



Changing the Way We Work: COVID-19 Community of Practice for Ontario Family Physicians

COVID-19 Vaccines: Lessons from vaccine pilots, evolving guidance, and more – March 26, 2021

A record of answers from CoP guests, panelists and co-hosts to in-session questions posed by participants, based on the guidance and information available at the time.

 Patients want to get vaccines from us, not from the vaccine clinic. Any advancement of providing vaccines to family doctors' offices?

This is the focus of the CoP today. We are working hard to advocate for our role, the lessons from the pilots will need to be used and spread across the province.

Does the MOHLTC require the second dose of AstraZeneca vaccine to be at 16 weeks?

Yes. Currently [second doses of] all vaccines are administered at 16 weeks except for the small groups of exceptions – "Operation Remote Immunity" to indigenous populations and LTCH/RH residents. [UPDATE, March 26, 2021: Ontario <u>Vaccine Clinical Advisory Group recommendations</u> include exceptions to the extended dosing interval to include transplant patients and certain cancer patients.]

• Is AstraZeneca vaccine recommended for 60+ y/o who have various health conditions (DM, autoimmune, etc.) or would Pfizer/Moderna be preferable?

While all available vaccines in Canada are safe and effective, NACI still recommends that in the context of limited vaccine supply, initial doses of mRNA vaccines should be prioritized for those at highest risk of severe illness and death and highest risk of exposure to COVID-19.

The highest risk of severe COVID19 disease and death is based on age, which is why patients over 80 and now 75 are being offered mRNA vaccines.

For now, the best vaccine is the one a patient aged 60+ can get (i.e., 63-year-old with DMII shouldn't wait until May to be vaccinated) especially given the third wave we are now in with the predominant UK variant.

 Given current study suggesting seniors and those with cancer will have markedly reduced response to vaccines if delayed to 4 months...is OCFP or any other medical organization making any statements? Having our seniors only e.g., 45% protected, may be better than none, but clearly may still put everyone at risk.

The OCFP is monitoring this closely as new data/research comes in; we will be following NACI guidance and updates on this. [See NOTE to earlier question re second doses.]





 On the CEP Vaccine info sheet, it indicates that the efficacy of Pfizer against severe disease at >7 days after dose 2 is only 75%. I have read in multiple other sources that efficacy against severe disease, hospitalization and death following 2nd dose is 100% for Pfizer. Why the discrepancy? According to that sheet it appears Moderna, and AstraZeneca are both significantly more protective at 100% against severe disease.

For the CEP Pfizer efficacy question: it should have read 75-100% efficacy 1-14 days after 2nd dose. It was an early typo that has been since corrected in more recent versions, technically in the Pfizer monograph, efficacy was reported to drop to 75% after 2 weeks. However, given that trial data is limited, we felt it reasonable to put a range for this vaccine since real world data will likely show it to be above 90%

• If someone has had a DVT, is it advisable to get the AstraZeneca vaccine?

Yes, after some countries paused use of the AstraZeneca vaccine, the European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) investigated connections to thromboembolic events (blood clots) and concluded that the vaccine is not associated with an increase in the overall risk of blood clots. While a possible link to rare blood clots with low platelets (thrombocytopenia) merits further investigation, the EMA, MHRA, and Health Canada have stated that the benefits of the AstraZeneca vaccine continue to outweigh the risks (EMA, March 18, 2021; UK MHRA, March 18, 2021; Health Canada, March 11, 2021). [NOTE: More info in the Ontario's Science Advisory Table brief on Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT), published March 26, 2021.]

• The trial studies for the efficacy of Pfizer were performed for 2 doses a with 21-day separation. What trials if any show that a 4-month separation have the same or better efficacy than the 21-day separation?

Take a look at this Lancet Pre-print that has good evidence re: Pfizer and AstraZeneca. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789264

For more details, please see our previous CoP: https://www.dfcm.utoronto.ca/covid-19-community-practice/past-sessions

Our e-modules will also be updated shortly to include this info. https://www.dfcm.utoronto.ca/covid19-vaccination-modules

And this is a great op-ed https://www.thestar.com/opinion/contributors/2021/03/17/why-one-covid-19-vaccine-dose-is-better-than-two.html

Pregnancy is listed as a risk population in phase two. News in the media this
morning is announcing that the Pfizer and Moderna vaccines are very safe and
effective for those pregnant. Are we to offer and encourage the vaccine to that
group?

Yes absolutely. Pregnant individuals that are eligible for the vaccine should be strongly encouraged to do so.





• When do we expect to have data on vaccinating children?

We are hoping to have enough data by the summer for NACI to make a recommendation.

 Please update us on the VOC and the effectiveness of the Pfizer vs Moderna vs AstraZeneca vaccine against them

Dr. Warshafsky reviewed this important question at our last session. The slides and recording are available here: https://www.dfcm.utoronto.ca/covid-19-community-practice/past-sessions

 Can retired Family Physicians be vaccinators? How are they covered with insurance?

Physicians who are retired can participate, details here from CPSO and CMPA about how this will work. You do need to re-apply for licensure if you are interested in taking on a more substantive roll with vaccination. https://www.cpso.on.ca/Physicians/Your-Practice/Physician-Advisory-Services/COVID-19-FAQs-for-Physicians

https://www.cmpa-acpm.ca/en/covid19/retired-physicians-and-residents

• I struggled to get a 73-year patient of mine about to undergo chemo a dose of vaccine. I receive special approval, she was given her appt by the director who gave the approval, and then she was turned away at the door. (now that 70+ is open she will be getting her shot today) ...but is there an option for those requiring vaccine before their age group—with a letter from us?

Unfortunately, there is not an option to get individual level exceptions to the prioritization framework.

 Is there any data yet on whether vaccinated people can get asymptomatic disease and spread it?

Yes, the newest data from places like Israel and UK show that the vaccines are very effective at preventing asymptomatic disease and transmission, consistent with their effectiveness against symptomatic disease. Here is a nice summary article - https://www.advisory.com/en/daily-briefing/2021/03/04/vaccine-transmission

• What about recent Bell's Palsy—any concern about getting the vaccine? What about timing—should it be delayed?

No direct link between Bell's Palsy and the vaccine. There isn't specific guidance about when to take the vaccine; I would wait until things stabilize so as to be able to distinguish vaccine side effects from the Bell's Palsy. More info here: https://www.ontariofamilyphysicians.ca/tools-resources/covid-19-vaccines/covid-vax-special-populations.pdf

 If someone received COVIDSHIELD, can the second dose be AstraZeneca if the first one is not available?

Yes. COVISHIELD and AstraZeneca are the same product molecularly and are interchangeable.





 As family physicians we have been vaccinating millions of Ontarians flu vaccines each and every year. Please explain why the Ministry of Health needs to run a pilot program. This is disappointing and frankly insulting to us and our patients. Ultimately the patients will suffer delaying vaccination process.

We agree this should not be a pilot; it is part of the rollout. Patients need us to be involved, particularly those who are vulnerable, hesitant and homebound. I can tell you the OCFP is widely advocating. Our recent study provided clear evidence about what patients want and need family doctors to be involved. We are working with partners including SGFP/OMA and AFHTO to push this at every turn.

 How soon after the first dose of AstraZeneca vaccine is there protection? How much?

With all the vaccines we expect 2 weeks until protection is at its max. Our vaccine administration sheets on the ministry of health website - https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19 vaccine.as px - have the details. For AstraZeneca it's about 75% after first dose.

• Is there any evidence that use of low dose prednisone e.g., for polymyalgia rheumatica may blunt covid vaccine antibody response?

According to the Canadian Immunization guide (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-8-immunization-immunocompromised-persons.html) prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days would be considered a dose that is immunocompromising.

• Is the 15-minute waiting period necessary for AstraZeneca vaccine? Are they really doing this in pharmacy?

Yes, this period is necessary for all vaccines in order to monitor for immediate allergic and anaphylactic reactions and treat appropriately. Pharmacies are following this as well.

 Vaccine roll out by age groups: will there be any consideration given for those that have lung disease and co-morbid conditions?

Phase 2 has prioritized groups of individuals with chronic high-risk health conditions. This should be communicated to HCP and the community by your local PHU. [NOTE: See Phase 2 prioritization. Individuals with health conditions are addressed on pages 15-16]

• Is it possible that COVaxON immunization data could directly upload to our EMRs to eliminate extra work of entering this info manually?

That is something being worked on actively, but unfortunately it is likely to be months until that functionality is available.

 Tools to vaccinate: 3 ml and/or 1 ml syringe? Needle 23-25g 1 inch? Provided or self-stock? Time to order if none on hand etc.

The Ministry provides all supplies for COVID-19 vaccines on a 1:1 basis. For each dose, the sites received a syringe, needle, etc.





• Is the 16-week gap for frontline physicians safe? Cannot the OCFP advocate for us? Especially as majority of the physicians who are supporting this delay have had their two doses themselves.

The provincial [primary care] organizations have been working on moving the needle on this. [NOTE: See first question and answer in this document for more context.]

• Why is the MOH so averse to have family physicians vaccinate in their office? Why do we have to prove that we can vaccinate in our offices? What is the reason for this?

It has been incredibly frustrating. We are strongly advocating for our role in vaccinating patients alongside Public Health efforts and pharmacy. [NOTE: We can't speak to the MOH's approach.]

 The "vibe" amongst many pharmacists, is that Family Medicine has "shut down" and hence [it is] "essential" to have this mass vaccination succeed. How can this highly incorrect perception be changed, at all levels?

There has been a narrative that family physicians may not be open to care, the OCFP has been advocating to address this at all tables, see our Open for Care campaign https://www.ontariofamilyphysicians.ca/news-features/family-medicine-news/~188-Family-Doctors-are-Open-and-Here-for-Care-and-More.

There are also research projects looking at this, including Tara Kiran + U of T colleagues in family medicine Keeping Doors Open study which showed that the vast majority are open for both virtual and in person care: https://www.dfcm.utoronto.ca/improving-quality-during-covid-19

 Do pharmacies have to load data into COVaxON too? And were pharmacists paid to administer the vaccine?

Yes pharmacies (and public health units) have to use COVaxON as well, all doses given have to eventually be logged into COVAX. Yes, pharmacists are being paid \$13/dose

 Doctors and patients are asking why MOH is working with pharmacies ahead of family doctors. Any answer to diffuse this concern—apart from the answer that primary care pilots are ongoing; this concern remains.

I am also getting this in my practice, I am being clear with patients that mass vaccine/pharmacy are the options now but that family doctors are pushing strongly for our involvement. If they are so inclined, I think them bringing this message to their local elected leaders is an option.

• It is shocking to have MOH, those at the "top", question Family Doctors' ability to vaccinate, vs pharmacists. How can this be, when we have done this many years?

We are strongly challenging this at the OCFP along with partners in AFHTO, SGFP/OMA. I think sharing these pilot stories is essential to help prove what we are/can do. Also, opportunities to use Moderna in primary care which we are seeing in Kingston and more recently Lambton PHU will be important to expand which vaccines we can use.





• Can there be a focus on getting all interested practices onboarded with COVAX, so we are ready to go when we get vaccinations?

We are glad that Ontario MD has been brought on to help training physicians, this has just happened and as you heard they are ramping up capacity to do this. We are pushing for this, as is David Kaplan, and certainly those who were in the pilots made clear that getting set up with COVAX is a rate limiting step.

 What happens in 4 months if the initial vaccine someone received is not available? Will the second dose be postponed further? It's unlikely that we will have the exact same number of different vaccines available on time. With the extended interval there is not much room to change anything. Will we have to accept a different type of vaccine?

As time goes on, we only expect to have more vaccine available, not less than now. We are also awaiting a number of trials to be completed on mixing/matching different vaccines to provide maximum efficacy. in 4 months from now it is likely that will be not just an option, but the preferred method to get an optimal immune response, particularly for those who had AstraZeneca or another lower efficacy vaccine for the first dose.

How are we going to prevent people gaming the system for their second doses, as
they are doing for the first right now? I was attending a COVaxON training
yesterday and they did not seem to be aware that COVaxON is the only system
that is unified in the province to prevent vaccine shopping, e.g., book first visit at
Costco, second at Shoppers or my FHT 4 weeks later because they won't know
about the previous one.

All vaccine administration sites must use COVaxON to record the vaccine. When they open COVaxON to administer it will flag how recently the previous dose was given, regardless of location. So, someone may book it, but they won't be given the vaccine when they get there.

• When can we expect to get AstraZeneca in our offices? Is there any indication from the government of what date we should plan for?

There is no clarity on the government's plan and timeline for the vaccine to come to us and our role. This has been part of our frustration and thus attention for advocacy. We are also pushing for Moderna to be given in our office as we know this is now possible, we see this being done in Kingston and Lambton in partnership with their PHU.

 I have been told that pharmacies have been able to vaccinate a much higher percentage of the AstraZeneca vaccine that has been released. The pilot sites have not been able to match this and as such further role out to primary care physicians will not be a preferred route. Any comments?

The pharmacies got a huge head start on the primary [care] practices. That being said >50% of doses in PC have been administered. The pharmacies are at about 70%. The pharmacies are also not serving higher-risk communities in Toronto. See this article: https://thelocal.to/plenty-of-pharmacies-but-no-vaccines-in-torontos-northwest/

(Response continues below)





In fact, among the top five neighbourhoods for COVID-19 infections (all in Toronto's northwest), none have a pharmacy offering the vaccine. In contrast, the five neighbourhoods with fewest infections have 12 pharmacies offering vaccinations. [NOTE: As of March 31, more than 90 per cent of doses allocated to primary care have been administered.]

 How can we promote the drive-through model? Safer for patients and very efficient...

I think we need to let practices sort out what model works for them given patients/staff/spacing including drive through. This is a good toolkit with planning/operational details https://covidtoolkit.ca/ [NOTE: See following question for another helpful resource.]

• With a very large (unused) parking lot at our clinic, does it make more sense to consider a drive-through vaccination process instead?

Yes, that is a great idea. There is a link on how to do it in the Toronto HHR playbook - https://quorum.hqontario.ca/en/Home/Posts/Vaccine-clinic-playbook [NOTE: See preceding question for another helpful resource.]

 Do you have any concerns about confidentiality using Google Forms to collect patient information?

Many practices using Google Forms are not collecting health cards [information]. Verto, Medeo and others are PHIPA compliant and have made it easier to do this and capture all the patient information for upload to COVaxON.

• For those immunizing in family physician offices, does COVaxON integrate with the Google Form for pre-registration?

Not integrated but practices create a CSV file from the Google form or other booking software and upload the CSV to COVaxON just before the clinic starts.

When will Phase 2, including those with chronic diseases, begin?

April, based on vaccine availability.

 Are the consent questions in COVaxON for AstraZeneca vaccine the same as mRNA vaccines?

Yes.

 Dr. Khan has just demonstrated that there are more cons than pros in getting their vaccine clinic running. How is [clinic rollout actually feasible in] smaller community practices!? We need more support and more funding in our smaller community family medicine clinics.

Agree that there is an administrative burden we need to be aware of. Support is required, local PHU units seem to be the most appropriate to help up with the distribution issues, and also having control over how many doses we get and when so we can plan for what our staffing/space allows. Smaller clinics working with larger clinics perhaps with support from PHU/OHT will be another option.





Is there some way to make the consent form more concise — a one pager?

Once you get used to the Consent process within process it actually goes very quickly. Much more quickly that I thought when reading it for the first time. Most vaccinators can consent and administer vaccine within 5 minutes.

These additional questions were answered live during the session. To view responses, please refer to the session recording.

- Could you please comment on using AstraZeneca vaccine re clot risk and reports of increased risk with patients with low platelets?
- There are constant concerns by patients who are at higher risk of Thromboembolic episodes (previous DVT, stroke, PE) to receive AstraZeneca vaccine and asking letters from us to receive other vaccine, how do we handle it?
- Can anyone comment on whether COVAX will be able to notify family physicians when their patients get vaccinated?
- Can you comment on COVaxON in the primary pilot sites? Is it reasonable to expect GPS to use it end-to-end? Or just as a vaccinator?
- If delayed dosing is "acceptable" for the community, why is the recommendation for nursing homes, senior lodges, indigenous, still 3-4 weeks apart? Isn't the high risk living at home worthy of the 3-4 schedule?
- Can anyone comment on the financial costs of running an immunization clinic in the primary care setting?
- Any comments about holding AstraZeneca vaccine for women age 20-55?
- The current excessive paper-based consent forms are insane. As is the clunky COVaxON system. How will we deal with an office vaccination process which is 10% needles and syringes and 90% administration?
- NACI makes mention of "studies" for a 2-month delay in their recommendations for delaying the second dose of the vaccine, yet at the end of their document, they don't list any references (this is unlike all of their other recommendations for vaccines). I can only find data that shows a delay of about 6 weeks is still potentially effective. Also, are there trials to show the delay of the second dose of all approved 2 dose vaccines, including Moderna?
- The gap of 4 months between 2 covid vaccine doses is that going to affect the protection percentage, and will that drop immunity protection percentage, will that necessitate that we give patients a third dose vaccine to ensure full benefit of vaccine?





[NOTABLE UPDATES]

- <u>Science Brief</u> from the COVID-19 Science Advisory Table on Vaccine-Induced Prothrombotic Immune Thrombocytopenia Following AstraZeneca COVID-19 Vaccination
- NACI's recommendation to suspend use of AZ vaccine in people under age 55
- Vaccine Clinical Advisory Group update on exceptions to vaccine dosing intervals