EMRs can be programmed to prompt staff with reminders to offer a test,<sup>23,42,49</sup> display patient HIV testing history,<sup>49</sup> and document when an HIV test offer is made.<sup>38</sup>

### **Train staff on how to offer, conduct and talk to patients about HIV testing**

Agencies adopting routine HIV testing in their settings should offer staff training to facilitate HIV testing integration.<sup>23,28,29,38,39,42,44,47,49,50,54,58,59</sup> All staff should be trained and supported to establish a clinic culture that promotes routine HIV testing.<sup>23,44</sup> Training can include information on HIV prevention and care,<sup>42</sup> HIV testing and counselling approaches,<sup>28</sup> testing guidelines,<sup>28</sup> and any policy changes adopted by the agency to promote routine HIV testing.<sup>23,57</sup> Clinics using rapid tests must train test providers how to use them.<sup>29</sup>

### **Develop tools to support staff to offer, conduct and talk to patients about HIV testing**

Agencies should use tools and resources to support staff to offer HIV testing routinely to patients.<sup>24,28,29,49</sup> Tools for staff, such as pocket cards and other materials that help them talk to patients about HIV and HIV testing,<sup>24,29,49</sup> and posters and brochures<sup>28,29</sup> for patients that promote HIV testing, can encourage providers to offer an HIV test and patients to accept one.

### **Monitor and evaluate the HIV testing program**

Agencies introducing a routine HIV testing program into their clinics should monitor and evaluate the program.<sup>38,42,49</sup> Program leaders should use data collected from the program to report on progress to staff and use this data to make the program more effective.<sup>52</sup>

### **Establish strong links to HIV-specific clinical services**

Agencies should establish links to HIV services for people diagnosed with HIV to facilitate continuity of care. If resources exist, onsite services can be established;<sup>42</sup> if they do not exist, agencies should strive to establish relationships/partnerships with HIV clinics to which clients can be referred.

### **What does this mean for Canadian service providers?**

There is moderate evidence to support that routine testing programs result in testing offers, patient acceptance of testing, and an increase in the number of patients tested for HIV. In addition, there is strong evidence that the positivity rates are above the cost-effectiveness threshold of 0.1%. Finally, there is moderate evidence that people who test HIV positive through routine testing programs are linked to care.

The routine offer of HIV testing in primary care settings is supported by PHAC and the U.S. CDC. Currently, routine HIV testing is policy in British Columbia and Saskatchewan, and a number of [routine HIV testing programs](#) exist in those jurisdictions.

There are a number of facilitators to the implementation of routine testing programs. Before implementing a program, consider how these can be operationalized in your program.

### **Methodology**

This review is based on a search that included the use of PubMed, Embase and CINAHL. MeSH search terms included HIV infections/diagnosis. Embase subject headings included HIV test. Keyword search terms included HIV; testing; screening; routine; opt-in; opt-out; targeted; and universal. The reference lists of relevant articles were reviewed for additional citations. All searches focused on research relevant to healthcare delivery in Canada.



## Resources

[The HIV testing process](#)

[HIV testing technologies](#)

[HIV Screening and Testing Guide](#) – Public Health Agency of Canada

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