

National Collaborating Centre for Infectious Diseases

Centre de collaboration nationale des maladies infectieuses

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### Routine (Opt-out) HIV Screening

The purpose of this paper is to outline the evidence of the effectiveness and challenges of routine HIV screening (opt-out) as compared to an opt-in approach in various health care settings.

#### What is Routine (Opt-out) Screening and How Does It Differ from Voluntary Opt-in Screening?

Opt-out screening offers testing to everyone, regardless of perceived risk or symptoms (1). Opt-out voluntary testing includes verbal consent, short (usually five minutes) pre-test counselling, and no post-test counselling if the test is negative. A client who tests positive is offered substantial support and expert post-test counselling. In contrast, opt-in voluntary testing requires written informed consent and pre-and post-test counselling, regardless of test outcome (2). Recently, U.S. Centers for Disease Control (CDC) and the World Health Organization (WHO) proposed to routinely test as many individuals as possible in various settings (3,4).

#### Why Routine Testing?

Health Canada estimates that in 2005, 27% of HIV-positive individuals (PHAs) in Canada were unaware of their infection (5). These individuals need to be diagnosed and in care to achieve optimal healthy survival (6). With antiretroviral therapies (ART), most individuals are living longer with HIV infection. A person diagnosed with HIV in 2003 and beginning ART, could expect to live This evidence review is part of a series on HIV prevention and control produced by the National Collaborating Centre for Infectious Diseases. It is intended to inform public health practitioners and community-based workers and guide their practice.

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an average of 13 years longer than if diagnosed in 1988 (7). Awareness of status may also reduce transmission risk as most individuals who test positive subsequently reduce their risky behaviours and take steps to protect their partners. This can lower transmission rates by three to six fold (6,8).

#### **HIV Testing in Canada**

In 2005, 2,483 Canadians tested positive for HIV infection. In the same year, 392,058 people were tested in Ontario (9), and 160,876 in BC (10). The Canadian Medical Association's (CMA) HIV testing policy, updated in 2007, recommends counselling before and after HIV testing, with written informed consent (opt-in) due to the potential psychological,

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social and economic consequences attached to a positive result (11). However, Canadian provinces adopt differing approaches to HIV testing.

#### **Prenatal HIV Testing**

In Canada, pregnant women are routinely offered HIV testing as part of prenatal care (2,12). The proportion of infants born to HIV-positive infected mothers has decreased from 39.5% in 1994, to 4% in 2005, as a result of screening and ART care programs (89% of HIV-positive mothers are on ART as of 2005) (5). In order to eliminate HIV transmission to infants, the CMA advocates routine opt-out prenatal HIV testing (13).

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#### **Blood Donors**

Mandatory HIV testing of blood donors occurs in Canada, regardless of consent. The CMA (11) endorses informed mandatory testing for blood, body fluids or organ donations. Through mandatory testing, with both an antibody and viral RNA test, HIV transmission is reduced to very low numbers (14). To date, only one HIV case has been found in Canada using the nucleic acid test (NAT) system to screen whole blood, with an overall HIV residual risk of one per 7.8 million donations (15). A residual risk of HIV transmission persists partly because of imperfect tests, human error and donations made during the "window period" of about 11 days before the viral RNA test becomes positive.

Programs enabling individuals to access anonymous HIV testing sites may help decrease the residual risk of HIV transmission. Some individuals may seek to be tested at blood banks to avoid assessment of stigmatized risk behaviour and the loss of confidentiality. Goncalez and colleagues (14) found that 8.8% of community donors came to the blood bank for HIV testing. Test seekers lied about their risky behaviours in order to be screened (14) and face-to-face screening methods are known to be ineffective (16).

## What is HIV Exceptionalism and how does it Relate to Testing?

Advocates of HIV exceptionalism fear that the epidemic would be driven underground if policies around HIV surveillance, partner notification, and screening do not include confidentiality, written consent, and 'formal' pre- and post-test counselling. Exceptionalism aims to protect the privacy rights of PHAs and to reduce societal discrimination.

The U.S. CDC and the WHO recently changed their guidelines regarding HIV testing and now encourage a "public health" approach to HIV control (3,4,17,18). These recommendations signal an end to HIV exceptionalism and an opt-in approach to HIV testing internationally. The U.S. and Botswana have recommended routine opt-out HIV testing for all people (8) and Kenya and Uganda are increasing routine testing of pregnant women, hospitalized patients, and patients with tuberculosis (18). Although concerns about stigma and the unique consequences of a positive test are still real today, they are being overruled in favour of increasing the number of people who have access to screening, who are counselled about sexual or injection risks, and who are encouraged to enter care.

#### Is the Opt-out Strategy Effective?

In Canadian provinces and territories using the opt-in approach to prenatal HIV testing (Yukon, British Columbia, Saskatchewan, Ontario, and Prince Edward Island), testing rates are lower than in those that have adopted the opt-out approach (Manitoba, New Brunswick, Northwest Territories, Nunavut, Alberta, Nova Scotia, Quebec, and Newfoundland and Labrador) (2,5,19–21).

In an Ontario study by Yudin and colleagues (21) 1,140 of 1,233 (92.5%) women who went for a prenatal visit accepted opt-out testing. They found race to be predictive of test acceptance,

with Asian women significantly less likely and Hispanic women significantly more likely to be tested. Study-based opt-out testing rates were significantly higher than the Ontario provincial opt-in average.

#### Internationally

Studies from the U.S., Canada, Singapore, Netherlands, and the U.K. have shown that the opt-in voluntary testing approach is associated with lower testing rates than either the opt-out or the mandatory newborn HIV testing approach (1,2,4,19,22). Researchers in San Francisco, California, report a significant increment in new diagnoses of HIV since testing guidelines were relaxed and written consent was eliminated (23).

Anderson, Simhan & Landers (24) investigated women who had received testing in seven U.S. prenatal clinics after an education intervention for health care providers focused on improving acceptance rates of opt-out testing, was introduced. The frequency of test offering at first visit and test acceptance before the educational intervention were 96.5% and 74.8%, respectively, increasing to 99.5% and 84.3% respectively following the intervention. This increase was statistically significant.

#### **In Acute Care Programs**

Studies have suggested that routine HIV testing programs in acute care programs are more effective than targeted screening programs (6,25,26). In Uganda, the percentage of positive results in hospitals and emergency departments (2% to 7%) exceeded the percentage at HIV testing sites (1.5%) and sexually transmitted disease clinics (2%) serving high-risk persons (27). Jenkins, Gardner, Thrun, Cohn, & Burman (25) retrospectively studied 348 newly diagnosed HIV-positive people and found that one third had clinical visits in the three years before diagnosis, and few presented with HIV-related symptoms. They recommended routine screening in high prevalence settings.

## What are the Challenges of the Opt-out Approach?

#### **Targeted Testing**

In a review comparing opt-out testing with targeted counselling and testing, Holtgrave (27) suggested that opt-out testing might reach 23% of Americans currently unaware that they are HIV positive. In contrast, targeted testing aimed at high-risk populations might identify about 75% of PHAs unaware of their status, and prevent about 36% of new HIV infections (28). Targeted counselling and testing still performed better after several assumptions (e.g., assumptions about levels of HIV infection or the effectiveness of counselling) were adjusted (27). Holtgrave concluded that to maximize public health impact, targeting and counselling elements should be carefully considered for inclusion in national testing policies.

#### **Different Settings**

As routine opt-out testing continues to be practiced in various settings, challenges remain that need to be addressed. Only 0.7% of U.S. hospitals in 2005 reported offering routine HIV testing to inpatients or emergency department patients (4). Ninety percent of patients referred from emergency departments did

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not show up for their HIV test, and 21% of HIV-positive results were not conveyed to the patient (4,28). In a study by Rudy and colleagues (29), PHAs reported that in physician offices or health maintenance organizations, jails, emergency rooms or hospital overnight visits, the counsellor spent inadequate time on counselling, compared to HIV test sites.

#### **Counselling Practices of Physicians**

Several studies reported that physicians are more likely to conduct screening than counselling (8). Barnett and colleagues (12) noted that non-urban physicians in B.C., Canada, were more likely not to offer counselling after an HIV test than urban-based physicians. Almost all B.C. physicians (98.1%) offered HIV

tests to their patients exhibiting high-risk behaviour, but fewer offered testing as routine prenatal care (88.9%). The median time physicians reported spending on pre-test counselling was six minutes, while patients with positive HIV results received a median time of 20 minutes.

Targeted testing aimed at high-risk populations might identify about 75% of PHAs unaware of their status, and prevent about 36% of new HIV infections.

#### **Research Gaps**

A body of evidence examining the consequences of opt-out policies such as those in the U.S. and Botswana should be built over the next few years. This should include an examination of HIV testing in specific settings and the ultimate effects on the course of the epidemic.

#### What Can we Conclude

Prospective and retrospective studies have shown much higher testing rates at opt-out sites than at opt-in sites. Opt-out screening may decrease discrimination associated with HIV infection because testing would be conducted irrespective of perceived risk. Routine HIV testing has also been shown to be cost-effective in populations with low and high HIV prevalence rates.

In routine opt-out testing, health care providers may conduct less counselling. The psychological impact of a positive HIV test result should be considered. It was the considerations of confidentiality, consent and counselling that led to policies of HIV exceptionalism. These considerations are now under review in the U.S. as evidence proves the effectiveness of ART on survival rates, shows the significant reduction of parent-to-child transmission worldwide, and reveals the effectiveness of treating more PHAs. Fundamental ethical principles of "do no harm" and the protection of privacy rights must be dominant in policy discussions of HIV testing. However, the public health community must consider the possibility that it will be unethical not to identify HIV infections with routine testing, as long as testing can be accomplished without causing harm.

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# highlights

- Individuals unaware of their HIV infection need to be diagnosed and treated to achieve optimal health. Most individuals who test positive subsequently reduce their risky behaviours and take steps to protect their partners, which lowers transmission rates by three to six fold.
- The opt-in voluntary testing approach is associated with lower testing rates than either the opt-out or the mandatory newborn HIV testing approach.
- The concerns about HIV stigma and the negative psychological trauma associated with a positive HIV test should be considered as evidence suggests that health care workers may provide less counselling during routine opt-out testing.
- Opt-out screening may decrease the discrimination associated with HIV infection as testing would be conducted irrespective of perceived risk.

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