CANVAS: COVID Vaccine Active Safety Surveillance

DOSE 1 SURVEY

1. [*Optional depending on recruitment method*] Did you receive your COVID-19 vaccine?

- o Yes
- o No

[*If no to 1, skip to **b)***]

1.1. *[If yes to 1],* What was the date? <dd/mm/yyyy>

1.2. *[If yes to 1]* Which COVID-19 vaccine did you receive?

- o Pfizer-BioNTech COVID-19
- o Moderna
- o Astra-Zeneca
- o …
- o I don't know

1.3. *[If yes to 1]* Lot number: _____ o I don't know

2. What sex were you assigned at birth:

- o Male
- o Female
- o Intersex
- o Prefer to self-describe as:
- o Prefer not to answer

3. What best describes your gender:

- o Man
- o Woman
- o Non-binary, genderqueer, agender, or similar identity
- o Two-spirit
- o Prefer to self-describe as:
- o Prefer not to answer

4. How old are you?

- o 15-19 years old
- o 20-29 years old
- o 30-39 years old
- o 40-49 years old
- o 50-64 years old
- o 65-79 years old
- o 80+ years old

5. In general, would you say your health is:

- o Excellent *(You do not have current medical problems. You regularly exercise or are very active.)*

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- Very good *(You do not have current medical problems. You often exercise.)*
- Good (*Your medical problems are well controlled. You are not regularly active beyond routine walking.)*
- Fair *(You are not dependent on others for daily help, but often your medical problems limit activities.)*
- Poor (*People need help with all outside activities and with keeping house.)*
- Very Poor *(Completely dependent for personal care, from whatever cause [physical or cognitive].)*
- I don't know
- Prefer not to answer

6. Are you currently immunocompromised (on cancer treatment, transplant recipient, on immunosuppressive therapy, HIV, etc.)

- Yes
- No

7. Do you have an auto-immune disease (lupus, rheumatoid arthritis, MS etc)

- Yes
- No

8. *[If female and 15-49 years old]* Are you currently pregnant?

- Yes
- No

8.1. *[If Yes to 8]* If so, what trimester are you in?

- 1st (0-14 weeks)
- 2nd (15-28 weeks)
- 3rd (29-42 weeks)

8.2. *[If No to 8]* Have you experienced a birth in the last 7 days?

- Yes
- No

8.3. [*If No to 8 and No to 8.2*] Have you experienced a stillbirth, or miscarriage in the last 7 days?

- Yes
- No

8.3.1. [*If Yes to 8.2 or 8.3*] If so, what trimester were you in?

- 1st (0-14 weeks)
- 2nd (15-28 weeks)
- 3rd (29-42 weeks)

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9. *[If female and 15-49 years old]* Are you currently breastfeeding?

- o Yes
- o No

10. Did you experience any of the following after your COVID-19 vaccine:

- o Redness, pain or swelling at the injection site
- o Redness, pain or swelling above the shoulder or below the elbow in the immunized arm
- o No, I did not have any redness, pain or swelling at the injection site

11. In the first week (7 days) after your COVID-19 vaccine did you develop a new health problem or did an existing health problem get worse?

- o Yes
- o No

[If No to 11, skip to a)]

11.1. *[If Yes to 11]*: Was this health problem severe enough to prevent/stop normal activities?

- o Yes
- o No

11.2. *[If Yes to 11]*: Was this health problem severe enough to miss work/school?

- o Yes
- o No

11.3. *[If Yes to 11]*: Was this health problem severe enough to see a health care provider?

- o Yes
- o No

11.3.1. *[If Yes to 11.3]* Did you see a health care provider for this health problem?

- o Yes
- o No

*[If No to 11.1 AND 11.2 AND 11.3 skip to **a)**]*

11.4. *[If Yes to 11.1, 11.2 or 11.3]*: Please check all the symptoms you experienced as part of your health problem. We are interested in the symptoms that started in the first week (7 days) after your COVID-19 vaccine. This does not mean these are common symptoms of COVID-19 or COVID-19 vaccines (check all that apply):

- o Any of the following: Feeling unwell, tiredness, weakness, muscle aches, fatigue, or chills.
- o Any of the following: Nausea, Vomiting, Diarrhea, or Stomach pain
- o Fever (temperature at least 38.0°C or higher)
- o Headache or migraine

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- Arthritis/joint pain/stiffness
- Inability to walk
- Loss of taste/smell
- Loss of vision
- Hoarseness (raspy or strained voice; "frog in throat")
- Sore throat
- Chest tightness/discomfort/pain/angina
- Difficulty breathing/shortness of breath without throat/tongue swelling
- Wheezing
- Cough
- Runny nose
- Nasal congestion(stuffed nose)/sinus congestion
- Swelling of the throat and/or tongue with difficulty breathing or swallowing
- Swelling of a part of your face or lips (excluding eyelids)
- Swelling of the eyelid(s)
- Redness of both eyes
- Painful eyes
- Itchy eyes
- Tearing or eye discharge
- Earache/ear pain/ear symptoms/decreased hearing/hearing loss
- Rash or hives
- Bruising or pinpoint dark red rash (NOT at injection site)
- Shingles
- Rapid heart rate (pounding or racing heart; palpitations)
- Symptoms of a blood clot or bleeding: swelling/pain in legs/blood clot/low platelets
- Sudden weakness or paralysis on one side of the face
- Numbness, tingling, pins and needles, decreased sensation or burning sensation anywhere in the body
- Dizziness/vertigo/light-headedness
- Fainting
- Seizure or convulsion
- Neurologic symptoms: weakness or paralysis of the arms or legs/confusion/change in personality/behavior or difficulty with urination or defecation
- Difficulty or pain with urination (urinary tract infection symptoms)
- Jaundice/yellowing of eyes
- Anaphylaxis
- Other (specify) _____

[display if Yes to 8]

- Preterm labour (regular contractions starting before 37 weeks gestation (>3 weeks before your due date))
- High blood pressure
  - [if yes to above] eclampsia/preeclampsia
- Vaginal spotting or vaginal bleeding
- Abnormal fetal heart rate (heart rate that is too fast or too slow)
- Other complication of pregnancy (specify: _____)

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11.5. *[If Yes to 11.1, 11.2 or 11.3]*: If you had more than one symptom that started in the first 7 days after your vaccine what was the most severe symptom?

- *[subset of symptoms chosen above: participant will choose one]*
-
- …

11.6. *[If Yes to 11.1, 11.2 or 11.3]*: How long after the vaccine did your health problem start or your existing health problem get worse?

- Within the first hour (60 minutes) after my COVID-19 vaccine
- Within the first day (1 to 24 hours) after my COVID-19 vaccine
- 2-3 days after my COVID-19 vaccine
- 4-5 days after my COVID-19 vaccine
- 6 -7 days after my COVID-19 vaccine
- 8 or more days after my COVID-19 vaccine

11.7. *[If Yes to 11.1, 11.2 or 11.3]*: How long did your health problem last?

- Lasted less than one hour (60 minutes)
- Lasted 1 to 10 hours
- Lasted one day (11-24 hours)
- Lasted 2-3 days
- Lasted 4-5 days
- Lasted 6 or more days
- It is still present

11.8. *[If Yes to 11.3.1]*: Earlier you answered that you saw a health care provider for the health problem. What type of medical visit did you have? (check all that apply)

- Virtual/telemedicine/phone
- In-person visit to a clinic
- Emergency room
- Hospitalization
- COVID-19 Testing [*if checked and only 11.3 = yes exclude from AE follow up*]
- Other: _____

11.9. *[If Yes to 11.3.1.]*: Did the health care provider give you a diagnosis?

- Yes
- No

11.9.1. *[If yes to 11.9]*: Specify the diagnosis: _____

11.10. *[If Yes to 11.3.1.]*: Did you receive any treatment?

- Yes
- No

11.10.1. *[If yes to 11.10]*: What was the treatment:

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- Antibiotics
- Antihistamines (e.g. Reactine, Claritin, Benadryl, etc)
- Tylenol (acetaminophen)/Advil (ibuprophen) /asprin
- Other, specify: _____

11.11. *[If 11.8="Hospitalization"]*: What was your admission date: <dd/mm/yyyy>

11.12. *[If 11.8="Hospitalization"]*: What was your discharge date: <dd/mm/yyyy>

11.13. *[If 11.8="Hospitalization"]*: Were you admitted to the ICU (intensive care unit)?

- Yes
- No

11.13.1. *[If yes to 11.13]*: For how many days? _____

12. Have you ever tested positive for COVID-19?

- Yes
- No

12.1. [*If Yes to 12*] What date did you test positive (provide most recent date if more than one positive test)? <mm/yyyy>

12.2. [*If Yes to 12*] What was the severity?

- Asymptomatic (no symptoms)
- Mild: prevented some normal daily activities
- Moderate: prevented all normal daily activities (bedridden)
- Severe: hospitalized

Since you answered that you required a medical consultation, a research staff member may contact you to collect more information.

a) *[If No to 11.1 AND 11.2 AND 11.3]* We are only collecting additional information for health conditions which resulted in a visit to a health care practitioner or missed time off work/school or prevented normal activities.

13. Do you know the date for your second COVID-19 vaccine dose?

- Yes : < dd/mm/yyyy>
- No

b) [*If no to 1]* For this survey, we are monitoring health events in people who received a dose of COVID-19 vaccine.

14. Can we contact you about future research studies?

- Yes, I give permission to be contacted for future studies
- No, I do not give permission to be contacted for future studies

Thank you for helping us to monitor the safety of Canada's COVID-19 vaccines.

[*If Yes to 13]* We will send you another survey one week after your next dose of COVID-19 vaccine.

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[*If No to 13]* We will send you another survey in 21 days to find out the date of your next COVID-19 vaccine.

In the meantime, if you would like to track study updates please visit:

http://cirnetwork.ca/network/[website to be determined]

Bettinger JA, *et al. BMJ Open* 2022; 12:e051254. doi: 10.1136/bmjopen-2021-051254