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Rapid HIV Screening Kits Raise Important Legal and Ethical Questions

MONTRÉAL - Health Canada has issued a licence on 15th March, 2000 to BioChem ImmunoSystems Inc. to sell a rapid HIV screening test kit that provides a result in 15 minutes. This kit has been licensed for use by health-care professionals at the "point of care."

In a 145-page report released today, the Canadian HIV/AIDS Legal Network warns that provincial and territorial governments must now exercise their regulatory authority to ensure that the rapid HIV test kit is only available in "those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented."

"The licensing of rapid HIV tests for point-of-care use raises important legal and ethical questions that must be addressed", says Dr. Ralf Jürgens, a lawyer and executive director of the Canadian HIV/AIDS Legal Network, and co-author of the report. "Our policies and practices regarding HIV testing should be driven not by the technology, but by a careful consideration of risks and benefits, informed by solid research."

Health Canada classifies medical devices based on their riskiness. Rapid HIV tests are a Class IV device, the highest risk category under the Medical Devices Regulations. Jürgens points out: "This is the first time a device in this category has been licensed in Canada for use outside a laboratory. We must prevent potential misuses."

Richard Elliott, Director of Policy & Research of the Legal Network and the other co-author of the report, explains: "Currently in Canada, the *standard procedure* for HIV testing involves a trained health-care worker drawing a blood sample from the person getting tested in a clinical setting, usually a physician's office or a testing clinic. The blood is then tested in a clinical laboratory to detect the presence of HIV-specific antibodies using a screening test. A negative result is reported if the screening test is nonreactive. Any blood sample that tests positive, however, undergoes a second, confirmatory test and the result given to the health-care provider

who ordered the test is always a confirmed one. Typically one to two weeks elapse before results are available because blood samples are generally tested in groups to decrease costs, and because time is needed to complete confirmatory testing. Every person getting tested, whether the test is positive or negative, must return to the testing site for a second visit to learn their results from the provider and to receive post-test counseling tailored to his or her results."

In contrast, Elliott explains, "the new rapid test can be done on-site. A result is available within 15 or 30 minutes after the blood sample is taken. The test is as good as the first screening test currently used in approved laboratories, ensuring a reliable negative test. For those testing negative, this permits the health-care professional to complete the HIV testing and counseling at a single visit. However, as with any screening test, the rapid test is 'hypersensitive' and will yield a significant proportion of false positive results. All positive results and all results that are equivocal must be confirmed, requiring that a blood sample be sent to an approved HIV testing laboratory, where it will undergo confirmatory testing."

"Until now, in order to minimize the reporting of false-positive results, no positive result was given to the person being tested until confirmatory testing was undertaken," says Elliott. This may now change. "But what are the implications of telling patients their screening results when a significant number of false positive results will occur?" asks Jürgens. "Imagine a person receiving a positive screening result without having understood that a screening test is only a screening test, that the result may be a false-positive result, and that it is imperative that the person come back to receive a confirmed result, which could well be negative. Because of the need to ensure that all people who receive a positive screening result have received best-practice counseling, only health-care professionals who have undergone a training program, including on how to provide counseling in the context of rapid HIV screening tests, should be allowed to use such tests. And rapid HIV screening should be accompanied by accelerated access to confirmed test results."

The Legal Network report points out that one of the potential advantages of rapid HIV screening is that, since the technology is simple, access to HIV screening could be improved in more remote areas. But quality control concerns must also be addressed if testing is to be done outside the laboratory. "Manufacturers and governments must take measures to ensure that rapid test kits used at the point of care are performing properly, are administered properly, and are interpreted accurately," says Jürgens.

Rapid HIV screening tests might also assist HIV prevention efforts in limited circumstances. Pregnant women of unknown HIV status who are in labour could undergo rapid screening; those screening positive could initiate

preventive measures to reduce the risk of mother-to-child transmission. Rapid screening could also provide more information for decisions about post-exposure prophylaxis (PEP) following exposures such as needle-stick injuries.

But Jürgens notes that the issue of HIV testing during labour is contentious, and reiterates that any testing for HIV must always be done with consent. "HIV testing without consent is unethical, illegal and professional misconduct. Rapid screening kits do not change the requirement for specific, informed consent to HIV testing. Colleges and associations of health care professionals need to adopt or update regulations and/or policies to this effect."

Says Jürgens: "The introduction of rapid HIV testing must not lead to abandoning the requirement that HIV testing is only done with the informed consent of the person being tested, with quality pre-test and post-test counselling, and with the confidentiality of test results guaranteed. Rather, Canada must re-commit to *quality* HIV testing and counselling."

In total, the report by the Canadian HIV/AIDS Legal Network contains 23 recommendations, directed to federal and provincial/territorial policymakers, health-care professionals, professional associations and regulatory bodies of health-care professionals, and those providing HIV testing and counseling and working in the field of public health. The report follows a 300-page report released by the Legal Network in 1998 (*HIV Testing and Confidentiality: Final Report)*, which established the Network as an international leader in the analysis of legal and ethical issues raised by HIV testing, and was produced with funding from Health Canada under the Canadian Strategy on HIV/AIDS.

The Canadian HIV/AIDS Legal Network is a non-profit organization engaged in education, legal and ethical analysis, and policy development regarding HIV/AIDS, with a mandate to promote responses to HIV/AIDS that respect the rights of people with HIV/AIDS. The Network is based in Montréal.

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Rapid HIV Screening at the Point of Care: Legal and Ethical Questions

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