CONSENSUS STATEMENT

Canadian consensus statement on HIV and its transmission in the context of criminal law

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INTRODUCTION: A poor appreciation of the science related to HIV contributes to an overly broad use of the criminal law against individuals living with HIV in cases of HIV nondisclosure.

METHOD: To promote an evidence-informed application of the law in Canada, a team of six Canadian medical experts on HIV and transmission led the development of a consensus statement on HIV sexual transmission, HIV transmission associated with biting and spitting, and the natural history of HIV infection. The statement is based on a literature review of the most recent and relevant scientific evidence (current as of December 2013) regarding HIV and its transmission. It has been endorsed by >70 additional Canadian HIV experts and the Association of Medical Microbiology and Infectious Disease Canada. RESULTS: Scientific and medical evidence clearly indicate that HIV is difficult to transmit during sex. For the purpose of informing the justice system, the per-act possibility of HIV transmission through sex, biting or spitting is described along a continuum from low possibility, to negligible possibility, to no possibility of transmission. This possibility takes into account the impact of factors such as the type of sexual acts, condom use, antiretroviral therapy and viral load. Dramatic advances in HIV therapy have transformed HIV infection into a chronic manageable condition.

DISCUSSION: HIV physicians and scientists have a professional and ethical responsibility to assist those in the criminal justice system to understand and interpret the science regarding HIV. This is critical to prevent miscarriage of justice and to remove unnecessary barriers to evidence-based HIV prevention strategies.

Key Words: Chronic manageable condition; Consensus statement; Criminal law; HIV risks of transmission

CONTEXT AND PURPOSE

As leading Canadian HIV physicians and medical researchers, we have a professional and ethical responsibility to inform policy formulation and the criminal justice system in matters related to the health and well-being of our patients and Canadian society¹. We developed the present statement out of a concern that the criminal law is being used in an overly broad fashion against people living with HIV in Canada because of, in part, a poor appreciation of the scientific understanding of HIV and its transmission. We are concerned that actors in the criminal justice system have not always correctly interpreted the

Énoncé de consensus canadien sur le VIH et sa transmission dans le contexte du droit criminel

INTRODUCTION: En raison, entre autres, d'une mauvaise appréciation des données scientifiques liées au VIH, la justice criminelle est beaucoup trop mise à contribution contre les personnes qui vivent avec le VIH et ne divulguent pas leur séropositivité.

MÉTHODOLOGIE: Afin de promouvoir une application de la loi canadienne fondée sur des données probantes, une équipe de six experts médicaux canadiens du VIH et de sa transmission a élaboré un énoncé de consensus sur la transmission sexuelle du VIH, sa transmission par les morsures ou les crachats et son évolution naturelle. Cet énoncé repose sur une analyse bibliographique des données scientifiques les plus récentes et les plus pertinentes (en décembre 2013) au sujet du VIH et de sa transmission. Il est appuyé par plus de 70 autres experts du VIH au Canada et par l'Association pour la microbiologie médicale et l'infectiologie Canada.

RÉSULTATS: Les données scientifiques et médicales établissent clairement que le VIH est difficile à transmettre pendant les relations sexuelles. Afin d'informer le système judiciaire, la possibilité réelle de transmission lors d'une relation sexuelle, d'une morsure ou d'un crachat est décrite le long d'un continuum de faible possibilité, de possibilité négligeable et d'aucune possibilité de transmission. Ce continuum tient compte des effets de facteurs comme le type d'acte sexuel, l'utilisation de condoms, la thérapie antirétrovirale et la charge virale. Les progrès considérables en matière de traitement du VIH ont transformé l'infection par le VIH en une maladie chronique gérable.

EXPOSÉ : Les médecins et les chercheurs spécialisés en VIH ont la responsabilité professionnelle et éthique d'aider les acteurs du système de justice criminelle à comprendre et interpréter la recherche sur le VIH. C'est essentiel pour éviter les erreurs judiciaires et pour écarter tout obstacle inutile aux stratégies de prévention du VIH fondées sur des données probantes.

medical and scientific evidence regarding the possibility of HIV transmission, and may not have understood that HIV infection is a chronic manageable condition. This may lead to miscarriages of justice.

HIV transmission is an area of scientific inquiry in which findings and opinions often require interpretation by properly qualified medical experts. Over the past three decades, there have been considerable advances in our scientific and medical knowledge of HIV, how to prevent it and how to optimize treatment for people living with HIV.

The present statement represents our consensus expert opinion regarding the possibility of HIV transmission and the nature of HIV

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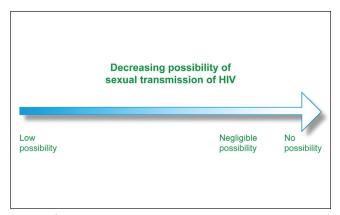


Figure 1) Decreasing possibility of sexual transmission of HIV

infection. While particular sexual acts are inherently difficult to study and the interpretation of the research related to sexual transmission of HIV is complex, there is broad consensus within the scientific and medical communities based on more than three decades of research. We have reviewed the most relevant and reliable medical and scientific evidence related to HIV and HIV transmission to arrive at our consensus statement. The present statement sets out, in clear, concise and understandable terms, our expert opinion regarding HIV sexual transmission, HIV transmission associated with biting and spitting, and HIV infection as a chronic manageable condition.

We have developed this statement specifically to inform the criminal justice system. We aimed to communicate the medical and scientific evidence in a manner understandable to an educated layperson, and have avoided excessive reliance on technical medical or scientific terminology or statistics. We also focused on the possibility of HIV transmission between individuals engaging in a specific act at a specific time because this is what is at stake in individual criminal cases. The present statement does not extend to HIV transmission at a population level in relation to HIV prevention efforts. The present statement is not intended to be used in the public health setting or to be relied on in the development or delivery of HIV policy and programs including prevention, information, education or counselling.

POSSIBILITY OF HIV TRANSMISSION

Assessing the possibility of HIV transmission

We assess the possibility of HIV transmission according to three categories: low possibility; negligible possibility; and no possibility. We define and rely on these categories for the purposes of informing the criminal justice system about the possibility of HIV transmission between individuals in specific circumstances at a specific time – in other words, the per-act possibility of HIV transmission. Our three categories should not be confused with relative HIV transmission risk categories traditionally used in public health, which describe activities from high risk to no risk.

It is our expert opinion that scientific and medical evidence clearly indicate that HIV is difficult to transmit during sex. Even activities generally considered risky, such as unprotected (ie, without a condom) anal and vaginal sex, carry a per-act possibility of transmission that is much lower than is often commonly believed. It is our expert opinion that the actual per-act possibility of HIV transmission through sex, biting or spitting lies along a continuum from low possibility, to negligible possibility, to no possibility of transmission (Figure 1).

Low possibility: The basic conditions of viral transmission are present. The majority of HIV transmission worldwide is linked to these activities. Although these activities are considered to be the main modes of HIV transmission, the per-act possibility of transmission remains low.

Negligible possibility: The basic conditions of viral transmission are potentially present. Isolated reports of transmission have been linked

to some of these activities, although they have been difficult to confirm. The efficiency of transmission appears to be negligible and transmission is highly unlikely, if not impossible in most circumstances.

No possibility: The basic conditions of viral transmission are not present. No occurrence of transmission has been reported. The virus is not transmitted by these activities.

Sexual transmission of HIV

Biology and physiology of HIV transmission: The transmission of HIV during sex is much less likely to occur than commonly presumed. In fact, HIV is difficult to transmit sexually when compared with some other sexually transmitted infections (STIs). Sexual exposure to HIV presents the possibility of HIV transmission only if specific bodily fluids from an HIV-positive individual come into contact with specific cells within the body of an HIV-negative individual. The three bodily fluids that play a principal role in the sexual transmission of HIV are semen (including pre-ejaculate), vaginal fluid and rectal fluid².

HIV-containing fluids can cause infection if they enter the sex partner's body through a mucous membrane. The mucous membranes involved in the sexual transmission of HIV are located in the foreskin and urethra of the penis; cervix and vagina; anus and rectum; and mouth and throat. For transmission to take place, HIV must first overcome the cellular defences of the mucous membrane and the body's immune response to pathogens, and then establish an infection in target immune cells. Transmission can only occur if there is a sufficiently high level of the virus in the HIV-infected individual's bodily fluid(s).

Significant factors associated with the sexual transmission of HIV The significant factors associated with the sexual transmission of HIV relevant to the formulation of our expert opinion are:

- type of sexual act;
- · condom use; and
- antiretroviral therapy use and viral load in the HIV-positive individual.

Type of sexual act: For principally biological reasons, some sexual acts involve a lower HIV transmission possibility than others. All other factors being equal, oral sex has a significantly lower possibility of transmission than vaginal or anal intercourse, and anal intercourse has a higher possibility of transmission than vaginal intercourse.

Condom use: Condoms are a cornerstone of HIV prevention. Latex and polyurethane condoms act as an impermeable physical barrier through which HIV cannot pass. When used correctly and no breakage occurs, condoms are 100% effective at stopping the transmission of HIV because they prevent the contact between HIV-containing bodily fluid and the target cells of an HIV-negative individual. Studies at a population level have also shown that even when factoring in possible instances of incorrect use or breakage, the consistent use of condoms dramatically reduces the possibility of HIV transmission. Where the present consensus statement discusses the possibility of HIV transmission in the context of condom use, it is assumed that the condom was applied to the penis and worn throughout sex, and that no condom breakage occurred.

Antiretroviral therapy and viral load: The medications used to treat HIV infection are referred to as antiretroviral therapy. Since the mid-1990s, HIV physicians have been using a combination of antiretroviral drugs to effectively manage HIV infection. Antiretroviral therapy stops HIV from making copies of itself, thereby significantly reducing the overall amount of HIV in an individual's body, which is referred to as 'viral load'.

In Canada, the commonly used laboratory tests can detect viral loads above 40 copies of virus per millilitre of blood. When the concentration of HIV falls below the level that is detectable by laboratory tests, the HIV-positive individual is said to have an 'undetectable' viral load. The goal of antiretroviral therapy is to render the HIV viral load undetectable. Most people living with HIV who take antiretroviral therapy are able to achieve an undetectable viral load. Being on

effective antiretroviral therapy, with a controlled viral load, results in improved immune function and a dramatic decrease in illness and mortality.

Moreover, because the lower the viral load, the lower the possibility of HIV transmission, being on effective antiretroviral therapy also dramatically reduces the possibility that the individual will transmit HIV. It is worth noting that some people have a low HIV viral load without taking antiretroviral therapy because their immune systems are able to control HIV. These people also have a reduced possibility of transmitting HIV during sex. While small short-lived increases in viral load, known as 'blips', can occur among individuals on effective antiretroviral therapy, they are not an indication that HIV therapy is 'failing' and are not considered to be clinically significant. They have not been shown to increase the possibility of HIV transmission during sex.

Possibility of HIV transmission associated with sexual acts

Vaginal-penile intercourse: Where neither a condom nor effective antiretroviral therapy is present, vaginal-penile intercourse poses a low possibility of transmitting HIV.

Where a condom is used or where the HIV-positive individual is on effective antiretroviral therapy, vaginal-penile intercourse poses a negligible possibility of transmitting HIV.

The estimate of the per-act probability of HIV transmission associated with unprotected penile-vaginal intercourse without antiretroviral therapy is often cited as one instance per 1000 sexual acts. Estimates based on the most recent scientific studies range between four and eight instances of transmission per 10,000 sexual acts.

Some studies suggest that the possibility of HIV passing from a man to a woman is twice as high as the possibility of HIV passing from a woman to a man. The possibility of HIV passing from a man to a woman decreases when ejaculation occurs outside of the body.

The use of effective antiretroviral therapy by individuals living with HIV has been shown in clinical trials to result in a very significant reduction in HIV transmission to HIV-negative individuals. Overall, the evidence suggests that the possibility of sexual transmission of HIV from an HIV-positive individual to an HIV-negative individual via unprotected vaginal intercourse approaches zero when the HIV-positive individual is taking antiretroviral therapy and has an undetectable viral load. Given that the possibility of HIV transmission is already approaching zero, using a condom in such circumstances would not alter the possibility of HIV transmission in any meaningful way. It would protect both partners from other STIs and unwanted pregnancy.

Anal-penile intercourse: Where neither a condom nor effective antiretroviral therapy is present, anal-penile intercourse poses a low possibility of transmitting HIV.

Where a condom is used, anal-penile intercourse poses a **negligible** possibility of transmitting HIV regardless of the HIV-positive individual being on effective antiretroviral therapy.

Where the HIV-positive individual is on effective antiretroviral therapy, anal-penile intercourse **likely** poses a **negligible** possibility of transmitting HIV even in the absence of condom use.

The estimate of the per-act probability of HIV transmission associated with unprotected anal-penile intercourse without antiretroviral therapy is often cited as one instance per 100 sexual acts where the HIV-positive individual is the insertive partner, and one instance per 1000 sexual acts where the HIV-positive individual is the receptive partner. The possibility of HIV transmission during anal intercourse also decreases when ejaculation occurs outside of the body.

The published data on the impact of effective antiretroviral therapy on HIV transmission, including the groundbreaking clinical trial referred to as HPTN 052 (Cohen MS et al, 2011), are principally from studies of heterosexual couples in which the predominant sexual activity was vaginal-penile intercourse. At this time, there are insufficient data to conclude that effective antiretroviral therapy provides similar levels of protection in relation to anal-penile intercourse. However, it is our expert opinion that the magnitude of the reduction in

the possibility of transmission via vaginal-penile sex observed with effective antiretroviral therapy in HTPN 052 can be extrapolated to anal-penile intercourse when the HIV-positive individual is the receptive partner. Given the significant protective effects of effective antiretroviral therapy, this magnitude of the reduction in the possibility of transmission can also likely be extrapolated when the HIV-positive individual is the insertive partner in anal-penile intercourse. However, because of the higher biological possibility of transmission associated with anal-penile intercourse when the HIV-positive individual is the insertive partner, more data are needed before we can give a more definitive opinion about the anticipated negligible possibility of transmission in this case. Using a condom in such circumstances would protect both partners from other STIs. Clinical studies are underway to assess the possibility of HIV transmission associated with insertive and receptive anal-penile intercourse when the HIV-positive individual is on effective antiretroviral therapy.

Oral sex: Oral sex performed by an HIV-positive individual on an HIV-negative individual poses **no** possibility of transmitting HIV.

Where **neither** a condom **nor** effective antiretroviral therapy is present, oral sex performed on a HIV-positive individual poses a **negligible** possibility of transmitting HIV.

Where a condom is used or the HIV-positive individual is on effective antiretroviral therapy, oral sex performed on a HIV-positive individual poses a **negligible** possibility of transmitting HIV.

Practising oral sex instead of vaginal or anal intercourse is one of the precautions an individual can take to reduce the possibility of HIV transmission.

Oral sex includes oral-penile sex (fellatio) and oral-vaginal sex (cunnilingus). While limited evidence suggests that HIV transmission from oral sex is plausible in cases of fellatio performed on an HIV-positive individual, transmission in such circumstances would be extremely rare. Fellatio without ejaculation in the mouth of the performing HIV-negative individual would pose a lower possibility of transmission than fellatio with ejaculation. Cunnilingus performed on an HIV-positive woman has never been definitely associated with transmission of HIV.

There are no studies investigating the impact of antiretroviral therapy on the possibility of transmission during oral sex. However, given the negligible possibility associated with this sexual activity and the ability of antiretroviral therapy to dramatically reduce the possibility of transmission, it is our expert opinion that the possibility associated with oral sex when the HIV-positive individual is on effective antiretroviral therapy approaches zero.

Other factors associated with the sexual transmission of HIV

Other factors have been associated with HIV transmission, including STIs and male circumcision. However, the influence of these other factors is eclipsed by either condom use or effective antiretroviral therapy in the HIV-positive individual. Each of these two significant factors has an overwhelmingly larger impact on the possibility of HIV transmission than either STIs or male circumcision.

The presence of an untreated STI, especially an ulcerative STI, in either partner has been associated with an increase in the possibility of HIV transmission. However, when used correctly and no breakage occurs, condoms are 100% effective at blocking the transmission of HIV; therefore, the presence of an STI would not increase the possibility of transmission. Clinical studies have not shown a conclusive correlation between an increase in the possibility of HIV transmission and the presence of an STI in individuals who are on effective anti-retroviral therapy.

Large-scale trials in Africa have reported that male circumcision reduces by almost two-thirds the possibility of an HIV-negative man acquiring HIV as a result of intercourse with an HIV-positive woman.

Possibility of HIV transmission associated with biting or spitting Being spat on by an HIV-positive individual poses **no** possibility of transmitting HIV.

Being bitten by an HIV-positive individual poses a **negligible** possibility of transmitting HIV when the biting breaks the other person's skin **and** the HIV-positive individual's saliva contains blood. Otherwise, being bitten by an HIV-positive individual poses **no** possibility of transmitting HIV.

Biting as a cause of HIV transmission is extremely rare and difficult to confirm. Saliva does not contain enough HIV to transmit the virus and unbroken skin is an effective barrier to the virus. In the small handful of cases in which HIV transmission was reported and attributed to a bite as the likely source, severe trauma with extensive tissue (ie, skin) damage and blood were present.

HIV AS A CHRONIC MANAGEABLE DISEASE

Dramatic advances in HIV therapy have transformed HIV infection into a chronic manageable condition. This shift is supported by scientific research demonstrating changes in the rate of death, the cause of death and the life expectancy of individuals living with HIV. The life expectancy for someone infected with HIV at 20 years of age is now estimated to be an additional 50 to 60 years after diagnosis due to the advent of antiretroviral therapy.

Recent modelling studies suggest that the death rate among some groups of people living with HIV is approaching that of the general population. Simply put, in Canada and other developed countries with advanced health care, HIV is no longer fatal. With early and proper care, individuals living with HIV can live long, healthy lives.

In addition to fewer deaths among people living with HIV, the causes of death are shifting away from AIDS-defining illnesses – infections such as *Pneumocystis* pneumonia (PCP) or cancers such as Kaposi's sarcoma – toward non-HIV-related causes. Broadly speaking, individuals living with HIV who receive care no longer die of AIDS, but of the same conditions as HIV-negative people. The main causes of death are now due to heart, liver and lung disease, and non-AIDS-related cancers.

Also, although HIV-related stigma and discrimination persists in our societies, the quality of life of individuals living with HIV has dramatically improved due to the availability of successful treatments.

CONCLUSION

The expert opinion set out in the present statement is based on a review of the most relevant and reliable medical and scientific evidence. The present statement represents our consensus expert opinion, as leading Canadian HIV physicians and medical researchers, regarding the possibility of HIV transmission in various circumstances and the health consequences of HIV infection. We developed this statement because we have a professional and ethical responsibility to assist those in the criminal justice system to understand and interpret current medical and scientific evidence regarding HIV. We are concerned that miscarriages of justice may result when such evidence is not correctly understood or interpreted.

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FOOTNOTES: ¹Canadian Medical Association, CMA Code of Ethics (updated 2004). Section 42 states: "Recognize the profession's responsibility to society in matters relating to public health, health education, environmental protection, legislation affecting the health or well-being of the community and the need for testimony at judicial proceedings". ²Blood may be involved in sexual transmission only in specific circumstances, such as sex during menstruation or rough sex leading to tissue damage and significant bleeding.

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