

Klachkova, Anastasiya (CSC/SCC)

From: Boudreau Harold (NHQ-AC)
Sent: February 2, 2021 2:01 PM
To: Worthington Dr. James (NHQ-AC); Clement Chris (NHQ-AC)
Subject: Updated Consent form wording following feedback from NMAC call today
Attachments: Moderna Consent form - final_EN_v2.docx; Moderna Consent form - final_EN.docx

Hi Jim/Chris,

See my updated version of the Consent form (V2) based on the NMAC call today. I spaced it out better to be on two pages, modified the paragraph on efficacy for better to understand language and tried my best to keep consistent with the term patient. Please review and let me know what you think. I will work to make the same changes to the French version

I added the original version for comparison.

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Patient Agreement for Delayed Administration of 2nd dose of Moderna COVID-19 Vaccine

Getting vaccinated against COVID-19 is an important step to protect yourself and others from COVID-19. Protection is critically important because COVID-19 can cause severe illness or death.

Health Canada has approved two COVID-19 vaccines to date, Pfizer/BioNTech and Moderna (mRNA-1273), which are classified as mRNA vaccines. These vaccines contain material from the COVID-19 virus that gives our cells instructions for how to make a harmless protein that is unique to the virus. Our bodies recognize that this protein should not be there and remember how to fight the COVID-19 virus if we are infected in the future. These vaccines are not live viruses and cannot cause COVID-19 infection.

CSC will receive quantities of COVID-19 vaccines necessary to offer vaccination to all CSC patients

However, CSC has only received a small quantity of the Moderna vaccine so far, with additional quantities presently expected in April 2021. As such, the vaccine is being prioritized according to National Canadian immunization guidelines (NACI – National Advisory Committee on Immunization) to ensure that elderly patients (over 70 years of age) and other older patients with significant medical conditions receive the vaccine as a priority.

The Moderna vaccine comes in vial that provides 10 doses. However, it has been seen that an additional dose is possible in certain vials. CSC has decided to offer this additional dose to patients where possible.

You have been identified as a potential recipient of the potential extra dose of the Moderna vaccine within this initial roll out. If you accept this as your first dose, the second dose unfortunately will not be available within the recommended time period of 28-42 days*, due to the limited supply currently available to CSC.

*The Moderna vaccine is recommended by the manufacturer to be given as TWO doses 28 days apart. NACI guidelines have recently recommended that the delay between doses can be extended to up to 42 days.

The Moderna vaccine was shown to prevent COVID-19 symptoms in 94-95% of patients who received TWO doses. In those who only received ONE dose of the vaccine, the ability of the vaccine to prevent COVID-19 symptoms was also shown to be high (80%), for up to 28 days after the first dose. However, information on how well the vaccine works after 28 days from the first dose is not yet known. CSC continues to monitor recommendations from NACI about time between doses affects how well the vaccine works and how a longer time between doses may affect the number of doses a patient may require in the future.

CSC is adopting the approach of offering the additional dose as a first dose of the vaccine as this first dose will provide you protection from the COVID-19 virus while waiting for your second dose. It is important to note that if you agree to receive this additional dose as your first dose, you will receive the second dose as soon as CSC receives additional quantities. This is presently expected to be in April 2021, however delays may occur that are not under the control of CSC.

Patient Name: _____ **Institution:** _____

- I understand the information provided above and my questions and concerns have been answered.
- I understand that refusing this offer of the potential 11th dose of Moderna vaccine will not affect my ability to receive the Moderna vaccine, when additional quantities are available.
- I accept to receive this first dose of Moderna vaccine on the understanding that although anticipated to come in April 2021, there is no confirmed date for the second dose.

Patient Agreement for Delayed Administration of 2nd dose of Moderna COVID-19 Vaccine

Patient Signature

CSC Health Staff member

Date

DRAFT - For discussion purposes

Patient Agreement for Delayed Administration of 2nd dose of Moderna COVID-19 Vaccine

Getting vaccinated against COVID-19 is an important step to protect yourself and others from COVID-19. Protection from COVID-19 is critically important because it can cause severe illness or death.¹

Health Canada has approved two COVID-19 vaccines to date, Pfizer/BioNTech and Moderna (mRNA-1273), which are classified as mRNA vaccines. These vaccines contain material from the COVID-19 virus that gives our cells instructions for how to make a harmless protein that is unique to the virus. Our bodies recognize that this protein should not be there and remember how to fight the COVID-19 virus if we are infected in the future. These vaccines are not live viruses and cannot cause COVID-19 infection.

CSC will receive quantities of COVID-19 vaccines necessary to offer vaccination to all CSC inmates.

However, CSC has only received a small quantity of the Moderna vaccine, with additional quantities presently expected in April 2021. As such, the vaccine is being prioritized according to National Canadian immunization guidelines (NACI – National Advisory Committee on Immunization) to ensure that elderly patients (over 70 years of age) and other older patients with significant medical conditions receive the vaccine as a priority.

The Moderna vaccine comes in vial that provides 10 doses. However, it has been seen that an extra 11th dose is possible in certain vials. CSC's experience to date has shown that an additional dose was possible for a number of vials used and has decided to offer this additional dose to eligible inmates.

You have been identified as a potential recipient of the potential extra dose of the Moderna vaccine within this initial roll out. If you accept this as your first dose, the second dose unfortunately will not be available within the recommended time period of 28-42 days*, due to the limited supply currently available to CSC.

*The Moderna vaccine is recommended by the manufacturer to be given as TWO doses 28 days apart. NACI guidelines have recently recommended that the delay between doses can be extended to up to 42 days.

The efficacy reported after receiving TWO doses of the Moderna vaccine was 94-95%. In those who only received ONE dose of the vaccine, the vaccine efficacy up to 28 days after the first dose was also reported to be very high, at 80%. However, the efficacy of the vaccine to prevent symptomatic COVID-19 after 28 days of the first dose is not yet known. CSC continues to monitor recommendations from NACI about the interval between doses and how a longer interval between doses may affect the number of doses a person may require.

CSC is adopting the approach of offering the extra dose as a first dose of the vaccine as ONE dose alone will provide you protection from the COVID-19 virus while waiting for your second dose. It is important to note that if you agree to receive this 11th dose as your first dose, you will receive the second dose as soon as CSC receives additional quantities. This is presently expected to be in April 2021, however delays may occur that are not under the control of CSC.

Patient Name: _____ **Institution:** _____

- I understand the information provided above and my questions and concerns have been answered.
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Patient Signature

CSC Health Staff member

Date