February 10, 2016

Subject: Zika virus update: Canadian Recommendations on the Prevention and Treatment of Zika VIrus

Dear midwives,

The Canadian Committee to Advise on Tropical Medicine and Travel (CATMAT), the Public Health Agency of Canada, and the Society of Obstetricians and Gynaecologists of Canada have released Canadian Recommendations on the Prevention and Treatment of Zika Virus (ZIKV).

The new recommendations provide guidance on the prevention, as well as on the evaluation of pregnant women with a travel history to a country with ongoing or widespread transmission of ZIKV, the evaluation of the fetus among pregnant women diagnosed with ZIKV infection, and the evaluation of the infant born to a women diagnosed with ZIKV infection or with suspected congenital ZIKV infection.

This is the Canada-wide national guideline but laboratory testing is organized at the provincial level through Public Health Ontario. Please refer to the new (February 9th) Public Health Ontario testing directions and algorithm table and Zika Virus Test Information Sheet for specifics on ordering serology for ZIKV for clients who meet the criteria. This replaces the February 4th PHO document that was linked in the email to midwives that you received on February 8th.

Information about Zika virus continues to evolve. The AOM is monitoring the situation and will inform midwives as new relevant information is released. For further support around Zika or other outbreaks, contact Julie Toole (julie.toole@aom.on.ca or extension 2266 at the AOM office).

Sincerely,

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Government of Canada Gouvernement du Canada

Canadian Recommendations on the Prevention and Treatment of Zika Virus

Prepared by the Committee to Advise on Tropical Medicine and Travel

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Introduction

Zika virus (ZIKV) infection is caused by a flavivirus transmitted through the bite of an infected Aedes mosquito, mainly *Aedes aegypti*. *Aedes albopictus* has also been associated with transmission of ZIKV [1]. Although infections in humans were documented in the 1950s, ZIKV has only recently emerged as a disease of significant public health concern. At time of writing, a large outbreak in the Americas has affected more than 20 countries. Outbreaks have also recently occurred on some

islands in the South Pacific. Before these outbreaks, known areas of endemic transmission were limited to Asia and Africa. It is likely that the virus will continue to spread because the principal vectors are found in many tropical and subtropical regions as well as in some warmer temperate regions [2, 3].

Currently, the significant and emerging concern about ZIKV is the spatial and temporal clustering of the ZIKV outbreak in Brazil with an increase in the incidence of children born with microcephaly [4]. This association has been supported in a small number of cases, through detection of ZIKV viral genome in amniotic fluid, placenta and tissues of affected fetuses and neonates [5]. In addition, an apparent increase in cases of Guillain-Barré syndrome has been noted in ZIKV affected areas of Brazil and El Salvador, and previously in French Polynesia [6].

The purposes of this statement are: to review the current understanding of ZIKV infection; and, to provide guidance for health care practitioners who provide advice to Canadians travelling to or living in affected areas and/or who manage travellers returning from these areas. Emphasis is placed on the sub-populations who appear to be at the greatest risk for ZIKV-associated harm, pregnant women and their developing fetuses.

Methods

This statement was developed by a working group of the Committee to Advise on Tropical Medicine and Travel (CATMAT). In addition to CATMAT members, the working group included representatives from the Public Health Agency of Canada and the Society of Obstetricians and Gynaecologists of Canada. Each member was a volunteer, and none declared a relevant conflict of interest. The statement complements several existing CATMAT statements including the Statement on Personal Protective Measures to Prevent Arthropod bites (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/12vol38/acs-dcc-3/index-eng.php) [7] and the Statement on Pregnancy and Travel (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/10vol36/acs-2/index-eng.php) [8]. A thorough literature search for relevant evidence related to ZIKV was conducted. Guidelines and reports from international and national public health organizations including, but not limited to, the Centers for Disease Control in the United States, the Pan American Health Organization and the World Health Organization were also reviewed.

Epidemiology of Zika worldwide

ZIKV was first isolated from Ugandan monkeys in 1947. Soon after (1952), human infections were detected in Uganda and Tanzania [9, 10]. However, subsequent human infections were rarely reported until 2007, when the first major outbreak of ZIKV disease was reported on the island of Yap (Micronesia) in the southwestern Pacific Ocean [11]. This was the first time that ZIKV was detected outside of Africa and Asia. Between 2013 and 2015, several significant outbreaks occurred on islands and archipelagos from the Pacific region including a large outbreak in French Polynesia [12, 13]. An outbreak was also reported in Cape Verde [14]. In 2014, the first report of local transmission in the Americas was reported on Easter Island [15]. It has since spread to a wide region of the Americas (http://www.paho.org/hq/index.php?option=com_content&view=article&id=11603&Itemid=41696&lang=en) including, at the time of writing, more than 20 countries and territories [16]. In some situations

transmission has been intense, for example the Brazilian Ministry of Health has estimated that 440,000 to 1,300,000 ZIKV infections occurred in Brazil in 2015 [6]. It is anticipated that ZIKV will continue to spread through the Americas, in particular in tropical and subtropical regions [17, 18].

Transmission

The mosquitoes associated with ZIKV can be active during the day and night, with biting activity often peaking in the morning and later in the afternoon. In vertebrate hosts, the incubation period is usually three to 12 days, with blood viremia (the period when ZIKV is present in the blood) usually lasting for three to five days. If bitten by a competent mosquito while viremic, the human (or other) host can infect the mosquito thereby completing the transmission cycle [18]. Vertical transmission between mother and developing fetus also presumably occurs during this period [19, 20]. Other routes of transmission include blood product transfusion [21] and possibly sexual contact; the virus has been detected in semen and several cases of sexual transmission have been reported [22 - 24].

Clinical Manifestations

Approximately 20-25% of those infected with ZIKV will manifest symptoms, including fever, myalgia, eye pain, and maculopapular rash [11, 25]. Early clinical manifestations are generally similar to other arboviral infections including dengue and chikungunya, with considerable overlap in symptoms, although ZIKV infections usually have milder clinical illness [25, 26]. Thus, the differential diagnosis of a febrile returned traveller from the Americas will likely include these arboviral entities, as well as malaria (http://www.publications.gc.ca/site/eng/463465/publication.html) [27] and other viral infections (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/11vol37/acs-3/index-eng.php) [28, 29].

Although rare, neurological complications, such as Guillan-Barré syndrome (GBS), have been reported following ZIKV infection, and excess GBS cases have been noted during periods of ZIKV circulation [6, 30, 31].

Blood viremia is estimated to last three to five days following symptom onset [30, 32], however viral RNA has been detected in saliva [13] or urine [33] more than a week after clearance of blood viremia. One report demonstrated ZIKV via polymerase chain reaction (PCR) in semen collected from a patient with confirmed infection who developed hematospermia two weeks following symptom recovery [22].

As described above, the recent outbreak in Brazil has been associated with microcephaly, defined as a head circumference measurement below the third percentile and disproportionate to the weight and length percentile measurements. Following infection, neutralizing antibodies for ZIKV are detectable, and, by extrapolation from other flaviviruses, immunity is presumed to be long-lived.

Risk to Canadian travellers

The Public Health Agency of Canada has recently published [1] an assessment of the risk of ZIKV to Canadians travelling to affected areas (/publications/diseases-conditions-maladies-affections/risks-zika-virus-risques/index-eng.php) in the Americas [34]. It makes the following statements:

- Based on the frequency of Canadian travel, the expectation of continued spread of ZIKV in the

Americas, and the number of observed ZIKV cases to date, we estimate the likelihood that Canadians travelling to epidemic regions will be exposed to ZIKV as **Medium** [2] (with medium confidence).
- Based on current understanding of the typical course of infection we estimate the general impact of ZIKV infection to be **Low** (with medium confidence).
- There is mounting evidence to support the possible link between infection with ZIKV and infant microcephaly, though much uncertainty remains. Substantial effort is being directed towards determining if there is a causal link, the effect of timing of infection on fetal development, and determining if there are other contributing risk factors (i.e. co-infection or serial infection with other viruses, nutritional status, or other environmental factors). Future scientific findings could change this judgement substantially, but if the increased incidence of microcephaly is caused by ZIKV (which is still under investigation), we estimate a **Very High** impact (with low confidence) on the unborn child of a woman who acquires ZIKV while pregnant [34].

In summary, it is estimated that ZIKV will have modest to no health impact for the large majority of non-pregnant travellers, though it might rarely be associated with neurologic sequelae such as GBS. However, though uncertainly remains, current evidence suggests that ZIKV could have a very serious impact on the health of developing fetuses.

At this time there is insufficient data to allow for robust estimation of the likelihood that travellers will be exposed to ZIKV in affected areas, or of the likelihood of fetal infection and fetal harm in the event that a pregnant mother is infected.

Prevention

There is no vaccine or immunoprophylaxis that protects against infections with ZIKV. Health care practitioners who provide pre-travel consultations and those who care for pregnant women and women who intend to get pregnant should outline the potential risks associated with ZIKV infection so they can make informed decisions about the risks associated with travel and an informed choice about whether or not to travel. Those who choose to travel or where travel is essential should be advised to follow strict personal protective measures (PPM) against mosquito bites at all times.

Recommendation to all travellers

CATMAT recommends that all travellers to areas where ZIKV is circulating use PPM (see below) against mosquito bites.

Recommendation to pregnant women and those who intend to get pregnant:

CATMAT recommends that all pregnant women and those who are considering attempting to get pregnant discuss their travel plans with their health care provider and consider postponing travel to areas in the Americas affected by the ZIKV outbreak. The Pan American Health Organization (http://www.paho.org/hq/index.php?option=com_content&view=article&id=11603%3Acountries-territories-zika-autochthonous-transmission-americas&catid=8424%3Acontent&Itemid=41696&lang=en) (PAHO) has a list and map of countries and territories with confirmed cases in the Americas

[35]. This outbreak is expanding and reporting may not be complete or up-to-date. For this reason some women may consider postponing travel to affected areas currently considered to have suitable conditions for sustained and high levels of ZIKV transmission, even if ZIKV is not currently being reported. This includes Mexico and most areas of South and Central America, the Caribbean, but not temperate areas of Argentina or Chile. For pregnant women who choose to travel to areas with ZIKV transmission or for whom travel cannot be avoided, strict PPM against insect bites are strongly advised (see below for more detail).

Based on current information on the incubation period and duration of viremia, and the unclear duration of viral persistence in tissues, women wishing to become pregnant should wait at least two months after their return from an affected area before trying to conceive.

There is some evidence that ZIKV can persist in semen for more than two weeks, although the true frequency and duration of viral shedding in genital secretions is not known, as a precaution, men who have travelled to an area with widespread transmission of ZIKV should use condoms with any partner who is or could become pregnant for two months after their return. Until more is known, and based on our experience with other viral infections where shedding in semen may be very prolonged, it is reasonable to consider the use of condoms for the duration of the pregnancy.

Personal protective measures:

Currently, no vaccine exists to prevent ZIKV infection.

PPM are recommended to protect all travellers to areas of risk. The mosquitoes that transmit ZIKV are often most active during daytime and evening hours [17]. For this reason, PPM should be used through all hours of the day and night. Use of PPM will also provide protection against other vector-associated diseases that occur in affected areas such as malaria, dengue, and chikungunya. Recommendations for PPM can be found in CATMAT's *Statement on Personal Protective Measures to Prevent Arthropod Bites* (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/12vol38/acs-dcc-3/index-eng.php) [7]. In summary, the statement recommends the approaches outlined in the Table below.

Protect yourself from bites:

1. Cover up:
   - Wear light-coloured, long-sleeved, loose fitting, tucked-in shirts, long pants, shoes or boots (not sandals), and a hat.
2. Use insect repellent on exposed skin
   - It is recommended that adults use repellents that contain DEET (20-30%) or icaridin (20%).
   - It is recommended that children 6 months to twelve years of age use repellents that contain icaridin (20%). As a second choice, this age group can use repellents with age-appropriate DEET concentrations as per label.
   - If bites cannot be avoided using a physical barrier, consider use of up to 10% DEET or 10% icaridin for infants under six months of age.
3. Protect living areas from mosquito entry:
   - Stay in a well-screened or completely enclosed air-conditioned room.
   - Reduce your risk in work and accommodation areas by closing eaves, eliminating holes in roofs and walls and closing any other gaps.

4. If mosquito entry into living quarters cannot be otherwise prevented (e.g. by screening):
    - Use a bed net (e.g. for sleeping or resting inside), preferably treated with insecticide.
    - Netting can also be used to protect children in playpens, cribs, or strollers.
    - Bed nets will also provide protection against diseases like malaria.
5. Apply a permethrin insecticide to clothing and other travel gear for greater protection
    - Although permethrin is not available in Canada, travel health clinics can advise you how to purchase permethrin and pre-treated gear before or during your trip.
    - Permethrin-treated clothing is effective through several washes.
    - Always follow label instructions when using permethrin.
    - Do not use permethrin directly on skin.

Source: CATMAT's *Statement on Personal Protective Measures to Prevent Arthropod Bites* (http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/12vol38/acs-dcc-3/index-eng.php) [7]

Insect repellents, insecticide treated bed nets and permethrin treated clothing/clothing treatments have been reviewed for safety in Canada and/or the United States. They are considered safe for children, pregnant and breastfeeding women if used in accordance with label directions.

Laboratory Diagnosis

Molecular testing using reverse-transcriptase real time PCR (RT-PCR) is conducted by some provincial laboratories in Canada. The National Microbiology Laboratory (NML) provides provincial support, along with confirmatory testing. Sensitivity is unknown, but presumed to be high, at least in the initial few days of illness, since ZIKV appears to circulate in the blood for the first three to five days after onset of symptoms [17]. ZIKV RNA may be present in urine for a few days after it is no longer detectable in blood [17, 36]. Specificity is presumed to be high. Information about NML's guidelines and testing recommendations are available for health care professionals on the Government of Canada's website (/diseases-conditions-maladies-affections/disease-maladie/zika-virus/index-eng.php).

Serologic testing is currently performed at the NML using an IgM-based in-house enzyme immunoassay (ELISA), with confirmatory ZIKV plaque reduction neutralization test (PRNT). Antibodies appear approximately five to six days after onset of symptoms [30]. For the acutely unwell patient with less than 10 days of symptoms, both RT-PCR and serology should be requested. For the convalescent patient with symptom onset over 10 days ago, only serology should be requested. Appropriate diagnostic specimens for RT-PCR testing include plasma/serum, urine, cerebrospinal fluid (CSF), amniotic fluid and placental tissue. Serology is usually only performed on serum; however, viral antibodies may also be detected in CSF in some cases of neurological disease.

As ZIKV is a member of the flaviviridae, serologic tests, including the IgM ELISA assay performed by the CDC, may be cross-reactive with other flaviviruses such as dengue, West Nile, and Yellow Fever (including vaccine recipients) [2]. Confirmation of ZIKV therefore rests on amplification of viral RNA by RT-PCR, or by confirmatory PRNT serologic testing which is laborious and time consuming. Confirmatory testing generally requires neutralizing IgG production, which may appear later than IgM. The specificity of the IgM ELISA is limited particularly during secondary flavivirus infections, and the sensitivity is ill-defined at this time, although it is presumed to be high. Patients whose serum samples are IgM positive and are also shown to harbour ZIKV specific antibodies by a PRNT assay are

confirmed cases of viral infection. It should be noted that for individuals previously infected with or vaccinated against flaviviruses may exhibit cross reactivity in PRNT tests as well and the test results may be difficult to interpret. Since dengue virus and ZIKV are transmitted by the same types of mosquitoes, co-infections with these viruses are possible. As noted above, if antibody is present against both of these viruses or other related flaviviruses, it may be difficult to determine the virus responsible for current versus previous or past infections.

PCR for ZIKV can be performed on amniotic fluid (when amniocentesis is technically feasible) to confirm infection of the fetus. At this time, the risk of adverse outcomes of pregnancy if the fetus is infected with ZIKV is unknown, so the risk of the procedure must be weighed against the benefits of this test result. A negative PCR likely means that the fetus is not actively infected at that moment, but would not eliminate the possibility of prior infection and potential injury to the fetus. It is not known when ZIKV RNA would be expected to appear in amniotic fluid after infection, nor how long it is likely to be detectable.

For postnatal diagnosis of congenital infection, PCR for ZIKV can be performed on placental tissue, umbilical cord blood or infant blood sample, and CSF for confirmation of congenital infection. It is likely, however, that infants or fetuses infected weeks prior to specimen sampling will no longer have detectable viral RNA.

Screening and Management

Evaluation of non-pregnant travellers returning from endemic countries

Testing for ZIKV infection should be considered in the diagnosis of any ill traveller with compatible epidemiologic and clinical history, when symptom onset is within three days after arrival in, to 14 days after departing from, a country where ZIKV transmission is ongoing or widespread. Testing for other similar viral infections and for malaria should also be done as appropriate.

Testing is generally not warranted for returned travellers whose clinically compatible illness has resolved, or for those who have travelled and remain asymptomatic, because of the currently limited availability of laboratory testing and uncertain benefit of such testing. Given that rare cases of neurologic disorders, including GBS, have been reported following ZIKV infection, returning travellers should be counselled to report any neurologic symptoms to their doctor. In the event of the diagnosis of GBS or other unusual neurologic syndrome, a travel history should be elicited. If ZIKV infection is thought to be potentially associated with the illness, a specialist should be consulted.

Screening in the context of pregnancy

Evaluation of pregnant women with a travel history to a country with ongoing or widespread transmission of ZIKV

Health care providers should inquire about travel history among all pregnant women. Those who have travelled to a country with ongoing or widespread transmission of ZIKV should be evaluated. Screening of pregnant women should be discussed on a case-by-case basis between the woman and

her health care provider. In these discussions, it is important to consider the problems with sensitivity and specificity of currently available diagnostic testing, overall test result interpretation, as well as the prolonged turnaround time of the available tests, which may be problematic in some cases. The decision to test should include consideration of how the results of the screening tests would be used to inform subsequent decisions. Diagnosis and identification of poor fetal outcomes will allow for appropriate counselling.

Pregnant women and their partners may be justifiably concerned about the risk of ZIKV infection to their fetus and may want to receive counselling to decide the best course of action, including the question of termination. The actual risks of ZIKV infection in pregnancy are currently unclear. Specifically, the risk of symptomatic vertical infection (with microcephaly/intracranial calcification) with maternal infection in a given trimester of pregnancy is entirely unknown although it is presumed that the risk is highest in the first and early second trimester. This uncertainty makes pregnancy counselling a difficult prospect. Regardless, discussion and informed decision making regarding options for management of ZIKV infection in pregnancy (much like any other congenital infection or congenital anomaly) requires thorough consultation with a Maternal Fetal Medicine Specialist or another specialist familiar with reproductive infectious diseases. As understanding of the risks of ZIKV infection in pregnancy becomes clearer, so too will the related counselling messages, which in turn will allow each patient to make her own individual decision about her pregnancy.

Testing (including PCR) should be offered to pregnant women with acute signs and symptoms compatible with ZIKV. Likewise, a pregnant woman who has a clinical history of a compatible ZIKV-like illness either during or after travel to an area with ZIKV transmission, or whose fetus is suspected of having a congenital anomaly should also be offered testing.

Asymptomatic pregnant women with a history of travel to a country where ongoing or widespread ZIKV transmission is known or suspected should be evaluated and counselled appropriately. A detailed travel history should be taken in order to assess risk of exposure to ZIKV (eg. date, duration, type of travel, exposure to mosquito bites). Testing should be considered, however, the decision to test should include consideration of how the results would be used. Serologic testing risks false positive results on the initial IgM testing and there is a subsequent three to four week delay in completion of confirmatory testing to detect ZIKV specific antibodies. Screening by ultrasound cannot reliably detect microcephaly until late in the second trimester.

The risk of microcephaly or other adverse outcome of pregnancy for a woman known to be infected with ZIKV cannot be estimated from currently available data. Although measurements of head circumference and biparietal diameter may occur as early as 15 weeks, there is no defined gestational age by which microcephaly can be ruled out. Serial monitoring by ultrasound with close attention to measurement trends over time is recommended. It is possible that changes in intracranial anatomy may not be elucidated until well into the third trimester.

Evaluation of the Fetus among Pregnant women diagnosed with ZIKV infection

Serial ultrasounds (every 3-4 weeks) are recommended in pregnant women with confirmed or suspected (if testing results are pending) ZIKV infection in pregnancy and for asymptomatic pregnant travellers returning from ZIKV affected areas, to help define risk and counsel the mother. Should central nervous system (CNS) calcifications or fetal microcephaly be noted at ultrasonography of the asymptomatic pregnant returned traveller, then specific ZIKV testing (along with other routine testing)

should be undertaken to help define the likely cause of the anomaly.

Evaluation of the Infant born to a Woman diagnosed with ZIKV infection or with Suspected Congenital ZIKV infection

Infants born to women with confirmed or suspected ZIKV infection in pregnancy, or those with microcephaly, intracranial calcifications or other symptoms of congenital ZIKV infection in whom the mother had potential geographic exposure to the virus, should be tested. This testing should include serology, PCR of serum (umbilical cord or infant sample), and PCR of placenta; if CSF is sampled, this can also be sent for PCR and serology. Infants with suspected or confirmed congenital ZIKV infection should also undergo further work-up including: routine lab tests (CBC and liver enzymes), head ultrasound, ophthalmologic examination, and hearing evaluation. Infants with confirmed congenital ZIKV infection should have neurodevelopmental monitoring throughout infancy to assess the potential for long term sequelae.

Infants born to women with symptoms of active ZIKV infection around the time of delivery are at risk for perinatal transmission of the disease. In the limited number of reported cases to date, perinatally infected infants have exhibited either no or mild symptoms and laboratory findings (rash, thrombocytopenia) [19]. Regardless, such infants should be monitored closely given the unclear spectrum of potential illness in this emerging infection. Testing with serology and serum PCR during acute illness is recommended. In such cases, care should be taken to ensure a thorough work up for other important and treatable causes of congenital infections, such as CMV and toxoplasma infection.

Treatment

There currently exists no specific antiviral therapy for the treatment of ZIKV infection. Treatment is supportive with antipyretics (acetaminophen in pregnancy), hydration and rest. Aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) should be avoided until dengue can be ruled out to reduce the risk of hemorrhage [37]. Symptomatic disease typically lasts for up to 7 days. Urgent medical care is recommended for any symptoms associated with GBS, and treating health care providers should be made aware of recent travel to area with ZIKV circulation and/or symptoms of ZIKV infection.

If ZIKV infection is confirmed in the setting of pregnancy, referral to a Maternal Fetal Medicine Specialist or Infectious Disease Specialist should be made. If microcephaly, intracranial calcifications or other abnormalities are identified, appropriate counselling by a Neonatologist and Pediatric Infectious Diseases Specialist on potential neurodevelopmental outcome should be offered to parents.

Additional resources and useful links

Government of Canada – For health professionals: Zika Virus (/diseases-conditions-maladies-affections/disease-maladie/zika-virus/professionals-professionnels-eng.php?id=health_prof)

Government of Canada – Travel health notice: Zika virus infection in the Americas (http://travel.gc.ca/travelling/health-safety/travel-health-notices/143?_ga=1.101883841.1113463633.1435244057)

Pan American Health Organization – Zika Virus Infection (http://www.paho.org/hq/index.php?option=com_content&view=article&id=11585&Itemid=41688&lang=en)

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Conflict of interest

None declared.

1 This assessment will be updated as new information becomes available. Readers should therefore check the Public Health Agency of Canada's website for updated risk assessment information.

2 Likelihood and confidence terminology is explained in the Public Health Agency of Canada's risk assessment.

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Government of Canada activities and initiatives

Canada welcomes 25,000 Syrian refugees

(http://www.cic.gc.ca/english/refugees/welcome/index.asp?utm_source=canada-

eng&utm_medium=canada-features&utm_campaign=refugees2015)
The Government of Canada is taking immediate action to welcome 25,000 Syrian refugees to Canada through a five-phase national plan. #WelcomeRefugees

National Inquiry into Missing and Murdered Indigenous Women and Girls

(http://www.aadnc-aandc.gc.ca/eng/1448633299414)
The Government of Canada has launched a national inquiry into missing and murdered Indigenous women and girls.

Pre-Budget Consultations 2016

(http://www.budget.gc.ca/pbc16/?utm_source=CanCa&utm_medium=Act+Ini&utm_campaign=PBC16)
Growing our Economy Together – Pre-Budget Consultations 2016. Have your say! #PBC16