New rapid HIV test opens Pandora's box of ethical concerns

A new HIV test that provides results in just 15 minutes is undoubtedly more convenient and faster, but observers say it also raises concerns about appropriate counselling, administration of the test and ways to deal with false-positive results (see pages 1545, 1605).

The Canadian HIV-AIDS Legal Network has responded to the new product with a 145-page report that urges provincial and territorial governments and regulatory bodies to run pilot studies on the new tests before mass marketing takes place. The studies would assess the need for counselling, training and quality control.

The test, which was approved by Health Canada in mid-March, is the country's first rapid screening test and the only HIV test possible outside a laboratory. It is considered as accurate as the current standard, the ELISA laboratory test, but results from that take 2 weeks.

The report's coauthor, lawyer Richard Elliott, says the Legal Network's major concern is the quality of counselling, especially given the number of false-positive results. This figure varies according to the HIV seroprevalence within a population, but it can be quite high. For example, 300 000

ELISA tests were conducted in Ontario last year, and 3000 were positive. After a second confirmatory test, only 1000 of the people tested were found to be HIV positive. (Patients are not notified of their status until after the second test.)

With rapid testing, however, patients would be informed of their status on the spot, before any confirmatory test had taken place. "It's crucial in counselling that they understand they may or may not be positive," says Elliott, director of policy and research at the Legal Network, a nonprofit group that takes the lead in analysing legal and ethical issues raised by HIV testing. It is urging regulatory bodies, provinces and territories to establish practice guidelines regarding who can provide rapid testing and to ensure training and counselling specific to the new test.

Elliott says the ease of rapid testing will increase the likelihood of poor counselling and lack of proper consent. "We're concerned that people will feel pressure to have this test done without adequately considering the ramifications of a positive result," he says.

"Pre-test counselling is the standard of care that must be met in any HIV testing," concurs Dr. Phil Berger, the chief of family and community medicine at Toronto's St. Michael's Hospital. "My worry is that [counselling] won't occur if testing is being done by a range of professionals who aren't necessarily trained in counselling."

The Health Canada licence stipulates that the test, which is marketed by BioChem ImmunoSystems Inc. of Montreal, can only be used by health care professionals at the point of care. However, each province and territory has its own definition of "health care professional," and in some cases it includes dentists and registered massage therapists. Many of these professionals are not currently trained to provide counselling, says Elliott.

There is also some concern that the test could make its way to the black market and be used for unscrupulous purposes by employers. Elliott argues that these people should be prosecuted. "I don't want to see circumstances where someone takes this kit and forces a spouse or child or employee to take it," he says. "It raises concerns about informed consent." US regulators have already approved home test kits for HIV that cost about US\$40. — *Barbara Sibbald*, CMAI

Fewer traffic deaths?

(Continued from page 1599)

find enough restaurant workers.

"This age group [18 to 20] is very important to the industry. Restaurants and bars are already competing with each other for the same employees. If this group is prevented from working, it's going to really hurt us."

Allan Pond, a 19-year-old bartender at a Winnipeg restaurant, says that without the income from his job, he would be forced to withdraw from

a BSc degree program he hoped would lead to medical school. "If you're too young to serve liquor or work as a bartender, then who is going to hire you?" Pond asks.

Many young people called a local radio station to voice their disapproval of the proposed age change, saying that it is already easier to purchase illicit drugs than alcohol. However, the president of the Winnipeg Students Association came out in support of the change.

"If you ask me, it's too easy for kids age 15 and 16 to get their 18-

year-old friends to buy them alcohol," says Andrew Morrow. "At 21, a person is more responsible for his behaviour."

Diane McGifford, minister responsible for the Manitoba Liquor Control Commission, said the government has no immediate plans to raise the drinking age, but there will be public consultations on the Liquor Control Act this spring and the drinking age is likely to be discussed. "I expect the college and many others will attend the hearings," says McGifford.— David Square, Winnipeg