INFECTIOUS DISEASE PREVENTION AND CONTROL

HUMAN IMMUNODEFICIENCY VIRUS

HIV SCREENING AND TESTING GUIDE

PROTECTING CANADIANS FROM ILLNESS

Public Health Agency of Canada
Agence de la santé publique du Canada

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HUMAN IMMUNODEFICIENCY VIRUS

HIV Screening and Testing Guide

Executive Summary

HUMAN IMMUNODEFICIENCY VIRUS
HIV SCREENING AND TESTING GUIDE

The Public Health Agency of Canada estimates that, in 2011, 25% of people living with HIV in Canada were unaware of their infection. This guide is designed to complement existing efforts to support care providers involved in HIV testing, including primary care providers, Public Health nurses, counsellors, social workers, community health workers, midwives, community-based service providers and others in an effort to reduce the number of undiagnosed HIV infections in Canada. This guide does not supersede any provincial/territorial legislative, regulatory, policy and practice requirements or professional guidelines that govern and inform the practice of care providers in their respective jurisdictions. Care providers should comply with local Public Health regulations when conducting HIV testing.

Advances in human immunodeficiency virus (HIV) treatment have slowed the progression of the disease to such a degree that HIV infection is now understood to be a chronic, manageable condition enabling more people with HIV to live healthy, long, and active lives. There are several benefits to reducing the number of undiagnosed HIV infections in Canada.

The testing process offers:

- All clients with an opportunity to relieve any anxiety about an unknown HIV status and to establish a baseline as part of an individual's overall health care.

- Clients testing negative with an opportunity to receive information about protective measures and behaviours necessary to prevent HIV infection.

- Clients testing positive with an opportunity to receive information, counselling, care, treatment and support in the management of HIV infection as well as to receive information about how to avoid possible re-exposure and how to prevent onward transmission of HIV.

It is recommended that the consideration and discussion of HIV testing be made a component of periodic routine medical care. This recommendation is based upon the current body of good quality evidence demonstrating the individual and public health benefits associated with normalising HIV testing. Earlier diagnosis and initiation of highly active antiretroviral therapy can lead to reduced morbidity and mortality associated with HIV infection and disease progression. Individuals who are unaware of their status are more likely to unknowingly spread the virus while those who test positive are more likely to take measures that prevent the onward spread of HIV.

In spite of these benefits, barriers continue to exist for reducing the number of undiagnosed cases of HIV in Canada. In 2010, the European Centre for Disease Prevention and Control published a synthesis of the evidence related to both the barriers and strategies to reduce these barriers (ECDC, 2010). The following chart outlines the barriers identified in the literature and the evidence-informed recommendations in this guide that are designed to address these barriers.

REPORTED BARRIER	RECOMMENDATIONS IN THIS GUIDE
Inability to accurately assess levels of risk for exposure to HIV by some clients and providers	Normalise HIV testing; simplify risk assessments; make the consideration of an HIV test part of periodic routine medical care.
Lack of comfort discussing HIV testing and knowledge about HIV among some clients and providers	Normalise HIV testing; simplify risk assessments; make the consideration of an HIV test a part of periodic routine medical care.
Provider time constraints for risk assessments and pre- and post-test counselling	Simplify risk assessments; streamline the provision of pre-test information using print, video, mobile and web-based resources; alternate approaches offered to provide negative results.
Cumbersome consent procedures	Verbal consent for HIV testing, as with other tests, is sufficient; testing remains voluntary.
Fear of stigma and discrimination associated with risk behaviours and/or testing HIV-positive	Normalise HIV testing and simplify risk assessment to reduce discomfort and stigma and increase uptake of testing; emphasize HIV as a chronic manageable condition and the benefits of treatment to reduce fear of HIV diagnosis.

In spite of the benefits associated with HIV testing, care providers should be aware that the fear of stigma and discrimination toward people living with HIV remains a considerable barrier to testing for some individuals. In addition to the fear of testing positive, some people fear having to disclose their status to previous, current and/or future partners. Care providers are encouraged to remain sensitive to such factors and work with clients to develop strategies to overcome these barriers and support positive attitudes toward HIV testing.

The guide offers greater flexibility and adaptability based on the context-specific needs of care providers and clients alike. The guide encourages the use of print and on-line resources to support client information needs to help inform discussions and decisions around HIV testing.

HIV testing remains voluntary and based on informed consent. Clients who understand the advantages and disadvantages of HIV testing; are able to interpret the meaning of the test result; and, who understand how HIV can be transmitted are considered capable of providing verbal consent to proceed with HIV testing. Written consent is not necessary.

The guide acknowledges that limitations in time, comfort levels, and a client's ability to properly evaluate and disclose their own level of risk can all affect the reliability of risk assessments. The

guide encourages a provider-initiated offer for HIV testing which can begin with a brief explanation to the client on how HIV is transmitted: through unprotected sex, the sharing of drug-use equipment, and from a pregnant mother to her child. Clients can then consider their own risks and indicate whether or not they would like to have an HIV test.

The guide highlights the importance of normalizing HIV testing. Reducing the number of undiagnosed HIV infections requires a balance between targeting tests to those most at risk with a less targeted approach directed to populations at "moderate risk" as well. Evidence demonstrates that many individuals who are, or perceived to be, outside of traditional high-risk populations are not being offered HIV testing. As such they are sometimes diagnosed late in the progression of HIV disease, in spite of many prior interactions with the health system. In addition, evidence suggests that self-perceived risk does not always accurately reflect actual risk, reducing the likelihood of patient-initiated requests for an HIV test. Diagnosing HIV infection in its earliest stages contributes to improved public health by reducing the period of time an individual might unknowingly spread the virus. Individuals who are diagnosed earlier experience reduced morbidity and mortality associated with HIV.

While the guide acknowledges that comprehensive risk assessments can be a barrier to HIV testing, instances do occur where clients may be unsure whether certain behaviours have placed them at increased risk for HIV. To assist in such an instance, detailed guidance is provided on the taking of a sexual history along with a review of HIV transmission risks.

Clients should be advised to maintain safer practices during the testing process and understand that follow-up testing may be needed during the window period to ensure that sufficient time has passed for the body to produce detectable HIV antibody. The guide offers a more detailed discussion about the window period and its effect on interpreting testing results.

Clients need to be made aware that positive test results will be shared with Public Health, which can assist in notifying previous and current partners of the need to be tested while protecting the client's anonymity and privacy. Other supports can be provided to assist with partner notification. Care providers are encouraged to discuss the public health benefits of disclosing one's HIV status to current and future partners in the event of a positive test result. In spite of the fact that an HIV positive diagnosis can be difficult news for some people, it is important to highlight the benefits associated with early diagnosis including available treatments and improved disease prognosis.

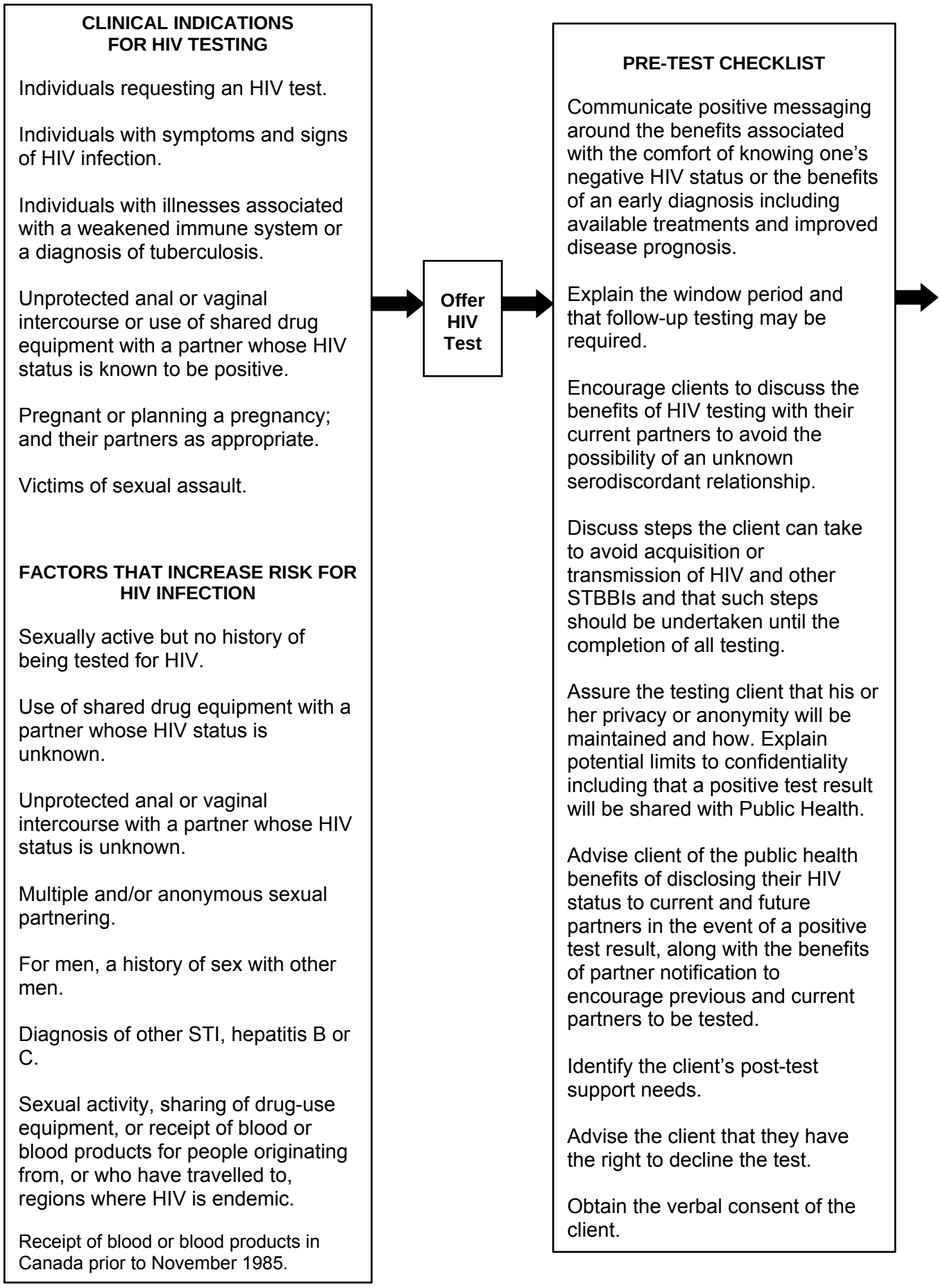
For the majority of HIV tests performed, results will be negative. Negative test results provide an opportunity to remind clients of those practices that can help them maintain an HIV-negative status. There are a range of referrals and resources available to assist clients in reducing future at-risk activities and maintaining a negative status. Clients testing negative who are part of a couple should be encouraged to discuss HIV testing with their partners to prevent them from being unknowingly involved in a serodiscordant relationship.

An HIV positive test result should always be provided in person and ideally by the initial care provider. Care providers should be prepared in advance by having information resources and support referrals at the ready for the client and be able to spend sufficient time to discuss the results and answer any immediate questions the client might have. With proper care and treatment, people with HIV can live long, healthy and active lives and clients should be made aware that HIV is now considered a chronic manageable condition. It is imperative that clients be informed about how to prevent the further spread of the virus and that the public health benefits of disclosure to any current or future partners be discussed. A partner notification plan

should be developed together with the client so previous and current partners can be notified of their need to be tested. A timeline should be established for the completion of a partner notification plan, which can be undertaken by the client, the provider, public health, or any combination of these three. Assurances that client privacy and confidentiality will be protected, to the greatest degree possible, can help allay fears that clients may have around partner notification; care providers should be aware that the fears around rejection, discrimination and even violence can be considerable for some individuals. Frequently, clients will only hear the positive test result, so it can be helpful to schedule a follow-up appointment within two weeks so further discussions can occur once the client has had some time to absorb the news.

The evidence is demonstrating that people living with HIV who are retained in care experience reduced HIV morbidity and mortality than those who are lost to care. Every effort should be made to ensure that all baseline testing such as CD4, plasma viral load and drug-resistance be completed, and that testing for a number of co-infections be done including hepatitis B and C, other sexually transmitted infections and tuberculosis. A referral to an infectious disease specialist treating HIV infection should also be provided.

Undiagnosed HIV infections in Canada represent a significant public health challenge. Including the offer of HIV testing as part of a client's routine care, when appropriate, can contribute to reducing the number of undiagnosed cases that are not benefitting from available treatments, while reducing the period of time that people may be unknowingly transmitting the virus.


CLINICAL INDICATIONS FOR HIV TESTING
Individuals requesting an HIV test.
Individuals with symptoms and signs of HIV infection.
Individuals with illnesses associated with a weakened immune system or a diagnosis of tuberculosis.
Unprotected anal or vaginal intercourse or use of shared drug equipment with a partner whose HIV status is known to be positive.
Pregnant or planning a pregnancy; and their partners as appropriate.
Victims of sexual assault.
FACTORS THAT INCREASE RISK FOR HIV INFECTION
Sexually active but no history of being tested for HIV.
Use of shared drug equipment with a partner whose HIV status is unknown.
Unprotected anal or vaginal intercourse with a partner whose HIV status is unknown.
Multiple and/or anonymous sexual partnering.
For men, a history of sex with other men.
Diagnosis of other STI, hepatitis B or C.
Sexual activity, sharing of drug-use equipment, or receipt of blood or blood products for people originating from, or who have travelled to, regions where HIV is endemic.
Receipt of blood or blood products in Canada prior to November 1985.
Offer HIV Test
PRE-TEST CHECKLIST
Communicate positive messaging around the benefits associated with the comfort of knowing one's negative HIV status or the benefits of an early diagnosis including available treatments and improved disease prognosis.
Explain the window period and that follow-up testing may be required.
Encourage clients to discuss the benefits of HIV testing with their current partners to avoid the possibility of an unknown serodiscordant relationship.
Discuss steps the client can take to avoid acquisition or transmission of HIV and other STBBIs and that such steps should be undertaken until the completion of all testing.
Assure the testing client that his or her privacy or anonymity will be maintained and how. Explain potential limits to confidentiality including that a positive test result will be shared with Public Health.
Advise client of the public health benefits of disclosing their HIV status to current and future partners in the event of a positive test result, along with the benefits of partner notification to encourage previous and current partners to be tested.
Identify the client's post-test support needs.
Advise the client that they have the right to decline the test.
Obtain the verbal consent of the client.

POST-TEST RESULTS CHECKLIST

INDETERMINATE

Retest client; counsel client to maintain risk reduction practices until all testing is complete.

NEGATIVE

If baseline testing is done while the client is in the window period, retest at three weeks and three months after most recent at-risk behaviour; counsel client to maintain risk reduction practices until all testing is complete. If no risk behaviour was present in the three months prior to the first test, a negative result is conclusive.

POSITIVE

Protect the **privacy** and **confidentiality** of the client. Information and support referrals are prepared in advance.

Provide the client with **sufficient time to absorb the results**, discuss the impact of a positive test result and ask questions. Set a follow-up appointment.

Focus on positive messages by highlighting advances in HIV care, treatment and support. Individuals who test positive should be made aware that HIV is now considered a chronic illness, and with the right treatment and support, people living with HIV can live long, active and healthy lives.

Advise the client about strategies for managing HIV and **link them to treatment specialists**. If not already completed with the HIV test, client should be tested for other STIs, hepatitis B and C, and tuberculosis.

Provide risk reduction information to prevent transmission of the virus as a critical element in post-test procedures. In circumstances where the care provider is not able to offer in-depth risk-reduction information, a referral to risk-reduction services should be provided.

Offer client referrals to specialized counselling services that are equipped to provide newly diagnosed individuals with the specific supports and resources that they need to manage their health and wellness.

Discuss disclosure of the result, when and how this might happen, and with whom. Work with the client to develop a partner notification strategy to inform current and former sexual and drug-equipment sharing partners of their potential exposure to HIV and the need to be tested. Public Health services should be offered to the client to assist in partner notification.

Care providers should make clients aware of the public health benefits of disclosing ones HIV status to current and future partners in the event of a positive test result.

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CONTENTS

1. INTRODUCTION AND GUIDING PRINCIPLES

A request was made by the Federal/Provincial/Territorial Advisory Committee on AIDS for the Public Health Agency of Canada to develop guidelines on HIV testing that reflect the realities facing care providers and their clients, as well as advances in HIV testing policy and practice. To inform the development of this guide, the Agency commissioned a literature review and consultations with key stakeholders, including people living with HIV/AIDS and other affected populations, academics, nurses, physicians, professional associations, non-governmental organizations, policy-makers, community workers, and legal and ethical experts. As a result, the recommendations outlined in the guide are based on the most up-to-date evidence and expert opinion.

1.1 INTRODUCTION

There is a critical need to optimize opportunities for care providers to offer HIV testing to people living in Canada; undiagnosed cases are considered “missed opportunities” to reduce HIV transmission and improve disease prognosis, productivity and quality of life for people living with HIV. The *HIV Screening and Testing Guide* has been developed in response to the need to reduce the number of undiagnosed HIV infections in Canada. **The Public Health Agency of Canada estimates that of the 71,300 (58,600-84,000) people believed to be living with HIV/AIDS in Canada to the end of 2011, about 25 percent (14,500-21,500) were unaware of their HIV infection** (PHAC, 2012). Targeted studies have demonstrated that a large proportion of people who report risk factors have been tested for HIV suggesting that those who are aware of their risks are more likely to pursue testing than those who are not. These estimates for Canada are in line with other low-incidence countries such as the United Kingdom, Australia and the United States, where undiagnosed cases of HIV are estimated to account for 21-30 percent of the HIV-seropositive population (PHAC, 2010).

Earlier diagnosis and treatment of HIV infection can contribute to improved health outcomes for the individual and evidence suggests that people who are aware of their HIV infection are more likely to adopt practices that will reduce the risk of passing on the virus to others (PHAC, 2007a). Emerging evidence is demonstrating that reduced individual viral load as a result of early initiation of Highly Active Antiretroviral Therapy (HAART), in combination with other prevention supports including condoms, has been associated with a relative reduction of 96% in the number of linked HIV-1 transmissions in certain populations as compared with delayed therapy (Attia, 2009; Cohen, 2011).

The guide is not meant to supplant or negate the existing practices of specialized HIV testing services where current approaches have proven successful. Instead, this guide is designed to support care providers involved in HIV testing, including primary care providers, Public Health nurses, counsellors, social workers, community health workers, midwives, community-based organizations and others, in an effort to reduce the number of undiagnosed HIV infections in Canada.

Novel approaches and improving technologies (such as rapid HIV testing), are helping to create more opportunities for care providers to offer HIV testing to the diverse range of people who may benefit from it. Consultation with a range of stakeholders suggests that, in an effort to improve testing uptake, care providers in Canada are increasingly tailoring their testing approaches to meet the context-specific requirements of their clients. Examples of tailored

approaches include combining pre- and post-test counselling, providing written information on HIV testing and prevention, developing strategies for repeat testers, and/or making referrals for gender-specific or culturally appropriate counselling.

The guide seeks to reduce the number of undiagnosed HIV infections in Canada by offering a framework for care providers to explore options that will enhance their ability to provide HIV testing, as well as to better tailor their testing approaches to meet the specific needs of their practice and clients. The guide includes strategies for augmenting pre-test counselling through brochures and web-based resources, strategies for combining pre-and post-test counselling, strategies for delivering negative results by secured phone or email, and options for post-test counselling in cases of negative results with referral to risk-reduction services. Other strategies that will likely help to increase the uptake of HIV testing in non-traditional venues such as outreach health services, through community-based organizations and utilizing trained individuals who are not “traditional” health care workers. The guide also recommends an increased integration of HIV testing with testing for other infections sharing common modes of transmission and illnesses that negatively affect HIV prognosis.

1.2 GUIDING PRINCIPLES

The recommendations presented in the guide adhere to the following guiding principles for planning and undertaking voluntary HIV testing in Canada.

1.2.1 PUBLIC HEALTH PROTECTION AND PROMOTION

The first guiding principle for recommendations presented in the guide is the importance of public health promotion and protection. Increasing the offer of HIV testing will facilitate early diagnosis and treatment, thereby reducing the burden of illness and delaying the progression of the disease. Increasing the offer of testing as a part of routine care also plays an important role in establishing a positive and supportive social norm towards HIV testing to address the associated stigma. Evidence further suggests that people living with HIV/AIDS who have knowledge of their HIV infection are more likely to adopt practices that will reduce the risk of HIV transmission to others (PHAC, 2007a and 2010). The guide aims to increase the total number of people aware of their HIV infection, to promote the benefits of early diagnosis, and to support people in reducing HIV transmission through risk-reduction counselling. In this sense, the guide places strong focus on preventing the onward transmission of HIV.

The guide places emphasis on the need to consider opportunities for integration of HIV testing with testing services for infections that have similar modes of transmission (other sexually transmitted infections and blood borne infections including hepatitis B and C), as well as illnesses that have a negative effect on disease prognosis for people living with HIV/AIDS (tuberculosis).

1.2.2 HUMAN RIGHTS AND THE “3CS”

This guide recommends that care providers in Canada recognize the “3Cs” of HIV testing, **counselling**, informed **consent**, and **confidentiality**. The guide acknowledges that extensive **counselling** practices in HIV testing can act as a barrier to testing for both clients and care providers. The guide presents a framework for providing counselling that reflects the realities facing care providers and their clients, while ensuring that testing clients continue to receive the information, resources and supports they need.

Voluntary testing means that the client chooses to be tested without threat or coercion and provides informed consent to proceed with testing. In Canada, voluntary HIV testing requires the care provider to obtain the **informed verbal consent** of the testing client prior to proceeding with the test procedures. Informed consent means that the client understands what is involved in the test procedures (advantages and disadvantages of being tested and of refusing to be tested), is prepared for a potential positive result, and provides permission to be tested (UNAIDS/WHO, 2004).

The maintenance of **confidentiality** is a concern for an individual who has decided to be tested for HIV. Privacy rights reside with the testing client, while confidentiality obligations reside with the care provider. Stigma and discrimination continue to act as barriers to HIV testing for many people. For some individuals, a positive HIV test result may lead to increased risk of violence, abandonment, legal ramifications, and/or social exclusion and isolation (UNAIDS, 2007). Care providers are provided with guidance for supporting clients in disclosing their HIV status to their sexual or drug-equipment sharing partners. Further discussion regarding ethical and professional responsibilities related to consent and confidentiality can be found in Appendix A.

1.2.3 HIV TESTING AS A COMPONENT OF ROUTINE HEALTH CARE

It is recommended that the consideration of HIV testing be made a component of routine care. Recommendations provided in this document include strategies for removing systemic barriers to HIV testing, such as in-depth comprehensive behaviour-based risk assessments and extensive pre- and post-test counselling. In general terms, the guide seeks to reduce barriers to HIV testing. Care providers should exercise discretion in their offer of HIV testing by discussing both the benefits and risks with the testing client; the provider should seek assurance that the client will not face harm as a result of testing.

1.2.4 ADAPTABILITY

An essential objective in the development of the guide has been to ensure that the recommendations provided are adaptable to each testing situation. In this sense, the guide can be applied with flexibility depending on the needs and realities of both the client and care provider. The guide provides recommendations on how to avoid harmful profiling practices, which may discourage HIV testing particularly among groups disproportionately affected by HIV. Lastly, the guide discusses differences in testing types and technologies and provincial/territorial public health laboratory services.

Stigma and Discrimination

Despite advances in HIV care, treatment and support, people living with HIV and AIDS in Canada continue to face stigma and discrimination. Stigma and discrimination of those living with HIV can stem from fear and discomfort with the infection and/or existing societal intolerance of the various populations/behaviours that place individuals at risk of HIV infection. People living with HIV may face stigma for assumptions that might be made about their membership in a stigmatized group (such as gay men, injection drug users) to which they do not belong (Gonzalez, 2011). According to UNAIDS (2007), stigma has grave consequences for people living with HIV/AIDS, such as subjection to discrimination and human rights abuses, loss of employment, property and/or housing loss or damage, rejection by friends and family, violence, and abandonment. Fear of these consequences may deter individuals from being tested and ultimately accessing appropriate care. Including the consideration of HIV testing as a routine part of periodic exams, contraception counselling, addiction counselling and other clinical services, can help reduce the stigma associated with HIV infection.

To overcome concerns relating to stigmatization, care providers should respect the cultural, sexual and gender diversities of clients by avoiding judgemental language, behaviours and attitudes. It is important for care providers to be acutely aware of the potential effects of stigma and discrimination on clients, and the degree to which a client's misperception of their risk as low may be shaping how people react and behave toward HIV and HIV testing. Where applicable, care providers should offer referrals to services and supports equipped to help newly diagnosed patients with the challenges of stigma and discrimination.

2. RECOMMENDATIONS FOR HIV TESTING

The purpose of this chapter is to make recommendations on who should be tested for HIV, and at what interval. The chapter also presents recommendations for increasing opportunities to offer HIV testing by integrating HIV testing with testing services for related infections and explores other possible occasions that evidence suggests may be effective in identifying undiagnosed cases. Additional provider and client resources, other HIV testing guidelines, and guidelines for HIV testing in specific contexts are provided in Chapter Five.

2.1 WHO SHOULD BE TESTED FOR HIV AND HOW FREQUENTLY?

It is recommended that the consideration of HIV testing be made a component of routine care. In general, care providers should take an active approach to HIV testing, offering HIV testing to clients whether or not clients have asked for a test. In the provision of routine medical care, and in discussion with the client, care providers should consider whether there is a benefit to an HIV test.

HIV testing is associated with several advantages:

- A negative test result is an opportunity for clients to take an active role in remaining HIV negative.
- The early detection of HIV, especially at the acute stage, can improve outcomes for individuals and prevent further transmission of HIV.
- Detection at any stage of the disease, prior to wasting and dementia, is an opportunity to initiate lifesaving treatment and other related healthcare services.
- Opportunities arise for conversations with clients about risk-reduction strategies.

2.1.1 TESTING RECOMMENDATIONS

An in-depth comprehensive HIV behavioural risk assessment is not a requirement for offering an HIV test. An assessment that the client understands how HIV is transmitted, the implications of testing (advantages and disadvantages), and how to interpret the test results is sufficient.

For occasions when clients may not be able to accurately estimate their risk, the guide includes more detailed guidance in Appendix B for conducting rapid risk assessments and a more detailed technical review of HIV transmission risks can be found in Appendix C.

Unless already known to be positive, an HIV test should be provided to:

- Individuals requesting an HIV test;
- Individuals presenting with symptoms and signs of HIV infection or with illnesses associated with a weakened immune system*;
- Individuals who are/have been sexually active and have never been tested for HIV;
- Individuals who have shared drug-using equipment[1] with a partner who is HIV-positive or whose status is unknown;
- Pregnant women, or those planning a pregnancy, and their partners as appropriate:
    - Pregnant women and their partners with a risk of HIV exposure should be offered HIV testing at the first pre-natal visit and testing for syphilis, chlamydia, gonorrhea and hepatitis B is also recommended. Testing for other sexually transmitted and bloodborne infections (STBBIs) may be appropriate.
    - Pregnant women who test HIV negative but who continue to be at risk of acquisition of HIV during pregnancy (ongoing risk behaviour, HIV-positive partner) could benefit from regular retesting and testing at the point of delivery.
    - Pregnant women who arrive for delivery without a prenatal HIV test on record should be offered rapid HIV testing.
    - *More detailed guidelines on HIV testing during pregnancy can be found in Chapter Five.*
- Victims of sexual assault; and,
- Individuals who have had unprotected anal or vaginal intercourse with a partner whose HIV status is unknown or HIV-positive.

In the event a client presents soon after a high-risk exposure, timely consultation with an infectious disease specialist, or a colleague experienced in HIV care, is recommended to help guide the patient assessment to determine whether a benefit exists to initiate post-exposure prophylaxis.

***Symptoms and Signs of HIV Infection**

Recognising primary/acute HIV infection can be a clinical challenge; symptoms can be nonspecific and may not be recognised at initial presentation. Symptoms and signs typically appear two to six weeks after exposure to HIV and this may include fever, myalgia, sore throat, headache, rash, nausea, diarrhea, and vomiting. This presentation is similar to those of many other illnesses, including other viral syndromes, influenza and mononucleosis; however, general lymphadenopathy, rash, thrush, and mucosal ulceration are sufficiently uncommon in most adult febrile illnesses that they should, when present, trigger suspicion of acute HIV infection. The natural history of HIV infection is discussed in more detail in Appendix D.

[1] *Drug equipment includes injection drug equipment such as needles, syringes, swabs, filters, spoons, tourniquets, water and more general drug equipment such as straws for snorting and pipes*

HIV testing should also be considered when other factors known to contribute to an increased risk for HIV acquisition are present, including:

- Multiple partnering (serial or concurrent) and/or anonymous sexual partnering;
- For men, a history of sex with other men;
- A diagnosis of other sexually transmitted infections, hepatitis B, hepatitis C, tuberculosis, or other infections known to be associated with HIV infection;
- Sexual activity, sharing of drug-use equipment, or receipt of blood or blood products for people originating from, or who have travelled to regions where HIV is endemic (Africa [see also Section 4.2.3], Asia, Caribbean, Central and South America and Eastern Europe); and,
- Receipt of blood or blood products in Canada prior to the introduction of blood HIV screening in November 1985.

2.1.2 COUPLES TESTING

Individuals with a risk of HIV exposure, in an ongoing sexual relationship with a regular partner, can benefit from being offered HIV testing as a couple rather than separately. Such an approach allows for a common understanding of the risks associated with HIV transmission, a shared understanding of each other's HIV status, and an opportunity going forward to undertake prevention, treatment and care decisions as a couple. Evidence indicates that couples who test together and are mutually aware of each other's results are more likely to adopt behaviours that will protect their partners, when compared to those who test alone (WHO, 2012). Couples testing reduces HIV transmission among serodiscordant couples whose status is unknown to them, and reduces the risk of HIV transmission/acquisition with sexual partners external to the couple. The principles outlined in this guide for the provision of voluntary HIV testing of individuals apply equally in the provision of HIV testing for couples.

2.1.3 OTHER OPPORTUNITIES FOR HIV TESTING

This guide strongly encourages the integration of HIV testing services with testing services for infections known to have the same modes of transmission and for infections which have a negative effect on the prognosis for people living with HIV infection. HIV testing could be provided concurrently with services such as:

- Tuberculosis clinical services
- Sexually transmitted infection clinical services
- Hepatitis C clinical services
- Antenatal care services
- Sexual health and family planning services
- Drug and alcohol treatment services
- Newcomer and travel health clinics
- Mental illness treatment and psychiatric services
- Cancer or oncology clinics

2.1.4 FREQUENCY OF RETESTING

Individuals involved in high risk practices should be screened for HIV at least annually. There is insufficient evidence to provide recommendations for the exact frequency of HIV testing for each scenario due to the number of variables involved with each individual's potential for exposure (and the ability to reliably obtain such information from a client). More frequent STI testing is

indicated for men who have sex with men (MSM) who have multiple (serial or concurrent) or anonymous partners. In addition, MSM who have sex in conjunction with illicit drug use (particularly methamphetamine use) or whose sex partners engage in these activities, should be screened more frequently (CDC, 2010).

Individuals whose baseline test is negative soon after a potential exposure are in the window period. Re-testing the client at intervals of three weeks and three months following the most recent possible exposure can confirm the initial negative result. There are individual variations in the time it takes to develop HIV antigen or antibody, and newer testing technologies permit earlier detection (more detailed information is provided in Chapter Four). However, in particular instances where the exposure is known to be high risk (such as unprotected sexual intercourse with a partner known to be HIV-infected) repeat testing at intervals during the window period (if each result is negative) can help identify infections at their earliest and most infectious stage. Care providers should counsel clients to maintain safer practices and to not substitute HIV testing for preventative approaches. Clients with a negative test result who continue to engage in at-risk behaviours will benefit from more frequent retesting than individuals who consistently take measures to prevent HIV acquisition.

In determining the need for, and the frequency of retesting for clients with a known HIV-negative baseline, care providers are encouraged to consider the following factors.

Populations at Increased Risk for HIV Exposure
Some groups in Canada are disproportionately affected by HIV infection, including gay, bisexual, and other men who have sex with men, people who share drug-using equipment, people from countries where HIV is endemic and Aboriginal peoples. Rates of reported HIV infections among women, youth and the middle-aged are growing in Canada.

Conversely, evidence is demonstrating that individuals from populations perceived to be “low-risk” are being diagnosed with HIV infection at very late stages of the disease, in spite of prior interactions with the health system. Presuming no need to test for HIV solely on the basis of a client’s reported or perceived inclusion in a “low-risk” population can result in higher rates of morbidity and mortality for these clients, and longer periods of time where HIV may be unknowingly transmitted (Health Protection Agency, 2011).

Partners
Clients may benefit from more frequent testing depending on the characteristics of their sexual partnering. Anonymous or multiple sexual partnering; serial monogamy (individuals who only have one partner at a time, but many in a series over time); and, individuals who are part of an exchange of sex for money, food, shelter, and so forth, are all at an increased risk for exposure to HIV and may benefit from frequent testing.

Local Epidemiology
Care providers are encouraged to understand the local epidemiology of HIV to be aware of any issues particular to their geographic location of practice. Population and behaviour-based data can help identify local issues of concern that care providers may need to consider when discussing HIV testing with their clients.

3. HIV TESTING PROCEDURES

Care providers are encouraged to use a flexible approach to pre- and post-test procedures that allows for tailoring according to each client's needs and situation. Abbreviated counselling may be more appropriate in some situations such as with pregnant women in labour, well-informed patients, repeat testers, and so forth. In this chapter, pre-test procedures are defined, including components for pre-test preparation and requirements for obtaining the informed verbal consent of the testing client. The chapter provides advice for undertaking post-test procedures and presents options for supportive post-test messaging and HIV risk reduction counselling. The minimum requirement for HIV testing is informed verbal consent and an understanding of the testing procedures and results.

> A recommended approach to increasing the uptake of HIV testing is to provide clients with a brief explanation on how HIV is transmitted (through unprotected sexual intercourse, the sharing of drug-use equipment, and from a pregnant mother to her child). Following that, simply asking the client if he or she would like to take an HIV test provides the client with an opportunity to evaluate their own sense of risk without feeling compelled to provide a detailed personal history. In prenatal settings, HIV testing should be considered part of routine prenatal care.

3.1 PLANNING FOR HIV TESTING

Providing extended counselling, while preferred, may act as a barrier to testing for both the care provider and the testing client. The considerable resources and time required to conduct extensive risk assessments and pre- and post-test counselling have limited the ability of care providers to offer HIV testing. Behaviour-based risk assessments may also deter individuals from accessing testing, as such practices may involve revealing sensitive personal information. Both providers and clients may feel uncomfortable discussing such topics and, consequently, may avoid testing. The result is "missed opportunities" to diagnose those unaware of their HIV infection and link them with the treatment, care and support they need.

Providing sufficient information and supportive resources in conjunction with HIV testing does not necessarily require expertise in counselling or therapy. The level of support required in any given testing situation is highly dependent on the type of test and the testing client. While some clients may require comprehensive counselling, others may only need an abbreviated discussion supplemented with information resources such as brochures or websites.

Care providers may also be able to combine pre- and post-test activities into a single session with a client. Thus, counselling in the context of HIV testing may involve providing clients with a range of supportive processes including information, discussion, counselling and/or referral. The recommendations provided in this chapter have been developed to help care providers tailor their approaches to HIV testing to reflect the needs of their clients and their current realities.

3.2 THE WINDOW PERIOD

Clients should be made aware of the “window period” which is the time after acquisition of HIV infection when the individual is highly infectious but tests negative on HIV antibody screening because antibodies are not immediately produced. Third generation tests are reactive (detect antibody) at 20 to 30 days following exposure. There are two laboratory markers (viral RNA, p24 antigen) that may be used to diagnose HIV infection prior to the development of detectable HIV antibody. The 4th generation combination tests (p24 antigen and 3rd generation HIV antibody) permit detection of acute HIV infection during the viremic phase. This reduces the window period to approximately 15 to 20 days (Branson, 2012). Making the diagnosis as early as possible can help prevent onward transmission of the virus, since the person is most infectious during this period. Some jurisdictions provide NAAT testing (to detect HIV RNA) for high-risk clients, in an effort to identify very early HIV infection.

- Testing is recommended at baseline and at three weeks following a known or suspected exposure to HIV.
- If the test is negative at three weeks, repeating the test three months following the most recent exposure can confirm the initial negative result. In instances where the exposure is known to be high risk (such as unprotected sexual intercourse with a partner known to be HIV-infected) repeat testing at intervals during the window period (if each result is negative) can help identify infections at the earliest stage.
- Individuals testing during the window period need to be counselled on the importance of engaging in safer sex/drug use practices to avoid the potential for onward transmission of HIV.
- An individual who continuously engages in risk behaviours remains in a continuous window period and should be encouraged to undertake testing more frequently than once per year.

3.3 PRE-TEST PROCEDURES

Pre-test procedures for HIV testing consist of a pre-test discussion between the care provider and client and may involve an abbreviated risk assessment.

3.3.1 PRE-TEST DISCUSSION

The primary purpose of the pre-test discussion is to obtain the client’s informed verbal consent to be tested. Providing clients with HIV information resources in advance of testing (such as in waiting areas) can help prepare a client for relevant and concise pre-test discussions with the care provider. This practice can allow clients to become familiar with HIV infection and HIV testing procedures prior to pre-test discussions, so that they may use the pre-test discussion to clarify any issues or concerns they may have. Care providers are also encouraged to use the opportunity to offer testing for other sexually transmitted or blood-borne infections (STBBIs).

Approaches to pre-test procedures will be specific to the testing situation, including the motivation of the testing client, any prior client experiences with HIV testing, and the resources and capacity of the care provider. Because clients who test positive are less likely to retain

some key elements of post-test counselling, some elements are included as part of the recommended elements of the pre-test discussion. The following describes the pre-test elements and activities beneficial when providing HIV testing:

- Communicate positive messaging around the benefits associated with the comfort of knowing one's negative HIV status or the benefits of an early diagnosis including available treatments and improved disease prognosis.
- Explain the window period and that follow-up testing may be required.
- Encourage clients to discuss the benefits of HIV testing with their current partners to avoid the possibility of an unknown serodiscordant relationship.
- Discuss steps the client can take to avoid acquisition or transmission of HIV and other STBBIs and that those steps should be undertaken.
- Assure the testing client that his or her privacy or anonymity will be maintained, and describe how. Explain potential limits to confidentiality including that a positive test result will be shared with Public Health.
- Advise clients of the public health benefits of disclosing their HIV status to current and future partners in the event of a positive test result, along with the benefits of partner notification to encourage previous and current partners to be tested.
- Identify the client's post-test support needs (risk-reduction services, counselling, etc.).
- Advise the client that they have the right to decline the test.
- Obtain the informed verbal consent of the testing client.

USING POINT OF CARE (RAPID) HIV TEST KITS

Different testing types need different approaches to pre- and post-test planning. Rapid testing involves an assessment of whether the client is prepared to receive a reactive test result in the same session, understands the meaning of non-reactive and reactive results, and will proceed to confirmatory standard testing if the rapid test result is reactive. In addition, the possibility of a false positive reaction and its implications should be discussed. **Health Canada requires that rapid test kits only be used in settings where pre- and post-test HIV counselling is available.** Any use of the kit for other than the approved and intended use could be viewed as a breach of ethical conduct by the care provider, who may be subject to a complaint to the provincial or territorial licensing body and liable for legal action.

3.3.2 RISK ASSESSMENT

It is no longer necessary for care providers to conduct extensive behaviour-based risk assessments when offering HIV testing to clients; risk assessment and risk reduction counselling may not be feasible in all settings. Care providers can provide a basic explanation of risk upon which a client can base his or her decision to test, and assess the client's ability to comprehend the significance of testing, including the advantages and disadvantages of knowing one's status. The care provider should be confident that the testing client has access to supports in the event of a positive test result.

The following questions should be considered during a pre-test discussion:

- Does the client have the capacity to understand and appreciate the consequences of taking or refusing an HIV test?

- Does the client understand the basic risks associated with HIV transmission?
- Does the client have supports in place in the event of a positive test result?

3.4 POST-TEST PROCEDURES

As with pre-test planning, post-test planning will depend on the testing situation and particularly on whether the test result is positive or negative. The following section describes post-test procedures for clients with negative and positive test results.

A NOTE ON REFERRALS – REGARDLESS OF TEST RESULTS

The offer of referral services and supports by care providers is an important element in post-test procedures for all clients, regardless of their test results.

AIDS service organizations, community-based ethnocultural services, Aboriginal AIDS service organizations, community-based GLBTQ organizations, child and family protection services, mental health services, addictions and rehabilitation counselling, women's networks, organizations providing legal advice, and other services are well positioned to provide the appropriate and specific support resources to clients who test positive for HIV. Referrals may also be used in providing appropriate post-test risk reduction services relevant to the specific HIV risks affecting clients testing negative.

Providers may wish to contact their public health department, provincial/territorial health information lines, AIDS Hotlines or local crisis centres in advance of communicating test results to obtain adequate referral resources to provide to their clients.

3.4.1 PROCEDURES FOR NEGATIVE TEST RESULTS

Clients testing negative should be made aware of the "window period" and, as appropriate, follow-up testing should be recommended, following baseline, **at three weeks and three months following the most recent at-risk behaviour.** In particular instances where the exposure is known to be high risk (such as unprotected sexual intercourse with a partner known to be HIV-infected) repeat testing at intervals during the window period (if each result is negative) can help identify HIV infections at the acute stage. Depending on the circumstances, it may be appropriate to test with either repeat antibody or HIV RNA tests (see Chapter Four). Clients who are part of a couple should be encouraged to discuss HIV testing with their partners to ensure they are not at increased risk due to an unknown serodiscordant relationship (see also 2.1.2).

Clients receiving a negative test result should be provided with information or a brief discussion on how HIV is transmitted and methods for reducing future risk of exposure to HIV. Where it is not within the capacity or resource allowance of the care provider to offer in-depth risk reduction counselling, information and referral resources should be made available (see Chapter Five).

It is ideal for negative test results to be provided in person as post-test counselling plays an important role in HIV care and prevention for clients testing negative. However, care providers can face challenges getting clients to return for their test results and follow-up. In instances

where negative test results cannot be provided in-person, providers need to use a *previously agreed upon alternative*, such as a secure telephone call, letter or email to deliver HIV negative results, as well as to offer information about the client's window period, any retesting requirements, and referrals to HIV risk-reduction counselling. *Every effort should be made to ensure that the information is provided confidentially and in a manner previously discussed with the patient so that information is accessed securely only by the individual involved.*

When providing negative test results through alternate methods, caution should be exercised with clients who are repeat testers as he or she may experience increased anxiety when their test results are not available and they are suddenly required to meet with the care provider to obtain these results. Recommending a range of tests in combination with each HIV test (other STBBIs) will allow care providers to indicate that patients will be asked to return for results if "*any of the test results*" are of concern.

3.4.2 PROCEDURES FOR CONFIRMED POSITIVE TEST RESULTS

The guide strongly recommends that positive test results be delivered in person, ideally by the initial care provider. Patients should not be told in advance if only positive results require an in-person follow up visit. When providing a client with a positive test result, it is important that sufficient time is available to spend with the individual to offer support. Prior to seeing the client, care providers should have resources readily available to provide to the client (see Chapter Five). Test results should be provided in a direct and clear manner: the test has detected antibodies for HIV and the client is HIV-infected. The following elements and activities are essential when communicating a positive test result:

- Protect the **privacy and confidentiality** of the client.
- Provide the client with **sufficient time to absorb the results**, discuss the impact of a positive test result and ask questions.
- **Focus on positive messages** by highlighting advances in HIV care, treatment and support. Individuals who test positive should be made aware that HIV is now considered a chronic illness, and with the right treatment and support, people living with HIV can live long, active and healthy lives.
- Advise the client about strategies for managing HIV and provide a **link to treatment specialists.** Individuals who are not fully engaged in HIV care lose access to sustained antiretroviral therapy (risking the development of viral resistance), prophylactic medications, and other medical services. Poor engagement in care is associated with poor health outcomes, including increased mortality and can contribute to ongoing HIV transmission in the community (Gardner, 2011).
- Provide clients testing positive with **risk reduction information** to prevent transmission of the virus. In circumstances where the care provider is not able to offer in-depth risk-reduction information, a referral to risk-reduction services should be provided.
- Offer client referrals to specialized counselling services that are equipped to provide newly diagnosed individuals with the specific supports and resources that they need to manage their health and wellness.
- Discuss disclosure of the result, when and how this might happen, and with whom. Work with the client to develop a partner notification strategy to inform current and former sexual and drug-equipment sharing partners of their potential exposure to HIV and the need to be tested. Public Health services can be offered to the client to assist in partner notification (see also 3.4.4).

- Make clients aware of the public health benefits of disclosing ones HIV status to current and future partners in the event of a positive test result. Care providers should never provide legal advice; provide clients with appropriate referrals for additional information such as the Canadian HIV/AIDS Legal Network (www.aidslaw.ca).

Clients being testing using a rapid HIV test kit with a reactive result should be made aware of the possibility of a false reactive and that confirmatory testing will be required to be fully certain of their HIV status. The client should be advised to maintain safer practices.

3.4.3 REPORTING POSITIVE RESULTS

All provinces and territories have reporting requirements for HIV-positive test results and/or AIDS diagnoses meaning that provincial/territorial health authorities must be informed of results. The reporting obligations vary across jurisdictions and may include non-identifying information, name-based results, and information about results from anonymous testing services.

3.4.4 DEVELOPING A PARTNER NOTIFICATION STRATEGY

Following a positive test result, clients and care providers should discuss and agree upon a strategy to inform current and former sexual and drug-equipment sharing partners. Partner notification is an important public health strategy designed to prevent further HIV transmission and reduce morbidity and mortality associated with HIV and AIDS. In Canada, partner-notification responsibilities and requirements are set out under provincial and territorial legislation, Public Health Acts, regulations and/or practice protocols.

Full disclosure of current or former partners is voluntary and may be dependent on the degree to which a client feels that their anonymity can and will be protected. Having Public Health assist in partner notification can help care providers and clients who might otherwise lack the resources and/or capacity to do this. It can also help protect client confidentiality and anonymity in the partner-notification process to the greatest extent possible. Providers are encouraged to use the range of Public Health services that may benefit their clients.

The process of partner notification includes:

- **Identifying** and **locating** the client's former and current sexual partners and/or drug-equipment sharing partners who might have been exposed, starting with the current or most recent partners and working back in time, stopping at the onset of at-risk behaviours or last known HIV-negative test.
- **Assessing** the risk of infection to which those partners may have been exposed through their contact with the client.
- **Informing** those partners that they may have been exposed to HIV.
- **Offering** voluntary HIV testing and testing for related infections to the former and current partners of the client. *Partners of people testing positive may be surprised to learn of their possible risk of exposure but should be provided all pre-, post-test, and risk-reduction counselling regardless of whether they already perceive themselves as potentially HIV-positive.*
- **Assisting** these partners in obtaining access to care, treatment and support as required.

In a discussion between a care provider and client, a partner notification strategy should be developed using at least one of the following three recommended approaches:

- With the consent of the testing client, **the testing provider may make a request to local Public Health officials** (provider referral) who can then undertake notification of potentially exposed sexual and drug-equipment sharing partners as identified by the testing client.
- **The testing client may prefer to independently contact his or her current and former sexual and/or drug-equipment sharing partners** (client referral) if this is agreed between the testing client and the test provider and there is a set time for confirming that partners have been notified.
- With the consent of the testing client, **the testing provider may contact the testing client's current and former sexual and drug-equipment sharing partners** (provider referral). The provider must protect the confidentiality and the anonymity of the client to the greatest extent possible. Partners of people testing positive may be surprised to learn of their possible risk of exposure to HIV. These contacts should be treated like all clients who present for HIV testing, and be provided with all the necessary pre- and post-test counselling regardless of whether they already perceive themselves as potentially HIV-positive.

3.4.5 PARTNER NOTIFICATION AND CLIENT SAFETY

Partner notification may lead to serious consequences for the testing client including potential stigma, violence and discrimination. Undertaking partner notification requires careful consideration of the client's situation and potential risks. Significant barriers to partner notification can exist for clients, including:

- Actual or feared abuse
- Fear of loss of child custody
- Fear of abandonment
- Fear of re-victimization for victims of sex crimes
- Fear of legal implications
- Fear of positive status being disclosed to others by a notified partner
- Unavailability of contact information for previous partners

Focusing on protecting the client's **anonymity** and **confidentiality** to the extent possible is fundamental to protect the rights of people living with HIV/AIDS and may also encourage clients to disclose the identities of former and current partners.

Web-based Tool to Support Partner Notification

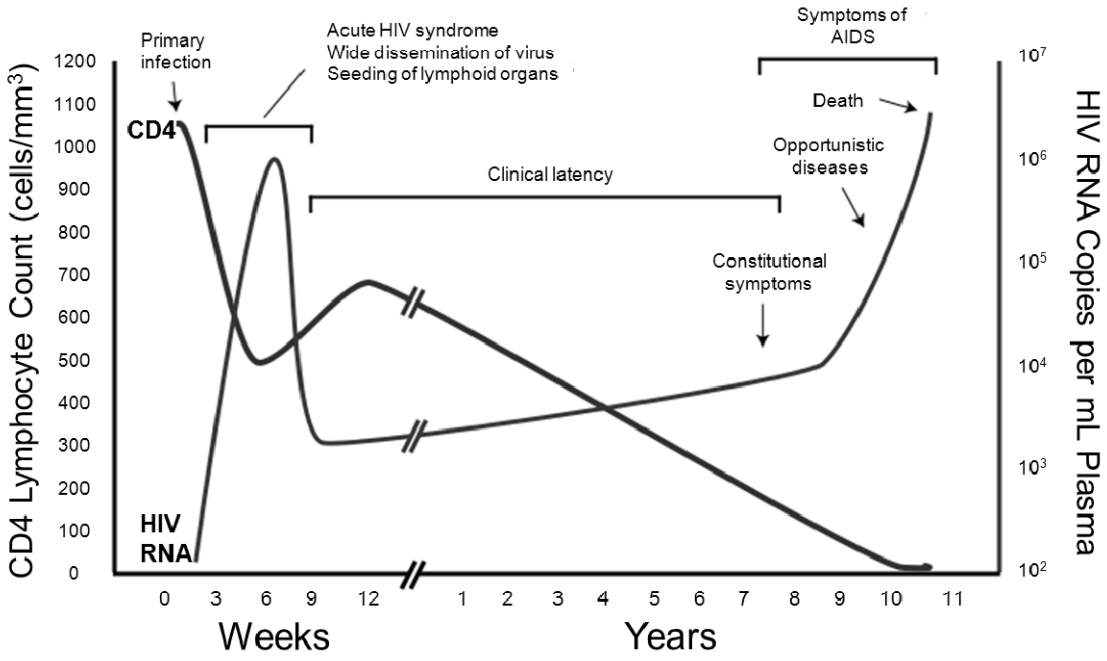
In cases where sexual partners may have met over the internet and only exchanged an email address/username, or for an individual who wishes/needs to contact a partner anonymously, web-based tools may help increase rates of partner notification. One such web-based service is inSPOT, which can be used from any location in Canada, allowing a person diagnosed with a sexually transmitted infection to send an anonymous e-card notifying sexual partners that they may be at risk for an STI, and encouraging them to seek out testing.

http://www.inspot.org/

3.4.6 POST-DIAGNOSIS CLINICAL MANAGEMENT

HIV clinical care guidelines recommend a number of baseline tests that should be done as soon as possible after diagnosis of HIV infection. These include viral load, CD4, and HIV drug-resistance assessment, as well as tests for a number of possible co-infections (such as Hepatitis B, C, STIs and tuberculosis) and complete blood count, blood chemistry, lipid, glucose, and liver function tests (Anon, 2011; Thompson, 2010).

Figure 1: HIV disease progression



The viral load (a measure of viral RNA in the plasma) is a marker of active viral replication and is reported as copies per millilitre. Viral load is extremely high during and immediately after seroconversion, often more than one million copies/ml. Once the body responds to the acute infection, viral replication is controlled or reduced, reaching a “set point” approximately six months after seroconversion. Viral load is monitored during treatment to ensure that treatment is effective; the goal of treatment is to reduce plasma viral load to an undetectable level.

Monitoring immune system function during HIV infection is important. The CD4 lymphocyte count is an important marker used to assess immune system function, the stage or progression of HIV infection and the need to start therapy. A CD4 count should be obtained as soon as possible after diagnosis, and then monitored prior to and regularly after treatment is initiated.

It is also important to assess HIV drug resistance as soon as possible after diagnosis. Although drug-resistant mutations may appear to diminish with ongoing viral replication, the parent virus that has a drug-resistant mutation still resides in viral “reservoirs”. Genetic sequencing of HIV RNA or DNA permits identification of specific mutations that are known to confer drug resistance. Information from the baseline drug-resistance test can be used to guide treatment decisions.

Laboratories offering HIV confirmatory testing usually also offer viral load and baseline drug-resistance testing and Public Health officials for your area can assist in how to order any of these tests and to locate possible referral clinics. If the testing venue does not provide follow-up care, it is important to ensure that clients with HIV infection are referred to appropriate services to meet their complex HIV care requirements.

3.5 DISCLOSURE OF HIV

Disclosure refers to the act of informing another person of the HIV-positive status of an individual. Disclosure can occur in many contexts, but the focus of this section is on disclosure to sexual and drug-equipment sharing partners, in instances where there is a potential for HIV transmission to occur.

3.5.1 THE PUBLIC HEALTH IMPORTANCE OF DISCLOSURE

When activities pose risks for HIV transmission, disclosure of HIV-positive status to sexual partners and to people with whom drug equipment is shared is an important public health goal for a number of reasons. Disclosure may motivate sexual or drug-equipment sharing partners to seek testing and adopt safer behaviours, which may ultimately protect them from infection and decrease the transmission of HIV. In addition, disclosure has a number of potential benefits for the HIV-positive client, including increased opportunities to receive social support, to discuss and implement HIV risk reduction with partners, to prevent co-infection from other sexually transmitted or bloodborne infections, and to plan for the future.

In keeping with the public health goal of preventing onward transmission, care providers should emphasize to HIV-positive clients the importance of voluntarily disclosing their status to sexual partners or to those with whom they share drug equipment and to avoid risky practices. Voluntary disclosure should be recommended to clients because it serves to empower individuals by respecting their autonomy and dignity and maintaining confidentiality as appropriate. Care providers can also work with clients to identify ways to address possible barriers to risk reduction (such as an ability to obtain and properly use condoms).

In Canada, Public Health is responsible for communicable disease control. Care providers should encourage affected clients to make use of Public Health services, community care, and support programmes that, in addition to increasing access to prevention and care services, offer support to facilitate disclosure.

3.5.2 BARRIERS TO DISCLOSURE

Care providers need to be sensitive to the fact that disclosure of one’s positive HIV status is a difficult and sensitive issue, and HIV-positive clients may be facing a number of potential risks. These risks may be considerable, such as loss of economic support, blame, threat of criminal sanctions, abandonment, physical and/or emotional abuse, discrimination, and disruption of family relationships. It is recommended that HIV-positive clients expressing concerns related to their ability to disclose be referred to their local Public Health department, or community-based AIDS organization, both equipped to provide support, counselling, and skill building to encourage behaviours that reduce risk of HIV transmission to others.

3.5.3 WORKING WITH CLIENTS UNWILLING OR UNABLE TO DISCLOSE

While the majority of people living with HIV/AIDS are very careful to take the necessary steps to prevent the spread of the virus to others, the care provider may learn or have a reason to believe that an HIV-positive client is not disclosing to his or her sexual or drug-equipment sharing partners when engaging in behaviours that represent risks for transmission. It is recommended that the care provider assess the willingness of the HIV-positive client to comply with voluntary measures to reduce the risk of HIV transmission.

In accordance with provincial or territorial Public Health legislation, care providers are to report to local Public Health when they have a reason to believe that the actions or behaviours of a client present a risk of infection to others. Public Health is equipped to work with those individuals who are unwilling or unable to disclose their HIV-positive status to sexual or drug-equipment sharing partners.

Once a client has been reported to Public Health, the local authorities will investigate the matter further pursuant to their powers, which vary by jurisdiction. The ultimate determination of whether the client is unwilling or unable to disclose will be made by local Public Health officials. Many jurisdictions employ a model similar to that endorsed by the Federal/Provincial/Territorial Advisory Committee on AIDS, which provides for a graduated response to persons who are unwilling or unable to disclose their HIV-positive status (PHAC, 2003). The public health approach to HIV testing and disclosure ensures that people living with HIV/AIDS are treated with dignity and respect while maintaining confidentiality and trust.

4. HIV TESTING TYPES AND LAB TECHNOLOGIES

This chapter provides information regarding available testing technologies, approaches to testing and interpretation of results. There are many different types of HIV screening tests that are licensed for use in Canada and can vary by jurisdiction. For questions or information specific to your province or territory please contact your local Public Health laboratory.

4.1 HOW IS HIV INFECTION DIAGNOSED?

Over the years, the technologies for HIV testing have improved in both sensitivity and specificity. There is no perfect test for HIV. It is important to provide the laboratory with complete clinical (including date of symptom onset) and risk information (including date of most recent potential exposure, if known) in order to ensure appropriate services. If the laboratory results are not consistent with the clinical picture, the situation and the need for follow-up testing should be discussed with laboratory staff.

4.1.1 DETECTION OF HIV ANTIBODY

The detection of HIV antibody is the most widely used means of diagnosing HIV. Different tests are used to detect antibodies produced in response to HIV infection (see Figure 2). These tests use HIV antigen attached to a surface to bind HIV antibodies (if present) in the sample. They detect HIV antigen-antibody complexes by means of an enzyme (attached to either antigen or antibody) that will bind to the complex to produce a measurable colour, hence the name enzyme immuno assay (EIA). EIA HIV antibody screening tests are often classified as 1st generation to 4th generation, each generation being characterized by improved sensitivity and/or specificity. First and second generation tests are no longer in use. In the case of 3rd generation screening technologies, HIV antibody is usually detectable in 50 percent of people at about 22 days after exposure; 95 percent of people at 34 days after exposure; and, 99 percent of people by three months after exposure (Busch, 1997). 4th generation tests frequently use chemiluminescent microparticle immunoassay (CMIA) which requires that the chemiluminescent reaction meet a particular threshold (in relative light units) to be considered reactive. These tests can determine the presence of both HIV p24 antigen and antibody and can reduce the window period to approximately 15 to 20 days in most patients.

These tests are carried out in a medical laboratory using sophisticated laboratory equipment. Results are reported as **non-reactive** or **reactive**. A series of test results is then interpreted as negative or positive for HIV antibodies, antigen or both. A lab may choose to report “borderline” results, which means that the result is so close to the “cut-off” value (at the borderline between reactive and non-reactive) that it’s possible there is a small amount of antibody present. Each lab will have a specific algorithm that has been validated in its own setting which usually requires a repeat of the screen test in duplicate. All samples that are repeatedly reactive (that is, reactive on at least two of the three tests) must then be confirmed with another method.

Simple/rapid assays do not require sophisticated equipment to perform and can be used in the laboratory or at the point of care (POC) to screen for HIV antibodies. While there are a variety of technologies for rapid assays, only one product is currently licensed for use as a POC device, the INSTI™ HIV-1/HIV-2 (bioLytical™ Laboratories Inc., British Columbia, Canada) and it must be used under professional supervision with pre- and post-test counselling (Constantine, 2005).

The INSTI™ HIV-1/HIV-2 kit is a “flow through” device that gives results within 60 seconds. The venous blood sample (usually from a finger stick) is diluted and allowed to flow through a permeable membrane to which HIV antigen is bound. If present, HIV antibodies in the sample will attach to the antigen. Next, a protein attached to a dark blue dye is added. The protein will attach to HIV antibodies bound to the membrane to produce a visible blue spot. Rapid/simple assays are generally equivalent to 2nd generation assays in sensitivity and specificity (≥99.0%), but it is important to consider supplemental testing if the client is potentially in the window period (Cook, 2010). Rapid/simple assays can yield false positive results particularly in low HIV prevalence populations, therefore all reactive samples from point-of-care or lab-based rapid assays require standard testing before a result can be considered confirmed.

4.1.2 DETECTION OF THE HUMAN IMMUNODEFICIENCY VIRUS

HIV infection can also be diagnosed by detecting the presence of the virus itself. Tests for viral load are used only in specific situations due to their limited accuracy (a high rate of false-positives) when compared to routine antibody testing. Viral load testing is done in select circumstances where testing for antibody is not useful for diagnosis, including:

- The testing of babies born to HIV-positive mothers. Maternal antibodies cross the placenta and are present in the newborn’s blood. These antibodies can be detected for up to 18 months, depending on the technology used, regardless of whether the baby has acquired HIV infection. As a result of this situation, the detection of HIV antibodies is not useful for diagnosing HIV in the baby.
- During the window period - the period from HIV exposure/infection until antibodies can be detected. The window period can last from three weeks to as long as three months. Testing for virus in intervals up to three months from the most recent HIV exposure, rather than antibody, will allow for earlier diagnosis.
- During advanced HIV disease or in marked immunocompromise, when the immune system may not be capable of producing detectable antibodies, although this situation is exceedingly rare.
- The testing of individuals who have received HIV vaccine during a clinical trial and may have acquired HIV antibodies as a result. In such cases, documentation of subsequent infection will require detection of the virus itself.

There are a number of different technologies that can detect the presence of the virus itself (p24 antigen) or its genetic material (DNA PCR, viral load) (Busch, 1997; Fiebig, 2003; Steckler, 2007; Brown, 2009). Most of these services are available by special request and require prior arrangement with the laboratory. 4th generation testing that detects antibody and antigen improves our ability to detect both acute and chronic HIV infection.

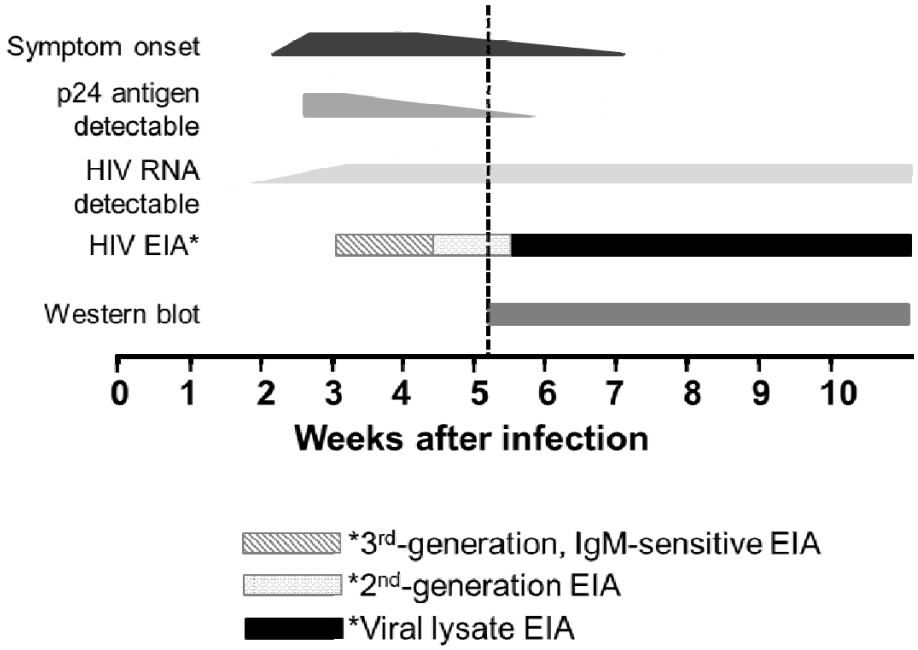
P24 Antigen

P24 antigen is a component of the virus itself (a core protein) that can be detected with EIA and CMIA methodology. Results are expressed as reactive or non-reactive; all reactive samples require confirmation with a neutralization assay (Stekler, 2009). Combination test which screen simultaneously for p24 antigen and HIV antibody using CMIA-based technology are the most recent development in HIV diagnostic technology. These 4th generation tests allow for the detection of acute, established, or very late HIV infection (Sickinger, 2008). These tests are able to detect p24 antigen and thus identify early window period infections which might otherwise have been reported as negative using the 3rd generation enzyme immuno assay (EIA) which detects antibody only.

RNA/DNA PCR
Nucleic Acid Amplification Technologies (NAAT) can detect viral genetic material (ribonucleic acid [RNA]) or viral genetic material that has been integrated into the host deoxyribonucleic acid (DNA). The Qualitative RNA/DNA Polymerase Chain Reaction (PCR) is positive if either HIV RNA or DNA is present in the sample. This test is presently available only by pre-arrangement with the laboratory, and is reported as a "research use only" test. It is used primarily in the diagnosis of babies born to HIV-positive mothers, but it can also be used as a supplemental test for someone with persistently indeterminate Western Blot results and for early diagnosis during the window period.

Viral Load
Detection and quantification of plasma HIV RNA is an important monitoring tool to assess the need for and effectiveness of antiretroviral treatment. HIV viral load can be determined using PCR, Branch DNA, Nucleic Acid Sequence Based Amplification (NASBA) and Transcription Mediated Amplification. All of these NAAT methods use an amplification step in order to detect and quantify HIV RNA (which is an indicator of viral replication). All are very sensitive and can quantify low levels of HIV RNA. These tests are primarily used for monitoring antiretroviral treatment, but have been validated by many labs as a supplemental test during the window period of HIV infection.

Figure 2: Testing Types and Timing (Branson, 2007)



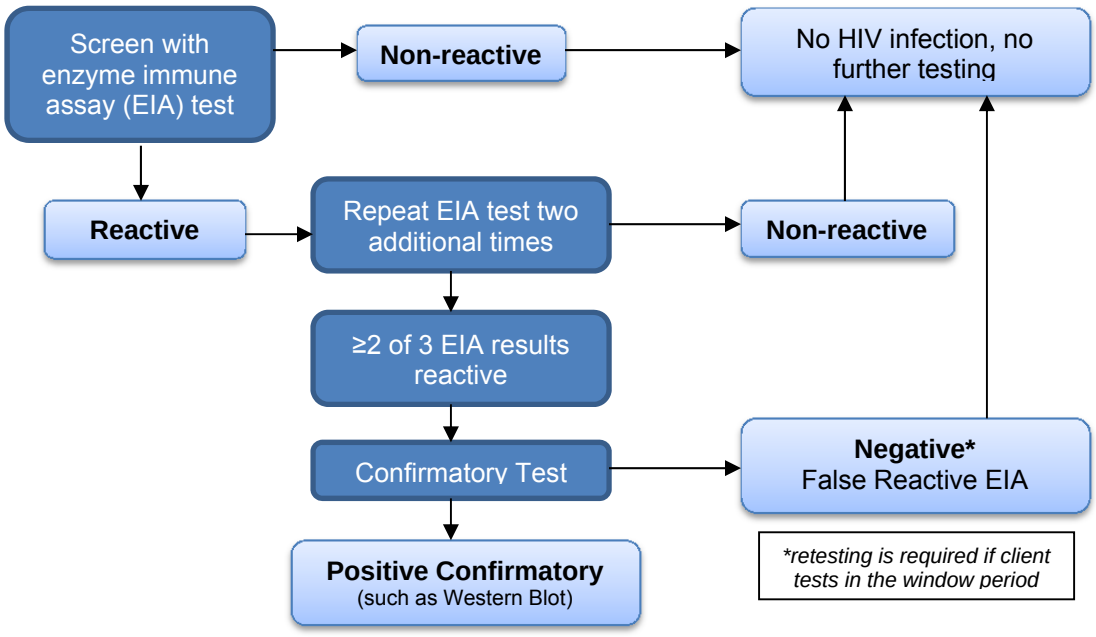
4.2 TERMS AND TECHNOLOGIES USED IN HIV TESTING

This section provides detailed definitions and descriptions of the terms and technologies used in HIV testing.

4.2.1 ALGORITHMS

Algorithms for HIV testing have been developed to ensure optimal sensitivity while preserving specificity by confirming reactive results as antibody-positive. The test sequence starts with the most sensitive screening test to identify all those with antibodies. A confirmatory assay (with a high-specificity test) is then performed only on the samples that tested reactive/positive on the initial screening test. This ensures that the screen test reaction is due to detection of HIV antibodies rather than a non-specific (false positive) reaction. In the case of indeterminate or inconclusive results, additional supplementary testing may be necessary to determine if someone is infected with HIV. Each laboratory develops and validates its own algorithm (checking results for samples from people known to be HIV infected/uninfected) to ensure that it provides the most accurate results possible. The positive predictive value and negative predictive value of a validated algorithm are close to 100%.

A typical laboratory testing algorithm follows:



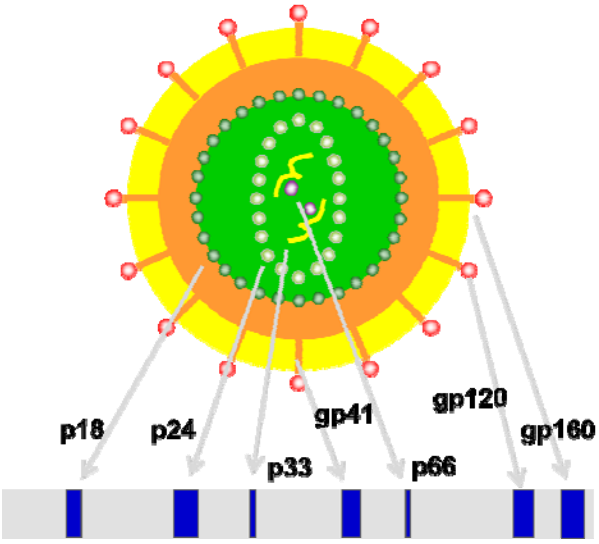
4.2.2 CONFIRMATORY TESTS - ANTIBODY

As shown in Figure 3, the Western Blot assay uses individual components of the whole virus embedded on a strip to bind patient antibody. Similar to the EIA methods described previously, the bound patient antibody is detected with an enzyme-labelled anti-antibody that produces a coloured reaction. Samples with no bands are considered negative. In general, samples with a reaction for both envelope (any of gp41, gp120, gp160) and core proteins (p24) are considered positive; those with one or more bands, but not enough to be considered positive, are classified

as “indeterminate” (see also 4.3.2). The presence of envelope antibodies alone is sufficient to confer HIV antibody positive status if there is a clinical diagnosis of AIDS. Although the Western Blot assay is very specific, it is not a very sensitive assay to antibodies developed in acute HIV infection, and it can take longer than most screen assays to become positive (Fiebig, 2003).

Line Immunoassays (LIA) or Recombinant Immuno Blot Assays (RIBA), are similar to the Western Blot assay, although they use recombinant or synthetic proteins rather than proteins extracted from whole virus preparations. The interpretation of results is also similar to Western Blot (Schüpbach, 2011). Although these tests offer improved sensitivity and specificity, they are not yet licensed in Canada.

Figure 3: Western blot assay



Radio Immune Precipitation Assay (RIPA) is widely accepted as the most sensitive and specific of the confirmatory assays for HIV antibody. It is not available as a kit and requires a very sophisticated facility and training to carry out the requisite virus culture and radioactive labelling. This test is available in Canada only at the National Laboratory for HIV Reference Services for special cases through consultation with and referral from provincial laboratories.

4.2.3 HIV SUBTYPES AND CLADES

HIV has two main subtypes: HIV-1, and HIV-2. HIV-1 is the predominant subtype in Canada and throughout the world, and has many “clades” or subspecies. HIV-2 is predominantly found in West Africa countries and can be found in countries with strong ties to West Africa. HIV-2 infection does not appear to be as easily transmitted and immunodeficiency takes longer to develop. Unlike HIV-1 which is highly infectious in the acute stage, HIV-2 infectiousness increases in the later stages of AIDS and the highly infectious stage is shorter when compared with HIV-1. HIV-2 does not play a significant role in the HIV epidemic in Canada. All screen tests licensed in Canada have the ability to detect both HIV-1 and HIV-2 antibodies; however, most confirmatory tests detect HIV-1 only, and suspected HIV-2 cases are to be confirmed at the National Laboratory for HIV Reference Services (NLHRS). Clients with risk behaviours originating in West Africa, or with persons linked to West Africa, may require a confirmatory test for HIV-2.

The HIV replication cycle results in many mutations, giving rise to a great deal of genetic diversity and subspecies of HIV-1 (A, B, C, D, F, H, J, K) and leading to the development of antiretroviral drug resistance.

4.2.4 REFERENCE SERVICES

Most provincial laboratories in Canada offer some reference services including confirmatory testing (Western Blot) and Qualitative RNA/DNA detection. In addition, the National Laboratory for HIV Reference Services (NLHRS) provides specialized services, including differentiation of HIV-1 and HIV-2, testing to resolve indeterminate cases, identification of potential new HIV subtypes and clades, diagnosis of HIV infection using different sample types (tissue, formalin fixed, CSF, dried blood spots, oral fluids, microscope slides, etc.), and technologies and reference services related to Human T-cell Leukemia Virus (HTLV). The NLHRS also provides national guidance and quality assurance programs related to HIV serology, viral load and other NAAT services.

4.2.5 CANADIAN ASSOCIATION OF HIV CLINICAL LABORATORY SPECIALISTS

The Canadian Association of HIV Clinical Laboratory Specialists (CAHCLS) (www.cahcls.ca) is comprised of HIV laboratory specialists from across Canada who meet annually to develop consensus and share expertise on HIV diagnostic technologies and practice, encourage research and information sharing, promote training and continuing education of HIV laboratory technologists, and develop partnerships with AIDS community organizations. This ongoing communication helps ensure the availability of state-of-the-art HIV testing services in Canada.

4.2.6 REGULATION OF THE SALE OF MEDICAL DEVICES IN CANADA

Because of the significance and consequences of the diagnosis (Health Canada, 1998a and 1998b), HIV diagnostic test kits undergo rigorous review of manufacturing, safety, effectiveness, quality and performance before they are approved for sale in Canada.

The onus is on the laboratory to validate and monitor (on an ongoing basis) the performance of the test device as part of its quality system requirements, and to report any problems with these kits. Laboratories that develop in-house testing methodologies are also responsible for validation, ongoing monitoring and quality assurance.

4.2.7 HOME TEST KITS

Currently, no HIV home test kits are licensed for use in Canada, however a rapid oral fluid specimen test kit is available in the United States. This kit has been found to have a lower sensitivity when self-administered than when administered by a health professional (^93% versus ^98%). In tests performed on known HIV-infected individuals, the home test kit produced about one false negative result out of every 12 tests performed. A person who is at high-risk or who has had any HIV risk activity in the previous 3 months who tests negative using a home test kit should be encouraged to undergo follow-up testing (see also 4.3.1). Despite a negative rapid HIV test result, all patients who have had any HIV risk activity in the previous 3 months should be informed of the benefits of repeat HIV testing. Testing of non-infected individuals produced about one false positive result for every 5,000 tests: individuals with reactive test results should undergo confirmatory testing.

4.3 CHALLENGES IN HIV TESTING

4.3.1 HIV TESTING IN THE "WINDOW PERIOD"

The window period is the time after acquisition of HIV infection when the individual is highly infectious but tests negative on HIV antibody screening because antibodies are not immediately produced. As shown in Figure 4, the timelines associated with the window period have changed with the evolution of more sensitive antibody screening tests. While 1st generation tests detected HIV antibody an average of 60 days following exposure the 4th generation combination tests (p24 antigen and 3rd generation HIV antibody) permit detection of acute HIV infection during the viremic phase. This reduces the window period to approximately 15 to 20 days. Making the diagnosis as early as possible can help prevent onward transmission of the virus, since the person is most infectious during this period. Some jurisdictions provide NAAT testing for high-risk clients (to detect HIV RNA), in an effort to identify very early HIV infection.

Testing is recommended at baseline and at three weeks after a known or suspected exposure to HIV. If results are negative, testing should be repeated at three months after the exposure. Client counselling within the window period should include the possibility that HIV infection is present in spite of a negative HIV test result. There are individual variations in the time to development of HIV antigen or antibody and newer testing technologies permit earlier detection. However, in particular instances where the exposure is known to be high risk (such as unprotected sexual intercourse with a partner known to be HIV-infected) repeat testing at intervals during the window period (if each result is negative) can help identify HIV infections in the acute stage. It is important to provide clinical, risk and exposure information to the laboratory performing the testing, so they can ensure that the appropriate testing (antibody, p24 antigen and/or NAAT) is done (Young, 2007).

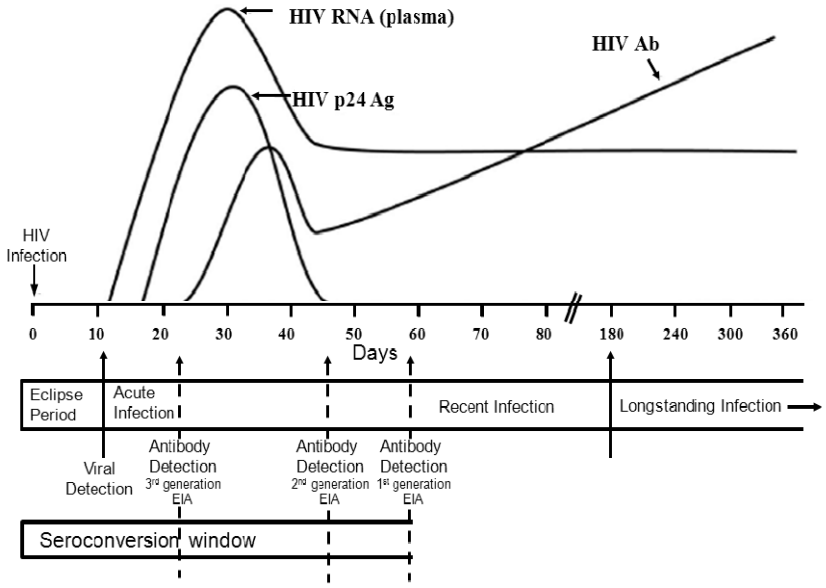
4.3.2 INDETERMINATE RESULTS DURING THE WINDOW PERIOD

Test results may be indeterminate (inconclusive) during the seroconversion process, as the Western Blot assay may take up to 60 days to become fully reactive. Some individuals without HIV infection will also have indeterminate results on Western Blot. All indeterminate results require follow-up specimens with complete clinical and risk information in order to resolve the HIV status with supplemental and, if necessary, reference testing. An indeterminate result can cause anxiety for an individual, so it is important to understand whether there is a risk for HIV infection to provide appropriate counselling.

4.3.3 CONFIRMATORY TESTING

The Western Blot assay is not as sensitive as the 3rd and 4th generation screening tests and may yield indeterminate results during the window period. New algorithms employing NAAT as a confirmatory test are currently being evaluated.

Figure 4: Antigen/Antibody detection periods



4.3.4 GENETIC DIVERSITY OF HIV

Genetic diversity is another challenge to serological and molecular tests. New mutations, clades and, potentially, subtypes may arise. It is possible that currently available tests might not be able to detect either the new virus or the resulting antibody if these are far enough removed from the strains used to develop HIV tests. This is one of the reasons it is important to provide the lab with clinical and exposure information. If the laboratory result is not consistent with the clinical picture, it is important to consult with the laboratory staff to assess the need for follow-up and reference testing.

4.3.5 QUALITY ASSURANCE PROGRAMS

All medical laboratories in Canada must be licensed by a governing body. Accreditation of medical laboratories requires that laboratories support their testing with rigorous quality control and quality assurance programs.

4.4 MODES OF HIV TESTING

Most jurisdictions in Canada offer several different modes of HIV testing.

4.4.1 NOMINAL HIV TESTING

The most common mode of testing is using the full name of the patient at all stages of the testing process. In this case, the provider has the name of the individual, and testing is carried out with the patient name on the requisition. Test results are recorded in the client's chart, and if positive, results are reported nominally to Public Health officials where required. Measures need to be in place to ensure strict confidentiality around protecting client results among all staff within clinical settings.

4.4.2 NON-NOMINAL (CODED) HIV TESTING

Many jurisdictions also accommodate non-nominal testing. In this case, the provider knows the individual's identity, but uses a code for the HIV lab test requisition, so the lab does not have the person's name. In this case, if HIV is reportable, the lab forwards the positive reports to Public Health officials who can then contact the provider to determine necessary follow up.

4.4.3 ANONYMOUS HIV TESTING

Special legislation authorizes HIV testing without requiring any identifying or health insurance information. Anonymous testing services are usually affiliated with sexually transmitted infection (STI) clinics serving at-risk populations and are meant to encourage those who are at highest risk of HIV, but who might be concerned about the Public Health reporting requirements, to proceed with testing. Anonymous testing is done in specially designated clinics that use codes to carry out testing; no identifying information is collected or recorded. Positive results are reported to Public Health officials in jurisdictions where this is required; however, no personal identifying information is included. Enhanced counselling is provided for all clients, and support and referral services are available. While anonymous testing provides some benefit, clients who test positive anonymously should be made aware that access to effective HIV treatment, along with the benefits of earlier initiation of treatment, cannot be provided until a nominal test is completed.

4.5 TYPES OF HIV TESTING SERVICES

4.5.1 STANDARD

The majority of healthcare venues carry out "standard" HIV testing. This means a tube of blood is collected in the clinic, hospital or physician's office and sent to the medical laboratory along with a requisition ordering an HIV test. Standard testing can be done in any type of setting (physician offices, clinics, hospitals). Test results are generally available within one week.

4.5.2 POINT-OF-CARE OR RAPID TESTING

Care providers can also make use of rapid testing technologies where available for use. Rapid tests requires that pre- and post-test procedures to be conducted in a single session and allows clients to receive their test results in a single visit. It is recommended that care providers operating in an emergency room setting take advantage of rapid testing technology to ensure diagnosis and post-test counselling reaches their clients. Some sites offer HIV point-of-care (POC) testing, which means the test is carried out at the site and results are available immediately. These are usually special settings designed to attract high-risk clients (STI clinics, needle exchange/risk reduction sites, gay men's health centres). In order to do POC testing, facilities need to provide pre- and post-test counselling. If the POC test is non-reactive and *the client is not in the window period*, post-test counselling can be carried out and the client can leave with the knowledge that they are HIV antibody negative. If the client is potentially in the window period, a standard lab test is also done to preclude possible acute HIV infection and the client is counselled to return for test results. If the POC test is reactive, a standard test should be conducted to confirm the reactive result, and the client should be counselled appropriately and advised to return for test results. Some jurisdictions require that clients with negative POC results also have a standard test. Most jurisdictions require that anonymous records of all POC

tests be provided to local authorities in order to evaluate testing programs and track the HIV epidemic.

4.6 WHERE TO ACCESS TESTING SERVICES

Standard HIV testing can generally be accessed through any health provider across the country. Each province is responsible for licensing the laboratories that provide HIV screening and confirmatory testing in its jurisdiction. In general, all provincial Public Health Laboratories provide both screening and confirmatory testing. Reference and specialized services, when required, are provided by the National HIV Reference Serology Laboratory after consultation with the provincial laboratory. It is advisable to contact your testing laboratory to confirm the specimen collection details.

Anonymous or POC testing locations can be found by calling a local HIV/AIDS hotline (see Appendix E).

5. OTHER RESOURCES

Prevention, support and treatment resources

- **CANADIAN AIDS TREATMENT INFORMATION EXCHANGE (CATIE)**
  CATIE is Canada's source for up-to-date information about HIV and hepatitis C.
  The organization connects people living with HIV or hepatitis C, at-risk communities, health and other care providers and community organizations with the knowledge, resources and expertise to reduce transmission and improve quality of life. CATIE provides access to a wide range of resources, conducts extensive educational outreach, and offers printed materials through the CATIE Ordering Centre.

  Visit CATIE online at: www.catie.ca or toll-free at: 1.800.263.1638

- **CANADIAN AIDS SOCIETY (CAS)**
  CAS is a national coalition of AIDS Service Organizations. A directory of organizations across Canada can be found at:

  http://www.cdnaids.ca/members.nsf/memberlistwebbyregion!Openview&language=english

  Contact CAS toll-free at 1.800.499.1986

Other HIV-related testing guidelines

- British Columbia Provincial Health Services Authority. (2011). ***HIV Pre and Post Test Guidelines*****.** British Columbia Centre for Disease Control, Vancouver, Canada.

  http://www.bccdc.ca/resources/guide-forms/HIVPrePostGuidelines.html

- British Columbia Provincial Health Services Authority. (2012). ***Point of Care HIV Test Guidelines for Health Care Settings.*** British Columbia Centre for Disease Control, Vancouver, Canada.

  http://www.bccdc.ca/SexualHealth/Programs/ProvincialPointofCareHIVTestingProgram/default.htm

- Saskatchewan Ministry of Health/Population Health Branch. (2012). ***Guidelines for the use of HIV Point of Care (POC) Test Kits in Saskatchewan***. Regina, Saskatchewan.

  http://www.health.gov.sk.ca/hiv-testing

- Saskatchewan HIV Provincial Leadership Team. (2012). ***HIV Information for Professionals***. Saskatoon, Saskatchewan.

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- Manitoba Health. (2010). ***Communicable Disease Management Protocol – Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS).*** Communicable Disease Control Branch, Winnipeg, Canada.

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  http://www.inspq.qc.ca/pdf/publications/1334_DepistageVIHPointServiceTrousseRapide.pdf

- Institut national de santé publique du Québec et Ministère de la Santé et des Services sociaux. (2010). ***Dépistage du VIH dans les points de service à l'aide de trousses de dépistage rapide - Supplément - guide québécois de dépistage des ITSS.*** Ministère de la Santé et des Services sociaux, Québec, Canada.

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  and
  http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2005/05-317-03_maj_mars2010.pdf

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  http://www.med.mun.ca/getdoc/d14e7458-a73e-468a-8290-12f107188daf/PDF-OCT-25-2010-Final-HCT-Report.aspx

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APPENDIX A: ETHICAL AND PROFESSIONAL CONSIDERATIONS

Policy concerning the ethical and professional roles and responsibilities of care providers is informed by the providers' respective institutional code of ethics as well as the professional colleges under which they are governed.

The following is designed to complement, not supersede, existing codes of conduct or jurisdictional health policies and regulations or any applicable laws and regulations of the jurisdiction.

Consent
In Canada, HIV testing is voluntary[1]. Voluntary testing means that the client is free to accept or refuse the offer of testing without threat or coercion (Evans, 2006).

Basic principles of consent under Canadian law require care providers to ensure that:

- The client has the capacity to consent to the test offer
- The client's consent to the test offer is voluntary
- The client has been properly informed of the benefits and risks of taking the test or refusing the test
- The client fully understands the offer

In their application of these basic principles, and in keeping with UNAIDS/WHO recommendations (2004), this guide recommends that care providers also inform clients of the following:

- The clinical benefit and the prevention benefits of testing
- The right to refuse
- The follow-up services that will be offered
- In the event of a positive test result and notification of public health, explaining the importance of anticipating the need to inform anyone at former, current or future risk, who would otherwise not suspect they were being exposed to HIV infection

In Canada, many care providers also provide additional information regarding HIV disclosure to previous and prospective partners as part of their protocols so that clients are better informed in making their decision to consent.

Although informed consent cannot be implied or assumed, it is not necessary for the testing client to provide written consent; verbal consent is sufficient to proceed with testing. Care providers should also note that it is a legal and ethical violation to perform an HIV test without informed consent. Under no circumstances should the tester exert pressure or use coercive techniques to obtain a client's consent.

[1] *Some exceptions exist where voluntary consent may not be a requirement; however, such circumstances exist outside of the provision of routine medical care as described in this guide and are therefore beyond the intended scope of this document.*

In the event that a client does not provide their informed consent to be tested, the care provider should engage the client in discussion about his or her reasons for refusing the test, without judgment. In the event a client declines the test, the provider should encourage the client to consider seeking an anonymous test (where available) and offer resources such as written information or websites on HIV testing and referral to relevant services.

Capacity to consent
In order for a client to give valid consent to an HIV test, he or she must have the capacity to consent. Capacity refers to an individual's ability to understand and appreciate the nature and consequences of decisions (Canadian Nurses Protective Society, 2011). If the care provider has reason to believe the client lacks the capacity to consent to an HIV test, the care provider should consult professional codes of conduct and governing provincial or territorial legislation for guidance. Note that there are special circumstances around age of consent and mental competence to which particular attention must be given.

Testing of minors
An individual who is under the legal age of majority may have the capacity to consent to HIV testing if he or she has the mental and emotional development to allow for a full appreciation of the nature and consequences of the test offer (Canadian Medical Association, 1995). Care providers should turn to professional codes of conduct and applicable provincial or territorial legislation for guidance in determining the capacity of a minor, or the role of parents/guardians in the provision of consent for HIV testing.

Mental incapacity
There may be situations in which an individual lacks the mental competence to understand and process information (such as level of consciousness, influence of drugs or other substances, disease, mental illness, age). Care providers should turn to professional codes of conduct and applicable provincial or territorial legislation for guidance on capacity assessments in the case of mental incapacity and for information about obtaining authorization from a substitute decision-maker.

Confidentiality
A person's decision to pursue HIV testing and his or her HIV status are both confidential pieces of information. A breach in client confidentiality and trust can result in serious harm to the client and legal implications for the care provider. Unintentional disclosure of an individual's HIV infection has been associated with violence and abuse, loss of employment, loss of or damage to property and/or housing, community rejection and social isolation (UNAIDS, 2007).

As with all medical information, it is the responsibility of the provider to maintain the highest standards of confidentiality regarding the medical records of clients who access HIV testing.

It is important that testing clients be informed of the **limits of confidentiality**, such as those outlined in provincial and territorial Public Health Acts. The reporting obligations identified in such statutes supersede physician/client confidentiality.

UPHOLDING CONFIDENTIALITY

- Inform the client of how HIV test results are recorded and stored, including any limitations that might be posed by electronic health records.
- Inform the client of how confidentiality is maintained by staff.
- Inform the client of the limits of confidentiality, such as those outlined in provincial/territorial public health acts and child protection legislation.
- Inform staff of what is considered a breach of confidentiality and the potential implications of a breach for both the client and the staff. Staff members should be committed to confidentiality and addressing errors when they occur.
- Avoid unnecessary identifying markers on client files, or in other file storage procedures, that could identify the client's HIV infection.
- Maintain client confidentiality in third-party clinical auditing.
- Communicate positive test results to clients as directly as possible; the original care provider should do so unless otherwise agreed to in advance by the testing client.
- Communicate test results in a private setting.

Pediatric confidentiality

It is only necessary for a child's parents or legal guardians, as well as the child's physician, to be aware of the child's HIV infection. Care providers are not obligated or permitted to inform the child's school or childcare services. Parents and legal guardians who choose to disclose their child's HIV infection should be encouraged to stress the child's right to privacy.

Testing and client privacy in non-traditional settings

In an effort to reduce barriers to HIV testing, HIV testing is increasingly being offered in non-traditional settings. For the purposes of this guide, "non-traditional settings" refers to testing undertaken in settings such as:

- Organizations for gay and bisexual men
- Migrant services
- Mental health services
- Correctional services
- Drug-related risk-reduction services
- Aboriginal health services
- University and college settings
- Perinatal services
- Abortion services
- Bath houses
- Mobile units
- Shelters (housing, women's, family protection, youth)
- Exotic dance bars and night clubs.

The offer of testing in non-traditional settings presents unique challenges to maintaining client privacy (such as HIV testing offered in bath houses in the presence of others). Care providers offering testing in non-traditional settings should consider any contextually unique challenges and develop effective strategies for ensuring that client privacy is respected.

APPENDIX B: PERFORMING A COMPREHENSIVE HIV/STI RISK ASSESSMENT

General principles
Information from the patient should be requested in a simple, non-judgmental manner, using language understandable to the patient.

History should enquire about the following:

- Genital symptoms associated with STI (discharge, dysuria, abdominal pain, testicular pain, rashes, lesions).
- Systemic symptoms associated with HIV/STIs (fever, weight loss, lymphadenopathy).
- Any previous history of tuberculosis.
- Personal risk factors and prevention (condom use, vaccination against hepatitis B and, in the case of individuals at risk, hepatitis A).
- Patient's knowledge of increased risk of HIV/STIs.
- Other pertinent elements of general history, such as relevant drug treatments, allergies and follow-up of previous problems.

A brief risk assessment should aim to quickly identify or rule out major risk factors associated with increased risk of HIV/STIs. Use of an HIV/STI risk assessment script such as the following may be helpful in rapidly assessing risk:

"Part of my job is to assess sexual and reproductive health issues. Of course, everything we talk about is completely confidential. If it's okay with you, I would like to ask you a few questions in this area."

- Are you sexually active now, or have you been sexually active? This includes oral sex, anal sex, or vaginal sex.
- Do you have any symptoms that might make you think that you have HIV or another STI? (Do you have any sores on or around your genitals? Does it hurt or burn when you pee? Have you noticed an unusual discharge from your vagina, penis or anus? Do you have pain when you have sex?)
- What are you doing to avoid pregnancy? (Do you or your partner use any type of birth control?)
- What are you doing to avoid HIV and other STIs?
- Do you have any concerns about relationship or sexual violence or abuse?
- Have you or your partner(s) ever used injection or other drugs (such as crystal meth)?
- For women also ask:
    - "When was your last menstrual period?"
    - "When was your last Pap test?"

Any patient whose current or past history identifies a potential risk factor for HIV and other STIs should have a more detailed history completed. This risk assessment questionnaire (abridged from the *Canadian Guidelines on Sexually Transmitted Infections*; PHAC, 2010) is intended to serve as a practical guide to assist clinicians in further evaluating an individual patient's risk factors and behaviours, as well as guiding counselling and testing recommendations.

HIV and STI risk assessment questionnaire

Category and Elements	Important Questions to Guide Your Assessment
Relationship	
• Present situation	• Do you have a regular sexual partner? • If yes, how long have you been with this person? • Do you have other partners?
• Identify concerns	• Do you have any concerns about your relationship? • If yes what are they? (e.g. violence, abuse, coercion)
Sexual risk behaviour	
• Number of partners	• When was your last sexual contact? Was that contact with your regular partner or with a different partner? • How many different sexual partners have you had in the past 2 months? In the past year?
• Sexual partners, orientation	• Are your partners, men, women or both?
• Sexual activities	• Do you perform oral sex (i.e., Do you kiss your partner on the genitals or anus)? • Do you receive oral sex? • Do you have intercourse (i.e., Do you penetrate your partners in the vagina or anus? Or do your partners penetrate your vagina or anus)?
• Personal risk evaluation	• Have any of your sexual encounters been with people from a country other than Canada? If yes, where and when? • How do you meet your sexual partners (when travelling, bathhouse, Internet)? • Do you use condoms, all the time, some of the time, never? • What influences your choice to use protection or not? • If you had to rate your risk for STI, would you say that you are at no risk, low risk, medium risk or high risk? Why?
STI history	
• Previous HIV/STI screening	• Have you ever been tested for HIV/STI? If yes, what was your last screening date?
• Previous STI	• Have you ever had an STI in the past? If yes, what STI and when?
• Current concern	• When was your sexual contact of concern? • If symptomatic, how long have you had the symptoms that you are experiencing?

Category and Elements	Important Questions to Guide Your Assessment
Reproductive health history	
• Contraception	• Do you and/or your partner use contraception? If yes, what? Any problems? If no, is there a reason?
• Known reproductive problems	• Have you had any reproductive health problems? If yes, when? What?
• Pap test	• Have you ever had an abnormal Pap test? If yes, when? Result if known.
• Pregnancy (for females)	• Have you ever been pregnant? If yes, how many times? What was/were the outcome(s) (number of live births, abortions, miscarriages)?
Substance use	
• Share equipment for injection/inhalation	• Do you use alcohol? Drugs? If yes, frequency and type? • If injection drug use, have you ever shared equipment? If yes, what was your last sharing date? • If inhalation drug use (e.g.. crack), have you ever shared equipment like pipes or straws? If yes, what was your last sharing date?
• Sex under influence	• Have you had sex while intoxicated? If yes, how often? • Have you had sex while under the influence of alcohol or other substances? What were the consequences? • Do you feel that you need help because of your substance use?
• Percutaneous risk other than drug injection	• Do you have tattoos or piercings? If yes, were they done using sterile equipment (i.e., professionally)?
Psychosocial history	
• Sex trade worker or client	• Have you ever traded sex for money, drugs or shelter? • Have you ever paid for sex? If yes, frequency, duration and last event.
• Sexual Abuse	• Have you ever been forced to have sex? If yes, when and by whom? • Have you ever been sexually abused? Have you ever been physically or mentally abused? If yes, when and by whom?
• Housing	• Do you have a home? If no, where do you sleep? • Do you live with anyone?

APPENDIX C: HIV TRANSMISSION RISK

This appendix is condensed from a more detailed technical report, *HIV Transmission Risk: A Summary of the Evidence*[1] which synthesises the scientific evidence on the risk of HIV transmission through sexual activities, injection and other drug use, and mother-to-child (vertical) transmission. Over 200 references formed the basis of the review, based on a search of the literature for the period between 2001 and May 2012[2]. The findings from this large body of evidence demonstrated the difficulties inherent in quantifying the risk of HIV transmission, in part due to the role of behavioural and biological co-factors, including viral load and the presence of co-infections, in increasing or decreasing the risk of transmission.

Sexual transmission

In Canada, sexual transmission is the most common cause for HIV infection. In 2008, an estimated 44% of new HIV infections were attributed to men who have sex with men (MSM), and an estimated 36% of newly infected individuals were exposed through heterosexual sex. These estimates were roughly the same as those for 2005.

Although there are challenges in quantifying risk by sex act, all studies consistently report that:

- Unprotected anal intercourse is a higher risk act than vaginal intercourse, which in turn is a higher risk act than oral intercourse; and,
- There is an increased risk associated with receptive intercourse as compared to insertive intercourse.

Anal intercourse

Based on the results of cohort studies and meta-analyses, the per-act risk estimate of transmission from receptive anal intercourse ranges from 0.5% to 3.4%, with several estimates in the mid-range of roughly 1.4% to 1.7%. Most of these estimates are based on studies of MSM. However, the risk appears to be similar among heterosexual populations. The risk of transmission from insertive anal intercourse is estimated to be lower, with risk estimates ranging from 0.06% to 0.16%. Anal intercourse carries a higher risk of HIV transmission for both receptive and insertive partners, when compared with vaginal intercourse, because rectal mucosa differs from vaginal mucosa. There is a higher density of lymphocyte follicles (i.e., HIV target cells) in rectal mucosa and it is more susceptible to abrasions than vaginal mucosa. The risk of transmission to the receptive partner resulting from unprotected anal intercourse has been estimated to be between 5 and 18 times higher than the risk from receptive vaginal intercourse.

Vaginal intercourse

The estimates for receptive vaginal intercourse (i.e., male to female[3]) have ranged from 0.08% to 0.2%. The risk estimates have been slightly lower, ranging from 0.05% to 0.1%, for insertive vaginal intercourse (i.e., female to male). Several studies have examined the risk of sexual transmission among heterosexual populations, without specifying the nature of the sex acts (i.e., vaginal versus anal intercourse), however, it is assumed that the majority of the sex acts were penile-vaginal. Higher rates have been reported for male to female sexual transmission, compared to female to male sexual transmission. This may be due to biological mechanisms,

[1] *Public Health Agency of Canada, 2013; Full report available upon request at: ccdic-clmti@phac-aspc.gc.ca*

[2] *The search focused on systematic, meta-analytic and narrative reviews, where they existed. For topics where no reviews existed, research studies were included.*

[3] *Transgender males who have not undergone genital reassignment surgery should be presumed to be at an equivalent risk for receptive vaginal intercourse.*

such as a larger anatomical surface, and higher numbers of vulnerable cell types in the vagina compared to the penis.

Oral intercourse
The risk of HIV transmission through oral intercourse has been difficult to quantify, in part because many individuals do not solely practice oral intercourse to the exclusion of other sex acts. However, it is clear that the risk of transmission by oral intercourse (whether penile-oral or vaginal-oral) is markedly lower than for anal or vaginal intercourse. The oral cavity has a thick epithelial layer, a low number of target CD4 target cells and the presence of antiviral antibodies, which makes it relatively resistant to HIV transmission. In a meta-analysis of 10 studies, only four studies reported a non-zero estimate of risk. While a pooled estimate of risk was not produced due to small sample sizes, their review suggested a low but non-zero transmission probability.

While precise measures of risk have been difficult to develop, it is likely that ejaculation and the presence of oral ulcers, oropharyngeal inflammation or STIs in the oropharynx increase the risk of HIV transmission to the receptive partner during oral intercourse. The findings of a case series of MSM believed to have acquired HIV through oral intercourse suggested that men with genital piercings are at higher risk of acquiring HIV when practicing insertive oral sex.

While there is assumed to be a low risk of HIV transmission from oral intercourse, there is a concern that this sex act may contribute to HIV transmission if there is a high frequency of unprotected oral intercourse in relation to higher risk practices, which are more likely to be protected. Unprotected oral intercourse has been identified as a significant route of transmission in the recent resurgence in syphilis cases among MSM.

HIV transmission in drug users
For people who inject drugs, estimates of the risk of transmission from a contaminated needle has been estimated to be between 0.7% to 0.8%. Sharing ancillary injecting equipment, such as filters or cookers, has been shown to increase the risk of transmission, even in the absence of sharing needles and syringes. Other factors that have been shown to increase the risk of HIV transmission for injection drug users include: unsafe locations, type of drug and frequency of drug injection. Non-injection drug users are also at risk of HIV infection. Drug use often alters sexual behaviours by increasing risk taking. As well, several drugs have been reported to be independent risk factors of HIV transmission.

Mother-to-child transmission
In the absence of any preventive intervention, it is estimated that mother-to-child transmission ranges from about 15% to 45%. As with other modes of transmission, maternal plasma viral load has been consistently associated with the risk of vertical transmission. Since highly active antiretroviral treatment (HAART) was introduced in 1997, which is used to suppress viral replication, the rate of mother-to-child transmission has dropped dramatically. While mode of delivery was once found to be associated with vertical transmission, since the introduction of HAART, it is unclear whether there are any additional benefits to elective caesarean section for women with low viral loads.

Obstetric events, including amniotic membrane rupture that occurs over a prolonged period and intrapartum use of fetal scalp electrodes or fetal scalp pH sampling have been found to increase the risk of perinatal transmission of HIV.

Mother-to-child HIV transmission can also occur through breastfeeding. The probability of breastfeeding transmission of HIV is in the range of 9% to 16%. Co-factors that are associated with risk of transmission from breastfeeding include duration and pattern of breastfeeding, maternal breast health and high plasma or breast milk viral load.

Other Factors Influencing HIV Transmission Risk

Within each route of transmission, estimates of the risk of transmission vary widely, likely due to the role of behavioural and biological co-factors. Viral load appears to be an important predictor of transmission, regardless of route of transmission. However, the evidence indicates that viral load is not the only determinant, and other co-factors, such as the presence of co-infections, play a role in increasing or decreasing the risk of transmission.

Viral Load

The strongest predictor of sexual transmission of HIV is plasma viral load (VL). A dose-response relationship has been observed, where each ten-fold increase in plasma VL resulted in an increased relative risk of transmission of 2.5 to 2.9 per sexual contact. The concentration of HIV in genital secretions also plays a major role in sexual transmission. While there is a strong correlation between HIV concentrations in plasma and in genital secretions, some studies have found genital tract HIV shedding in 20% to 30% of men and women without detectable plasma viral load. Much of what is known about the impact of viral load on the sexual transmission of HIV is derived from studies of heterosexual populations. Very little is known about the relationship between HIV viral load and rate of transmission through anal intercourse.

Studies of the association between viral load and infectiousness have largely been conducted within the context of sexual transmission. Of the limited studies that have been conducted among people who inject drugs, community viral load was shown to be associated with HIV incidence. As well, higher viral loads have been found during outbreaks of HIV among people who inject drugs. With these limited data, it is still unclear to what degree increases in viral load are related to increases in HIV transmission among IDU.

Maternal plasma VL has been consistently associated with the risk of vertical transmission. Prospective cohort studies have shown that rates of transmission increase with corresponding increases in maternal plasma VL. The amount of virus present in the genital tract has also been found to have an impact on the risk of mother-to-child transmission. An analysis of HIV-positive women who had vaginal deliveries found that the presence of HIV in the genital tract was associated with a three-fold increase in the risk of vertical transmission, and each ten-fold increase in the mean titer of HIV DNA was associated with a corresponding increase in the risk of vertical transmission. While data are limited, studies suggest that viral load, in plasma and breast milk, is also an important determinant of transmission risk from breastfeeding.

Co-infections

Sexually transmitted infections (STIs) have also been found to affect the sexual transmission of HIV. STIs increase susceptibility to HIV by a factor of two to four and the infectiousness by two to three times. Concurrent STIs and co-infection with either hepatitis C or active tuberculosis disease increase the risk of vertical transmission.

Circumcision

Male circumcision decreases the risk of vaginal to penile sexual transmission by 50% to 60%. However, there is little epidemiological evidence to support a direct protective effect of male circumcision for women or for the prevention of HIV among MSM.

APPENDIX D: NATURAL HISTORY OF HIV INFECTION

Human immunodeficiency virus (HIV) is a retrovirus that infects the cells of the immune system. It is transmitted via exposure to body fluids that contain lymphocytes or free infectious viral particles (blood, spinal fluid, genital secretions, and breast milk). The routes of infection are: unprotected sexual intercourse, sharing of injection-drug use equipment (needles and other drug equipment contaminated with an HIV-positive person's blood) and from an HIV-infected mother to her unborn child. Although rare, HIV can also be transmitted through an occupational exposure such as a needlestick injury or other event where blood to blood exposure could occur. All blood and blood products used in Canadian healthcare settings now undergo extensive screening for HIV prior to use, so new infections related to their use have been virtually eliminated (Kleinman, 2009).

The virus can enter the body through unprotected mucous membranes where cells may become infected with HIV (sexual transmission, blood splashes, etc.). The presence (in either partner) of a sexually transmitted infection (e.g., chlamydia, syphilis, or herpes simplex) can enhance HIV transmission because of lesions and/or an increased number of lymphocytes. Using a needle contaminated with HIV-infected blood deposits the virus directly into the blood system, where infection of lymphocytes will occur. Transmission from mother to child can take place in utero, during delivery through exposure to the mother's blood or vaginal secretions, and through breast milk (Constantine, 2005). Seroconversion occurs when an individual changes from being HIV antibody negative to HIV antibody positive.

Once the virus has entered a macrophage or lymphocyte, the infected cell will migrate to a lymph node. The infection is dispersed through the lymphatic and circulatory systems: each infected cell is capable of producing 1000 or more viral particles capable of infecting other cells. The early acute stage of HIV infection is characterized by a period of uncontrolled viral replication and extremely high levels of virus in the bloodstream (viremia). This usually occurs two to three weeks after exposure; a person in this stage is highly infectious with exceptionally high concentrations of HIV in their blood and body fluids. The body produces antibodies and other cell-mediated responses that eventually control, but do not eliminate, viral replication. The virus integrates its genetic material into the host lymphocyte genome, which makes it possible for it to reproduce in future generations of the cell line.

Following acute HIV infection, an infected person may experience a period of latency for many years; despite the lack of symptoms/signs, the virus continues to replicate at a lower rate. HIV slowly destroys the immune system, leaving the individual vulnerable to many infections and other conditions (Constantine, 2005).

APPENDIX E: PROVINCIAL AND TERRITORIAL HIV/AIDS HOTLINES

Alberta:	1-800-772-2437
British Columbia:	1-800-661-4337
Manitoba:	1-800-782-2437
Newfoundland and Labrador:	1-800-563-1575
New Brunswick:	1-800-561-4009
Northwest Territories:	1-800-661-0844
Nunavut:	1-800-661-0795
Eastern Arctic:	1-800-661-0795
Nova Scotia:	1-800-566-2437
Ontario:	1-800-668-2437 (English) 1-800-267-7432 (French)
Prince Edward Island:	1-800-314-2437
Quebec: Portail VIH/sida du Québec (http://pvsq.org)	811 1-877-Portail (767-8245)
Saskatchewan:	1-800-667-6876
Yukon:	1-800-661-0408 ext. 8323