

Dr. Robichaud – JMPC Discussion on COVID-19 Vaccination with mRNA Vaccines

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Contents

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|--|---|
| Summary message from Dr. Robichaud – Medical Director, John M Parrott Centre | 1 |
| Benefits of the COVID-19 vaccine: | 2 |
| Risks of contracting COVID-19: | 2 |
| COVID-19 in LTC residents:..... | 2 |
| COVID-19 in the General population: | 2 |
| COVID-19 VACCINE SAFETY:..... | 2 |
| Is the COVID-19 vaccine 100% safe? | 2 |
| How was this vaccine developed so quickly? | 2 |
| Motivation for Safety | 3 |
| COVID-19 CONSENT DISCUSSION POINTS: | 3 |
| FAQ relevant to LTC residents and/or staff: | 3 |
| What are the absolute contraindications to getting the mRNA vaccine..... | 3 |
| What if I am taking a blood thinner or have a bleeding disorder?..... | 4 |
| What if I am Pregnant or Breastfeeding? | 4 |
| What if I am Immunocompromised or have an Autoimmune disorder? | 4 |

Summary message from Dr. Robichaud – Medical Director, John M Parrott Centre

Overall, the novel COVID-19 mRNA vaccines represent a scientific breakthrough in vaccine technology and have the potential to significantly benefit the health and wellness of residents living in long-term care homes, as well as long-term care staff who help the most vulnerable in our society.

The covid-19 vaccines have been shown to be effective and have a good safety profile. For many of those living or working in the long-term care sector, the medical data on relative risks and benefits of the COVID-19 vaccines will favor vaccination. If you have more questions and want more discussion around benefits and safety of vaccination, please review the sections below and their respective sources.

I will be taking the COVID-19 Vaccine despite being immunosuppressed and having an autoimmune condition. I will encourage my family, friends, co-workers and patients to do the same unless they have a contraindication. For the vast majority of people, the covid-19 vaccine appears to be safe with effectiveness of around 95%.

I am not aware of any benefits of contracting the COVID-19 virus, but I know of many benefits of receiving the COVID-19 vaccine.

Benefits of the COVID-19 vaccine:

- You are much less likely to contract COVID-19 and much less likely to be severely ill, require hospitalization, need to be on a ventilator, or die.
- You are helping protect the most vulnerable people in our society, such as LTC residents, who have an extremely high risk of dying if they become sick from COVID-19.
- You are helping protect our healthcare system from being overwhelmed like has been the case in other countries. During the early stages of the pandemic, in Italy, physicians were forced to make difficult choices about who could live and who would die from COVID-19, because they did not have enough ICU beds or ventilators for everyone.
- You are helping bring our society back to “normal”, where we can get closer to reconnecting with our friends and families, travelling and growing our economy.
- You will help save lives – the lives of mothers, fathers, daughter, sons, grandchildren who would have otherwise passed away from COVID-19.

Risks of contracting COVID-19:

COVID-19 in LTC residents:

- For LTC resident, the COVID-19 virus is, simply put, lethal. CIHI Data from the June 2020 snapshot highlights that LTC homes and retirement homes account for **80% of all COVID-19 death in Canada**. For Canadian LTC resident, the chance of dying from COVID-19 as of May 2020 was about **35% overall** and for the most frail individuals requiring ICU, can be much higher.
 - Source: CIHI Snapshot June 2020 – Pandemic Experience in the LTC sector

COVID-19 in the General population:

- Covid-19 can occur in healthy individuals, including young and pregnant patients.
- Severe illness can include complications to important organs including lungs, heart, kidney and blood vessels (blood clots).
- Even if a healthy individual survives their COVID-19 illness, patients may suffer from residual and ongoing psychiatric, physical and emotional symptoms.
- Pregnant women appear to be at increased risk for severe disease necessitating maternal intensive care unit admission and mechanical ventilation
 - Source: Uptodate: Covid-19 Clinical Features
 - Source: Uptodate: Covid-19 Pregnancy issues and Antenatal care

COVID-19 VACCINE SAFETY:

Is the COVID-19 vaccine 100% safe?

- It is true that we don't know 100% about either the COVID-19 virus or the COVID-vaccine. This is true about many diseases and many medications, many of which we have all taken. Eating food is not 100% safe – there can be risks of allergic reactions & food poisoning, but the benefits outweigh these small risks.

How was this vaccine developed so quickly?

The rapid development of the COVID-19 vaccines does NOT mean it is less safe. Previous vaccines have taken longer for multiple reasons:

1. **Funding** - Funding is usually a barrier to vaccine development –the COVID-19 pandemic has created a global incentive to rapidly develop a vaccine. Governments and businesses have worked together to provide the money required to rapidly develop a rigorously tested vaccine.

2. **Research subjects** - For most vaccines, it takes time to find enough people to enroll in your study and enough people sick with the virus. The COVID-19 pandemic has infected millions of people around the globe and the number of people enrolled in the COVID-19 vaccine research studies are higher than for many other vaccines or medications.
3. **Scientific Knowledge:** Never before has there been such a large-scale coordinated effort to work towards developing a vaccine. mRNA technology was not discovered for this vaccine –we have known about this technology for quite some time. The COVID-19 pandemic provided the urgency for researchers, governments and pharmaceutical companies to turn this research into an effective vaccine.
4. **Genetic Science** - Sequencing the first human genome cost about \$1 billion and took **13 years** to complete (1990). Now, we are able to sequence a genome in a matter of days for a tiny fraction of the cost. It makes sense that we are able to develop a vaccine faster than we did in the past.

Motivation for Safety

- Vaccine development is strictly regulated by a multitude of advisory boards, oversight processes and ethics committees.
- The COVID vaccines may be the first vaccines developed where the vast majority of the people who worked on the medication, plan on taking the medication. The people who made these vaccine, from the scientists, doctors, politicians and pharmaceutical company executives, have a vested interest in ensuring the efficacy and safety profile if they plan on taking the vaccine themselves.

COVID-19 CONSENT DISCUSSION POINTS:

It is normal to have questions about the COVID-19 vaccine. As an overview, please visit these website from the Canadian Public Health Agency and Ontario Government, which summarize important information on the COVID-19 vaccines:

- <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html>
- <https://covid-19.ontario.ca/covid-19-vaccines-ontario>

FAQ relevant to LTC residents and/or staff:

What are the absolute contraindications to getting the mRNA vaccine.

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- **Severe allergic reaction** (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- **Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine** or any of its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to **polysorbate** (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix B for more information on ingredients included in mRNA COVID-19 vaccine

Source: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>

What if I am taking a blood thinner or have a bleeding disorder?

- 1) COVID vaccine may be given to all anticoagulated patients and those with bleeding disorders
- 2) There is a small risk of bruising and bleeding at the injection site. Recommendations are to apply prolonged pressure for 3-5 minutes at the injection site to reduce bruising.
- 3) No need for additional INR monitoring if on Warfarin.

Source: *Thrombosis Canada Dec 15, 2020 recommendations:* [Antithrombotics-and-COVID-19-Vaccines-15-12-20.pdf \(thrombosiscanada.ca\)](https://www.thrombosiscanada.ca/antithrombotics-and-covid-19-vaccines-15-12-20.pdf)

What if I am Pregnant or Breastfeeding?

According to the Society of Obstetricians and Gynecologists of Canada Consensus Statement “For individuals who are at high risk of infection and/or morbidity from COVID19, it is the SOGC’s position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and vaccination should be offered”.

“8-11% of pregnant women will require hospitalization for COVID-related morbidity and between 2-4% of pregnant women will require admission to an intensive care unit (ICU)”.

Source: SOGC https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOCG_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

What if I am Immunocompromised or have an Autoimmune disorder?

Important Consent points:

- Consent discussion needs to balance risks of acquiring COVID infection versus acknowledging that vaccine studies did not include these people, and that vaccines are potentially less effective in those who are using immunosuppressive therapy.
- Although the risks/reduced efficacy of the vaccine has not been formally studied, it is very clear that the risk of dying from COVID-19 is higher in those who are immunosuppressed and have chronic conditions.

Here are several different source providing discussion on the risk/benefit of vaccinating those who are immunosuppressed or have autoimmune disorders.

1. Centre for Disease Control & Prevention (CDC)

“Immunocompromised persons

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies [might be at increased risk for severe COVID-19](#). Data are not currently available to establish vaccine safety and efficacy in these groups. Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited. Immunocompromised individuals may receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all [current guidance](#) to

protect themselves against COVID-19 (see below). Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.

At this time, re-vaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs. Recommendations on re-vaccination or additional doses of mRNA COVID-19 vaccines may be updated as additional information is available.

Persons with autoimmune conditions

No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.”

SOURCE: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

2. National Advisory Committee on Immunization (NACI) Guidance:

“NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are immunosuppressed due to disease or treatment until further evidence is available (Strong NACI Recommendation). However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group in this population if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. (Discretionary NACI Recommendation)”.

Source: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7>

- 3. Canadian Rheumatology Association:** “Patients above 70 years old are considered high risk for severe illness with COVID-19 and therefore vaccination should be considered regardless of underlying diagnosis or treatment...There is currently no data to make a recommendation of whether DMARDs (Disease-Modifying Anti-Rheumatic Drugs) should be withheld during COVID-19 vaccination. Studies on influenza vaccination has suggested that withholding 2 doses of methotrexate following vaccination improves vaccine response. It is unknown if this holds true for the COVID-19 vaccine or for other DMARDs. Concerns for potential disease flare should be considered when making these decisions.”

Source: <https://rheum.ca/wp-content/uploads/2020/12/CRA-Position-Statement-on-COVID-19-Vaccination-v2-FINAL.pdf>

4. Canadian Association of Gastroenterology:

The CAG endorses the CDC recommendations for the use of mRNA covid-19 vaccines in special populations, after assessing the evidence using the GRADE approach. Specifically, in patients with IBD not on immunosuppressive therapy, we recommend the COVID-19 vaccine be given (Strong recommendation, moderate-certainty of evidence). In patients with IBD on immunosuppressive therapy, we suggest the COVID-19 vaccine be given (conditional recommendation, low-certainty of evidence).

Source: <https://www.cag-acg.org/images/publications/CAG-COVID-19-Vaccines-in-IBD-Patients.pdf>