

HIV Testing Processes

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Outline of this Unit

- Understanding window period and testing markers
- HIV testing options and reporting process
- Provincial testing guidelines
- Routine HIV testing
- Point of Care testing
- Pre and post test discussions

Window Period

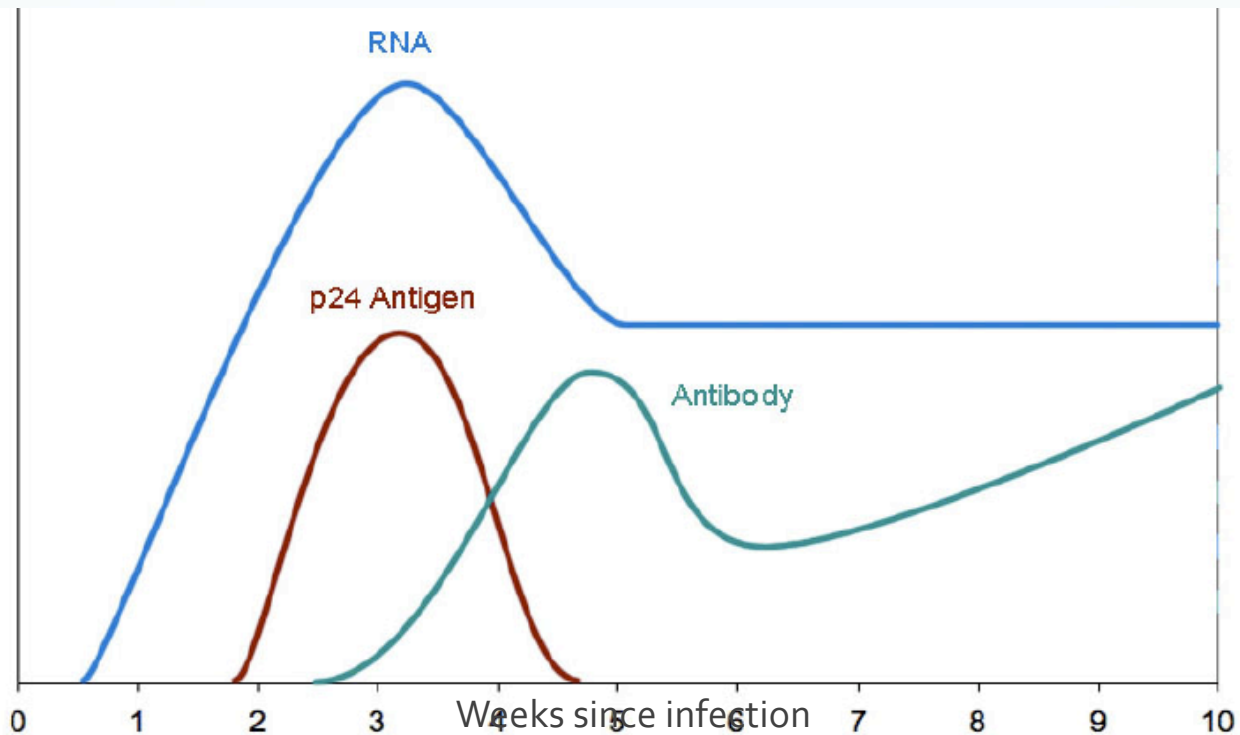
Infection



Detection

- The “window period” is the time from when someone is infected with the virus to when it can actually be detected on a test
- It is difficult to measure as it can vary from client to client
- HIV antibody test:
 - This includes the standard laboratory blood test and the Point of Care Test:
 - > 95% of individuals will show detectable antibodies by 4-6 weeks
 - > 99% by 3 months

Serological Markers for HIV



- The most common HIV tests:
 - are based on the detection of 3 biological markers of HIV infection
 - appear at different times following HIV infection

Serological Markers for HIV

RNA:

- 1st marker to appear is viral RNA, which is the presence of virus in the blood
- The test that detects this is the **RNA NAAT Test**, 7-15 days after infection

P24 Antigen:

- 2nd marker to appear, it is a protein found in the core of the virus
- detected by the **4th generation EIA test**, which detects both the p24 and antibodies, 16-18 days after infection

Antibody:

- Last marker to appear. Does not detect virus. Only screens for antibodies. Detected by the **3rd generation EIA test**, 20-34 days after infection

Laboratory Testing Process for HIV

Blood Test

-----POC Test

3rd Generation EIA Test

- Labeled: HIV-1 & 2 Ab/Ag EIA
- False Positives can occur here, at approx 5/1000 tests
- If reactive, lab will run 4th gen EIA

IF ANY DEGREE OF REACTIVITY, CONFIRMATORY TESTS APPLIED:

4th Generation EIA Test

- Labeled: HIV-1 & 2 Ab/Ag EIA
- False Positives can occur here, at approx 5/1000 tests
- If Reactive here, lab will run Western Blot

Western Blot

- Labeled: Anti-HIV-1 Western Blot
- Considered "gold standard" for confirmation of HIV infection (>99.9% sensitivity & specificity)
- If Reactive here, considered final
- If indeterminate or non-reactive, lab will run NAAT test

Individual RNA NAAT Test

- Labeled: HIV-1 Quantitative NAAT
- In the case of a weak EIA result or indeterminate western blot, the lab will run a NAAT
- a NAAT can rule out HIV infection

How do I explain the window period of the HIV antibody blood test or POC?

“If you are concerned about anything that’s happened in the last 4 weeks then it may not show up on today’s test. And sometimes it can take up to the 3 months before HIV will show on a blood test after infection.”

OR

“If it has been 4 weeks since a potential exposure to HIV and we get a negative result from today’s antibody test, then that result is 95% accurate. If it has already been 3 months since a potential exposure, then it will be 100% accurate.”

Summary of HIV Tests & Window Periods (WP)

Standard Anti-HIV Blood Test

- Antibody test for HIV 1&2. (Only detects antibodies and NOT virus.)
- WP: 4-6 weeks

4th Gen Antibody/Antigen Combo

- Combo of antibody test and p24 antigen
- WP: 2-3 weeks

Western Blot

- “Gold Standard” Antibody test
- WP: 6-8 weeks

Individual NAAT (HIV RNA)

- Nucleic Acid Amplification (Uses amplification to detect viral RNA)
- WP: 1-2 weeks

Pooled NAAT

- Tests a group of blood samples together (pooled samples) using NAAT
- If positive found in the pool, then individual samples will be tested
- WP: 10-12 days

Examples of Lab Test Results

HIV Negative result

Anti-HIV -1&2 EIA Non-reactive

Interpretation: No evidence of HIV infection.

HIV Positive result

Anti-HIV-1&2 EIA Reactive

HIV-1&2 Ab/Ag EIA Reactive

Anti-HIV-1 Western Blot Reactive

HIV-1 Quantitative NAT HIV- 1RNA
detected

Interpretation: Findings indicate HIV infection.

Positive Acute HIV Infection

Anti-HIV-1&2 EIA Reactive

HIV-1&2 Ab/Ag EIA Reactive

Anti-HIV-1 Western Blot Indeterminate

HIV-1 Quantitative NAT HIV- 1RNA
detected

Interpretation: Findings indicate HIV infection.

False Positive, HIV Negative

Anti-HIV-1&2 EIA Reactive

HIV-1&2 Ab/Ag EIA Reactive

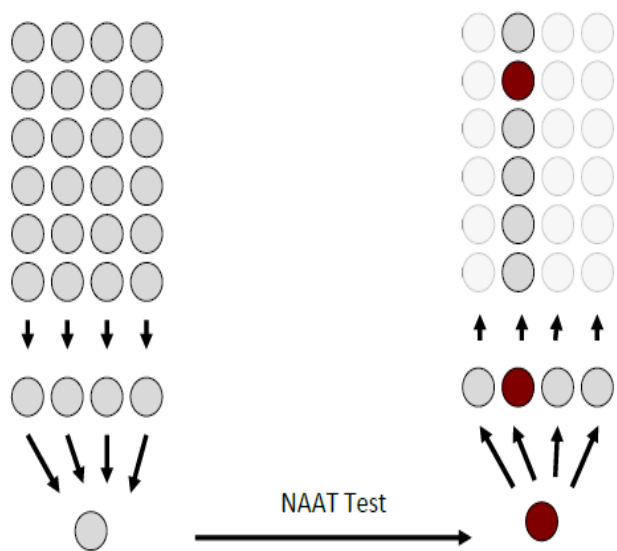
Anti-HIV-1 Western Blot Indeterminate

HIV-1 Quantitative NAT No HIV- 1RNA
not detected

Interpretation: No evidence of HIV infection.

Pooled NAAT Study

Pooled NAAT testing, British Columbia (Pre-screened by 3rd gen EIA)



- Blood samples of males (including transgendered) >18 y.o. age
- From 6 clinics with high rates of HIV infection among MSM clients
- Several samples are combined and tested as a single sample, using the NAAT
- If pooled sampled tests positive, then original individual samples are tested to determine which one was positive

Results from Pooled NAAT Study

- Results from Apr 2009-Mar 2012:
- 2 social marketing campaigns
- 176 new diagnosis
- 54 were AHI's (Acute HIV Infection)
- Of the 54 AHI's:
 - 25 were within the window period for the initial 3rd generation test
 - would have been missed without the pooled NAAT screening

HIV as a Reportable Illness & Testing Options

HIV is “reportable”/ “notifiable” to public health

Reportable Illnesses: part of the Public Health Act of BC

- Some examples include:
 - Creutzfeldt-Jacob Disease
 - Diphtheria
 - Mumps
 - Meningitis
 - Syphilis
 - Viral Hepatitis
 - HIV added to BC’s List in 2003

Why is HIV reportable?

- Reporting helps track the provincial picture of the HIV epidemic
- It also connects a person who is newly diagnosed to a public health nurse that works with the Medical Health Officer (MHO)
- Public health can:
 - Assess that person’s supports and make referrals where necessary
 - Draw baseline bloodwork
 - Set up medical appointments with primary care providers
 - Provide options and assistance in helping that person’s partners get tested

BC HIV Testing & Reporting Process

HIV Test Offer/Request

Pre Test Discussion/ Informed Consent

Blood Specimen Sent to Provincial Laboratory

Result is sent back to testing provider

If confirmed positive result,

Prov Lab reports this to local MHO/Public Health

(If client wanted to be tested non-nominally, then the lab will report it without the full name)

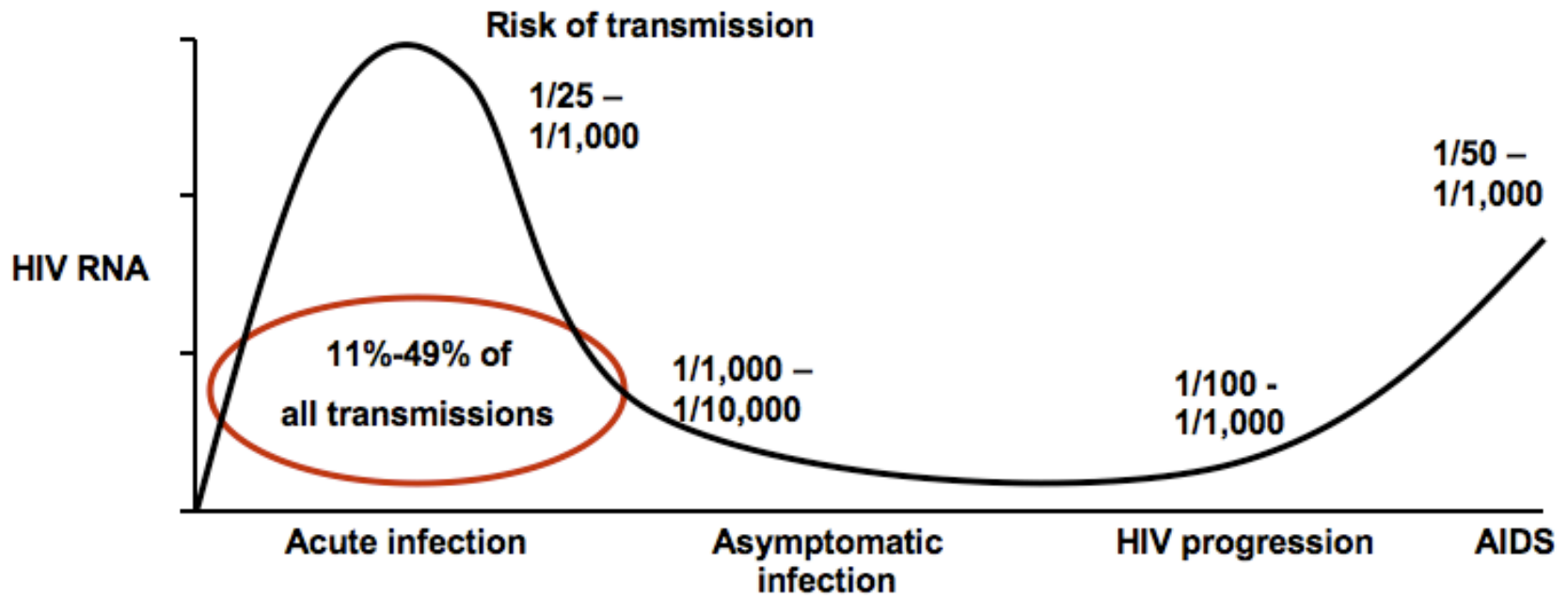
Public Health:

- Works with testing provider and the newly diagnosed person to:
- Assess that person's supports
- Link them to local agencies
- Organizes follow up visit with HIV specialists
- Help client get blood work
- Offers to help inform partners to get tested and where they can get a test

Testing Options in BC

Testing Option	What goes on the lab requisition?	What information is does the lab send back to the testing provider?	What information does the lab send to the MHO?
Testing with Nominal Reporting	<ul style="list-style-type: none"> • Full Name • Date of Birth (DOB) • Gender • PHN (may be included but it is not necessary for an HIV test) 	<ul style="list-style-type: none"> • Positive results and Negative results are sent back to the testing provider with: • Full Name • Date of Birth (DOB) • Gender • PHN (if it was included) 	<ul style="list-style-type: none"> • Positive results are sent to the MHO: • Full Name • Date of Birth (DOB) • Gender • PHN (if it was included) • Negative Results are not sent to the MHO
Testing with Non-Nominal Reporting	<ul style="list-style-type: none"> • Full Name • Date of Birth (DOB) • Gender • PHN (may be included but it is not necessary for an HIV test) 	<ul style="list-style-type: none"> • Positive results and Negative results are sent back to the testing provider with: • Full Name • Date of Birth (DOB) • Gender • PHN (if it was included) 	<ul style="list-style-type: none"> • Positive results are sent to the MHO with: • Initials Only • Date of Birth (DOB) • Gender • PHN is not included • Negative Results are not sent to the MHO
Anonymous Testing (only available at a few sites: www.smartsexresource.com)	<ul style="list-style-type: none"> • Anonymous HIV testing links a person to their test result using a numbered code that only they know • No identifiable or 	<ul style="list-style-type: none"> • Anonymous Testing Code # 	<ul style="list-style-type: none"> • Anonymous Testing Code #

Why is early testing important?



Detected Acute HIV infections represent 6% of all new HIV infections & are responsible for approx 50% of all new cases.

New HIV Testing Guidelines for BC

Provincial health officer Dr. Perry Kendall released new HIV testing guidelines for health-care providers in BC to know the HIV status of all patients under their care (May 2014). It states that obtaining informed consent is the same as for any other diagnostic test or treatment.

It specifically recommends healthcare providers offer an HIV test:

- Routinely, every five years, to all patients aged 18-70 years
- Routinely, every year, to all patients aged 18-70 years who belong to populations with a higher burden of HIV infection
- Once at age 70 or older if the patient's HIV status is not known

AND offer an HIV test to patients including adults 18-70, youth and the elderly, whenever:

- Ordering diagnostic bloodwork for a new or worsening medical condition
- They present with symptoms of HIV infection or advanced HIV disease
- They or their providers identify a risk for HIV acquisition
- They request an HIV test
- They are pregnant
- You test for or diagnose a sexually transmitted infection (STI), hepatitis C, hepatitis B or tuberculosis

New **HIV** Testing Guidelines for the province of British Columbia



hivguide.ca



**HIV TESTING GUIDELINES
FOR THE PROVINCE OF BRITISH COLUMBIA
2014**



Office of the
Provincial Health Officer

RECOMMENDATIONS FOR TESTING ¹³

We recommend that health care providers know the HIV status of all patients under their care.

Specifically, we recommend that providers offer an HIV test,

- **Routinely**, every five years, to all patients aged 18-70 years
- **Routinely**, every year, to all patients aged 18-70 years who belong to populations with a higher burden of HIV infection

or if the patient's HIV status is not known
patients including adults 18-70, youth and the
or worsening medical condition that warrants
laboratory investigation

- They present with symptoms of HIV infection or advanced HIV disease
- They or their providers identify a risk for HIV acquisition
- They request an HIV test
- They are pregnant

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Routine HIV Testing

- Aka Provider-initiated testing
- Does not require in-depth risk assessment
- Facilitates detection of unsuspected HIV
- Prevention & treatment services must be assured
- Informed consent is still obtained
- Does not replace targeted testing

VCH/PHC

Acute Care Testing Program

- At several ER departments and other hospital units, patients are asked if an HIV test can be included as part of their other blood work

CURRENT FINDINGS:

- Offer rate: approximately 45%
- Acceptance rate of the 45% that are offered: approximately 94% of patients say **yes**
- 111 new HIV diagnosis from 2010-2014
- Many of new diagnosis were found to be heterosexual, >age 65
- Examples of initial admitting diagnosis (before HIV status was known):
 - failure to thrive
 - chest pain
 - dysphagia
 - fever of unknown origin
 - stroke
 - heart attack
 - congestive heart failure

Importance of Culturally Safe & Competent Testing for Aboriginal Communities

How are Aboriginal people affected by HIV?

- 5 % of the general population in BC is Aboriginal
- But disproportionately represented in new HIV infections:
- 12.6% of all new infections in BC
- Aboriginal people also face more post-diagnosis disparities in access and outcomes
- Aboriginal people are more likely to:
- Initiate treatment later or receive inadequate treatment
- Die from AIDS without ever accessing care

Testing should include:

- Assessment of “community readiness”
- Confidential & Non-judgmental, harm reduction approach
- Focus on current situation/life experience
- No pressure or preaching to reduce risks
- Discuss the test, provide opportunity to ask questions, assess supports
- Awareness & inclusion of supports that may include healing circles, sharing circles, smudging, seeking guidance from Elders

Point of Care Testing (POC) Rapid HIV Testing

Rapid HIV POC Test

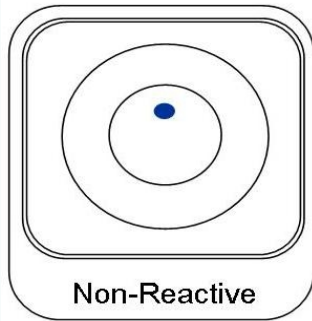
- “INSTI” test: finger-poke test that provides results within 60 seconds
- Provides an accurate negative (>99% sensitivity and specificity, similar to standard 3rd gen EIA)
- It is only a screening tool and cannot diagnose HIV. A preliminary positive result or other non-negative result requires a confirmatory blood test sent to the lab.
- Chance of false positive: approx. 5 per every 1000 tests
- Sites offering POC testing also need to meet minimum quality control procedures and reporting requirements
- Programs interested in offering POC Testing need to contact both:
 - HIV Hope to Health Team at Vancouver Coastal Health (604-875-5600 ext.21241)
 - Provincial POC Program at BCCDC (POCinfo@bccdc.ca)

Rapid HIV POC Test: The Steps



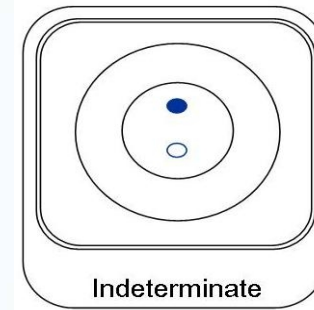
- 1) A finger is poked and blood is collected into a pipette
- 2) This blood is added to solution #1, the first of 3 solutions in total
- 3) Solution #1 is poured into the testing membrane
- 4) This is followed by solution #2 and #3 and produces an immediate result

POC: Potential Results



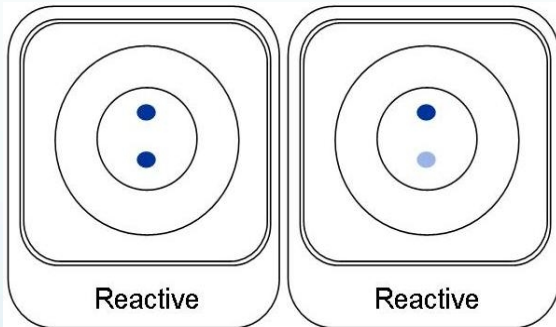
Negative Result

- One blue control dot at the top, means the test performed correctly
- No other visible dots = negative result



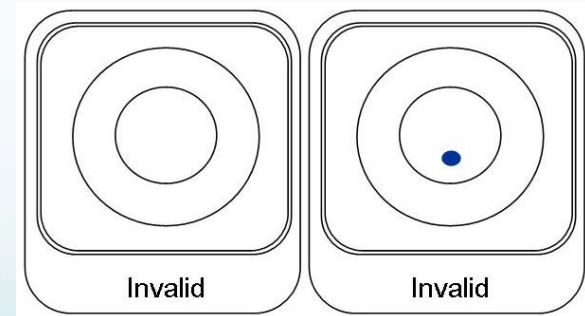
Non-Negative Result - Indeterminate

- One blue control dot at the top, means the test performed correctly
- A ring instead of a filled in dot is seen in the test area below.
- Requires blood work to confirm and rule out possibility of false positive



Non-Negative Result - Preliminary Positive

- One blue control dot at the top, means the test performed correctly
- Second dot in test area below, faint or dark = Preliminary Positive.
- Requires blood work to confirm and rule out possibility of false positive



Non-Negative Result - Invalid

- No control dot seen at the top, means the test did not perform correctly
- Requires that the test is repeated just once more, if same result, confirmatory blood work is indicated

Recommended Use of POC:

Clinical Scenarios

- Pregnant women near term or in labour with undocumented HIV status or ongoing risk of HIV infection in pregnancy
- Testing source during accidental exposures
- Clinical diagnosis of acutely ill patients (ex: opportunistic infections, emergency departments)

Characteristic Settings

- Settings with client populations with high HIV prevalence (Primary care clinics with MSM, IDU)
- Settings where not returning for test results is common among high risk clients (Street involved, Outreach, STI Clinics)
- Settings accessed by high risk clients where provision of a POC HIV test result will improve public health follow-up or connection to HIV clinical care (ER, detox, jail)

Potential topics for Pre-Test & Post-Test discussions

- where more in-depth discussions maybe necessary:
 - ex: client presents for STI test, and /or POC testing is provided
 - ex: settings that offer broad STI services: youth clinic, STI clinics, outreach settings

Pre-Test Discussion

1. Description of HIV testing, transmission and window period
2. Description of positive or negative result
3. Discuss benefits and any risks to testing
4. Early access to treatment
5. Decreased transmission of virus to others
6. Access to voluntary partner counseling and referral services
7. Impact of unexpected or positive result on personal safety
8. Requirement to report non-negative results to public health
9. Voluntary nature of HIV testing and right to decline
10. Option to choose full name or initials and DOB for reporting of non-negative results to public health (nominal or non-nominal reporting)
11. Alternatives to HIV testing
12. Follow-up and supports available for positive and negative results

Potential topics for Pre-Test & Post-Test discussions

- where more in-depth discussions maybe necessary:
 - ex: client presents for STI test, and /or POC testing is provided
 - ex: settings that offer broad STI services: youth clinic, STI clinics, outreach settings

Post-Test Discussion

1. Provide the result in a simple and straight-forward manner (For POC, providing result as a preliminary & requires HIV lab test)
2. Provide the client time to consider the result
3. Ensure the client understands the result
4. Provide time for the client to ask questions and discuss immediate concerns of the client
5. Provide support and empathy for emotions that the client may have in response to the test result
6. Determine support systems for the next 2 to 7 days while the client is awaiting confirmation of the result
7. Discuss partner counselling and referral services
8. For Lab result: Discuss disclosure options and strategies and legal requirement to disclose status to potential sexual partners
9. Describe follow up services, medical referrals and community supports
10. Discuss prevention of HIV transmission and prevention strategies

Health File can also be used in place of Pre-Test Discussion



HealthLinkBC



STI Series - Number 08m
September 2011

HIV and HIV Tests

What are HIV and AIDS?

Human Immunodeficiency Virus (HIV) causes an infection that damages the immune system. The immune system is the part of the body that fights infection and disease.

Over time HIV infection may lead to a serious disease called Acquired Immunodeficiency Syndrome (AIDS).

How can I get HIV?

HIV passes from one person to another by:

- having vaginal, anal or oral sex without using a condom
- having a different sexually transmitted infection (STI) like syphilis, chlamydia or gonorrhoea, which makes it easier to become infected with HIV
- sharing used needles or other drug-using equipment
- blood-to-blood contact such as blood transfusions in countries where the donated blood is not tested
- sharing used tattoo equipment
- a mother who has HIV infection passing it to her baby during pregnancy, delivery or breastfeeding
- sharing razors or toothbrushes, if there are open sores – this is rare

What are the symptoms of HIV?

Many people with HIV do not have any symptoms and do not know that they have HIV. Some people will have a severe flu-like illness soon after being infected.

The only way to know that you have HIV is to have an HIV test.

What is an HIV test?

When someone becomes infected with HIV, his or her body makes certain proteins called antibodies. The HIV test looks for these antibodies. If antibodies are found during testing the result is positive for HIV infection.

Most people who have an HIV infection will develop antibodies 4 to 6 weeks after being infected with the virus. Almost all people who have an HIV infection will develop HIV antibodies that can be found on an HIV test after three months.

What are the types of HIV tests?

There are two types of HIV tests available. One of these is a standard HIV antibody test done using a blood sample taken from your arm. The result is available in 1-2 weeks.

The second type of HIV test is called a point-of-care test using a drop of blood taken from your finger. The result is available at the time of testing. When a point-of-care test result indicates that HIV antibodies may be present, a standard HIV antibody test is required to confirm HIV infection.

Why test for HIV?

Having an HIV test and knowing your test result will help you to make decisions about your health.

It is your choice to have an HIV test. Talk to your health care provider before having the test if you have any concerns or questions about the HIV test or your HIV test result.

What about HIV test results?

If your HIV blood test is negative and it has been more than 3 months since you may have been exposed to HIV, then it means that you likely do not have HIV. If it has been less than 3 months since you may have been exposed you may still have the virus, but the test cannot detect the antibodies. You will need to have a second test after the 3 months have passed to be sure.

What if my HIV test is positive?

If your HIV test is positive it means that you have an HIV infection. Your health care provider will talk with you about the supports and treatments available. Although HIV is a life-long infection and there is no cure, there are medications available to help people with HIV.

You can still live a full and good life if you have an HIV infection; getting early and ongoing health care is important.

Who has access to HIV test results?

In B.C., positive HIV test results are shared with public health to ensure that you and your partners are offered support and follow-up. At the time of having an HIV test, you may choose whether to use your full name or a combination of your initials and birth date as your identifying information.

In B.C., laboratory test results are kept in a provincial laboratory system called the Provincial Laboratory Information Solution (PLIS). The results of your HIV test may also be found in your electronic health record within your health authority. Health care providers who are providing you with care will be able to see portions of your health care record. How much a health care provider can see of your record depends on their role and health care providers who are not providing you with care will not be able to access your record.

What about my partners?

If you have an HIV infection, it is important to tell your sex partner(s) and people who have shared your needles or other drug-using equipment so that they can make decisions about their health and getting tested.

If your HIV test is positive your local public health nurse can help you to notify partners in a confidential way.

How can I prevent HIV infection?

- always use condoms for any vaginal, anal, and oral sex
- talk with your sex partner(s) about getting tested for HIV and other sexually transmitted infections
- use new needles and drug-injecting equipment every time you inject
- use only properly sterilized equipment for tattooing
- if you are sharing sex toys use a new condom for each person

If you believe that you have been infected with or exposed to HIV within the past 72 hours, you may go to your local emergency room for advice about whether to take medications to prevent developing HIV infection.

Ways to reduce your risk of getting a sexually transmitted infection

The more partners you have, the more likely you are to be exposed to a sexually transmitted infection.

To help protect yourself and your partner(s) from an STI, use a condom during any vaginal, oral, or anal sex.

Latex and polyurethane male and female condoms help prevent the spread of many sexually transmitted infections including HIV.

A new condom must be used each time you have sex.

If a condom breaks, a pregnancy or sexually transmitted infection may occur. If a condom breaks during sex and you are concerned, talk to your health care provider.

Use only water-based lubricants with male latex condoms. Oil-based lubricants such as petroleum jelly, lotion or baby oil, can weaken and destroy latex.

Store latex condoms at room temperature (not too hot and not too cold) and check the expiry date on the condom package.

Spermicides containing nonoxonyl-9 (N-9) may increase the risk of infection/transmission of HIV and other sexually transmitted infections, and is not recommended to prevent HIV or these infections.

For more information, see HealthLink BC File #080
[Condoms Help Prevent Sexually Transmitted Infections \(STIs\)](#)



BC Centre for Disease Control
an agency of the provincial health services authority

For more HealthLink BC File topics, visit
www.HealthLinkBC.ca/healthfiles/index.stm
or your local public health unit.

Click on www.HealthLinkBC.ca or call 8-1-1
for non-emergency health information
and services in B.C.

For deaf and hearing-impaired assistance,
call 7-1-1 in B.C.

Translation services are available in more
than 130 languages on request.

Links

- [New HIV Testing Guidelines for BC](#)
- [BCCDC HIV Pre and Post Test Guidelines](#)
- [BCCDC Point of Care Test Guidelines for Health Care Settings](#)
- [HIV Laboratory Testing: A Resource for Health Professionals](#)
- [Canadian Aboriginal AIDS Network \(CAAN\) Diagnosis and Care in HIV Infection in Canadian Aboriginal Youth](#)
- [Canadian Aboriginal AIDS Network \(CAAN\) Assessing Community Readiness Manual:](#)
- [BCCDC HIV Testing Training Videos](#)