used the tonic but are forced to travel to Peru for additional treatment because of the TPD ruling. Featured in the CBC story was a 14-year-old boy in British Columbia, who is apparently one of the seven Canadians who have taken the herbal tonic at a laboratory site in Peru where experiments are being conducted.

AMMA Corporation is sponsoring the development of the tonic and claims that all study participants have experienced a reversal of symptoms. However, there is no published information about the design of the experiments, the outcomes, the patients' characteristics, or the composition of the tonic. AMMA says that the story has generated a flood of requests for the tonic from people with hepatitis C. AMMA says it has enough tonic only to ensure an uninterrupted supply to those already receiving it by traveling to Peru.[2]

According to the CBC report, the TPD based its decision on a lack of information about the tonic. The purpose of the SAP is to grant approval for access to medicines that are not licensed for sale in Canada or available through clinical trials or compassionate-access programs. The SAP is intended to help facilitate access for patients with "serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable."[3] SAP applications are assigned a high priority and are usually processed in one to three days. In granting special access, the TPD does not recommend use of the drug or render an opinion "that the drug is safe, efficacious or of high quality."[4]

In order for special access to be considered, a physician must complete and submit a form.[5] The physician must explain why a particular drug is needed, why this drug is the best choice, what other therapies have been considered and/or tried, and why no other drug is suitable. The physician must also provide sources of information that support the physician's decision.

The controversy created by the refusal stems in large measure from the lack of clarity in the TPD's own policy. While on the one hand the TPD says that it is responsible for determining whether a drug is sufficiently safe to grant special access, it also says that an SAP authorization does not constitute an opinion or statement that a drug is safe. It is not clear just what standards the TPD applies when deciding whether a drug is sufficiently safe for special access. Moreover, given the short turnaround time for requests under the SAP, and no apparent requirement to submit data about the drug being requested, a comprehensive review of the drug is not possible.

– Glen Hillson

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[1] Canadian Broadcasting Corporation. Medical standoff threatens teen's life. 20 September 2002. Text available on the CBC British Columbia site at http://vancouver.cbc.ca.

[2] J Matthews. Hep C sufferers swamp trial drug producers. 23 September 2002. Text available on the site of CBC British Columbia at http://vancouver.cbc.ca.

[3] Quoted from the description of the SAP on Health Canada's website at www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/sap.html.

[4] See "Special Access Programme (SAP) Instructions for Making a Special Access Request" on the SAP webpage, supra, note 3.

[5] See "Special Access Request Form" on the SAP webpage, supra, note 3.

Medical Association Calls for Routine HIV Testing of Pregnant Women

The Canadian Medical Association says that routine HIV testing of pregnant women is necessary because there are still babies being born with HIV infection. Critics respond that routine testing is the same as mandatory testing, that there is no reason to waive the requirement for informed consent accompanied by pre-test counselling, and that physicians need to do a better job of offering HIV testing to pregnant women.

In August 2002, the annual general meeting of the Canadian Medical Association (CMA) adopted a motion calling for routine prenatal HIV screening of all pregnant women. CMA delegates said that routine testing is necessary because there is no standard federal or provincial policy on testing pregnant women for HIV, and that it is unacceptable that babies in Canada are born with HIV despite the availability of effective pre- and postnatal treatment regimens.

Routine testing means that the HIV test would be included on laboratory forms along with a battery of other tests normally given during prenatal care. Theoretically, pregnant women would be able to opt out of the HIV test when they are asked to give their consent for all the tests listed on the laboratory form. However, critics of routine testing say that placing the HIV test on a laboratory form with other tests may only imply consent. They hold that informed consent, accompanied by pre-test counselling, should be given specifically for the HIV test; if specific, informed consent is not obtained for an HIV test, then routine testing is tantamount to mandatory testing.

Critics also argue:

- that informed consent with pretest counselling is the current standard of professional care in Canada for all HIV testing;
- that there is no valid reason why this requirement should be abrogated in the case of pregnant women;
- that physicians need to ensure that all pregnant women are offered HIV testing; and
- that it is particularly important to counsel a pregnant woman and to obtain her informed consent because the sooner she is informed about the advantages and disadvantages of testing and available treatments, the more likely she is to make decisions that will ultimately benefit herself and her child.

Both the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society have spoken out against the routine testing of pregnant women.[1] As well, in its guiding principles for HIV testing of women during pregnancy, published in March 2002, the Federal/Provincial/Territorial Committee on AIDS say that "voluntarism, confidentiality and informed consent" should guide policy and practices in this area.[2] The committee did not take a position specifically on routine testing.

The Canadian Public Health Association (CPHA) also supports voluntary testing. In 1998, the CPHA passed a resolution calling for increased testing of HIV, but rejecting mandatory testing and upholding the principles of confidentiality.[3] The association recommended that further efforts be undertaken to increase voluntary testing and called for the inclusion of anonymous-testing sites as a prevention tool to encourage individuals to test for HIV.

– Paul Kenney

Paul Kenney is the Director of the Canadian HIV/AIDS Clearinghouse. He can be reached at pkenney@cpha.ca.

[1] See L Stoltz, L Schap. *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate.* Montréal: Canadian HIV/AIDS Legal Network, 1999 (www.aidslaw.ca/Maincontent/issues/testing/e-preg.pdf). See also the Canadian AIDS Society's position on HIV Testing of Pregnant Women at www.cdnaids.ca/web/position.nsf/cl/cas-pp-0004.

[2] Guiding principles for human immunodeficiency (HIV) testing of women during pregnancy-2002. *Canada Communicable Disease Report* 2002; 28(13): 105-107 (available via www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc).

[3] *HIV & Public Health Policy*. Ottawa: Canadian Public Health Association, 1998.

HIV Study among Pregnant Aboriginal Women Raises Concerns

An unlinked HIV seroprevalance study among pregnant Aboriginal women in BC reveals an alarming trend and raises ethical questions about certain types of research in Aboriginal communities.

Controversy is brewing over a four-year seroprevalence study being conducted among Aboriginal women for Health Canada and the BC First Nations Chiefs' Health Committee. Blood samples from First Nations women undergoing routine prenatal blood tests are being tested for HIV and HTLV-1 (human T-lymphotropic virus, type 1) after information about the identity and community of the donor have been removed. Women can refuse to participate in the study.[1]

So far, the rate of HIV in pregnant Aboriginal women in the study is about seven times higher than in pregnant women as a whole. Blood samples from 10 of the approximately 3200 Aboriginal women in the study were found to be HIV-positive.[2] The study has raised concerns because it is not possible to notify the women from whom these blood samples were taken and to provide them with treatment and support.

Activists differ in their views of the study.[3] Some argue that the study does little to help the individuals and communities being studied and will only add to their fear of negative stereotypes. They claim that