

March 23, 2021

## HIROC and COVID-19: Your Questions Answered – Bulletin Number 16 – Ontario Subscribers

HIROC, working closely with the Ontario Hospital Association (OHA) and our external legal partners, is committed to providing you, our Subscribers, with the information you need now for your COVID-19 response.

This is our sixteenth bulletin where we answer your COVID-19 questions regarding:

- [Vaccine Administration](#)
- [Consent](#)

As a reminder, you can request an email copy of previous bulletins by replying to this email, or sending a request to [communications@hiroc.com](mailto:communications@hiroc.com).

Additionally, Subscribers have access to the Questions & Answers page by logging in to [HIROC.com](https://hiroc.com) and selecting *COVID-19: Your Questions Answered* from the Member Portal Links dropdown.

We encourage you to reach out anytime if you need clarity around any risk, safety, claims, or coverage issues.

**For the purpose of explaining some insurance issues relating to COVID-19, we are, of course, summarizing some of HIROC's – and in certain circumstances, our excess insurers' policy coverages. The policy wording is not changed by this overview. As always, the facts and circumstances of each claim will determine if, and how, coverage under the HIROC policy would apply.**

We will continue to provide information around coverage and risk management as the situation unfolds.

As your trusted healthcare safety advisor we encourage you to reach out anytime — we're here for you!

## Vaccine Administration

### 1. Question: We are receiving questions from staff and our community about the prioritization of vaccination distributions, how should we respond?

#### Answer:

It is recommended that you follow your local Public Health Unit's direction, based on the current Ministry of Health guidelines. The most recently published guidelines can be located here:

- [https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/Guidance\\_for\\_Prioritizing\\_HCW\\_covid19\\_vaccination\\_2020-01-08.pdf](https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/Guidance_for_Prioritizing_HCW_covid19_vaccination_2020-01-08.pdf)

Key messages from the Ministry of Health guidelines:

- Demand for SARS-CoV-2 vaccine will initially exceed available supply; prioritization must be set among healthcare workers.
- Sub-prioritization of healthcare workers will assist with vaccine delivery to healthcare workers in parallel with vaccination of other Phase 1 priority populations.
- Healthcare workers are prioritized based on risk of exposure, patient populations served, and incidence of COVID-19 outbreaks.
- An ethics and equity lens should be applied to all prioritization decision-making.

Regarding roles and responsibilities, the [COVID-19: Guidance for Prioritizing Health Care Workers for COVID-19 Vaccination](#) indicates the following (version 3, 2020-Mar-17):

Role	Responsibilities
<b>Ministry of Health</b>	Set priorities, sequencing and targets, support healthcare system in implementation of the vaccine program.
<b>Public Health Unit</b>	Lead local vaccination programs working with partners from health and municipal sectors; conducts prioritization in accordance with provincial guidance and direction and in consideration of local context. PHUs should establish committees on prioritization that include diverse views from affected parties and groups to inform local decision-making.
<b>Ontario Health</b>	Support vaccination program coordination with local health system partners.
<b>Associations, Unions, and Regulatory Colleges</b>	Work with MOH and PHUs to support vaccination of their members. Work with membership to share information with PHUs and on behalf of PHUs to support immunization planning and rollout. Help to mobilize membership for purposes of vaccination, such as facilitating public health communications with members.

Please be sure to check the Ministry of Health's (MOH) COVID-19 website regularly for updates to this document.

**2. Question: Do we need an agreement to work with our Public Health Unit to administer vaccinations?**

**Answer:**

It is important to clearly identify the respective roles of your Organization and Public Health particularly; what is your Organization's role and what is not your role. Our understanding is that there is not currently a standard agreement that is being used by all Public Health Units. HIROC and the OHA have worked with various Subscribers on their agreements. Through that work, and with the generous support of our Subscribers, we have developed or arranged for access to sample agreements. These sample agreements may be of assistance for immediate role clarity with partners to operationalize distribution and administration of vaccinations. We would ask that you please feel free to contact us if we can be of assistance.

Furthermore, the Ministry of Health has published a [COVID-19 Vaccine Clinic Operations Planning Checklist](#) as well as [Vaccine Storage and Handling Guidance – Pfizer-BioNTech and Moderna COVID-19 Vaccines](#) document. In HIROC [Bulletin #15](#) we provided some considerations for establishing a vaccination clinic.

If your Organization has a COVAX agreement directly with the Ministry of Health, it is important to consider the accountabilities and roles under this agreement. If you do not have your own COVAX agreement with the Ministry and are instead entering into an agreement with a Public Health Unit (which has a COVAX Agreement with the Ministry), it will be all the more important to have clarity as to your role and how the Ministry-Public Health Unit COVAX agreement applies to you and what responsibilities you are assuming in respect of COVAX through your agreement with a Public Health Unit.

**3. Question: What considerations should we reflect on around the authority to administer the SARS-CoV-2 vaccine?**

**Answer:**

It is necessary to distinguish between various aspects of the Chief Medical Officer of Health's (CMOH) Order, for example between a) questions related to the vaccine itself, – storage, priority populations, special consideration populations, dosages, intervals between doses etc., b) questions related to who can administer the vaccine to vaccine recipients; and finally c) what are the implications of being subject to a COVAX agreement with the Ministry of Health. These issues are dealt with in the following sections of this bulletin.

**Official Authority and Guidance for COVID-19 vaccinations in Ontario**

We understand that various arrangements are in place for how authority to vaccinate is obtained. In our previous Bulletin 15 and in our Vaccine Risk Forums, we identified the documents through which authority is granted by the Chief Medical Officer of Health. Specifically, the December 29, 2020 Order (CMOH Order) and O. Reg. 9/21 provide for vaccination by Registered Nurses and, pharmacists under specific conditions (an agreement with

the Ministry). There has been a further amendment to the [CMOH's Order dated February 5, 2021](#), and subsequent guidance by the CMOH particularly in relation to the interval between the first and second dose of the relevant vaccines.

### **Compliance with COVAX Agreements Where Applicable**

It is important to understand that if a Hospital or other health organization (other than a Public Health Unit) has a COVAX agreement with the Ministry of Health, it is required to follow the CMOH's orders for vaccination procedures. If you are entering into an agreement with Public Health, it will be important to understand whether that would also require your compliance with the CMOH's Order. It is very likely that such an obligation does exist, but it is important to review the Agreement carefully to confirm this.

### **Alternative Orders and No-COVAX Agreement directly with the Health Organization**

We have received many questions as to whether alternative directives or guidelines can be followed in relation to the interval between the first and second dose of the vaccine. HIROC does not have clinical expertise in this regard. We would refer you to the [OHA video on 'The Science Behind Vaccine Dose Intervals: Answering Healthcare Worker Questions.'](#)

From a risk perspective, it may be necessary in the future to determine whether health organizations and professionals have met the standard of care as they navigate the evolving vaccination rollout. We anticipate that questions will be answered based on the opinions of qualified experts and on the preponderance of recommended and accepted practice at the time care was delivered.

In the current circumstances, there appears to be consistent advice in respect of the recommended maximum dose intervals. If there is a concern that the centralized guidance about dose intervals is not appropriate and an alternative course of action may be desirable, it will be necessary for the vaccinating organization to balance the risks of harm caused by second dose delay against the potential harm caused by initial dose delay to an unvaccinated population.

On balance, our legal experts recommend that it is more prudent to follow the official guidance. If there are situations where experts are of the opinion that an exception exists, then it is advisable to seek clinical and legal advice and to document the conditions and rationale under which the exception was made. We are currently seeking confirmation that the official guidance will be documented in a formal change to the CMOH's Order and recommend that you regularly check the [Ministry's website](#).

We also note that maintaining alignment with the CMOH's Order is important as a first step to achieve consistent practice.

### **Possible Exceptions – Who Can Administer the Vaccine?**

We direct your attention to question four below, for information as to who is currently authorized (either under legislation or the CMOH Order) to administer the SARS-CoV-2 vaccine in Ontario. There may be situations where additional orders may be required to facilitate the administration of the vaccines by other healthcare professionals, as permitted by their scope of practice and where formal delegation is in place and is legally allowed. Any questions as to whether vaccination is within the health professionals' scope of practice should be directed to the applicable professional College and its written response obtained.

If a physician contemplates writing an order delegating the administration of the vaccine or seeks to vary any aspect of the vaccination process, including dose intervals, we suggest that they consult with the CMPA. There are circumstances where non-regulated health professionals may act as delegates. For example, the Medical Director for Paramedic Services may delegate to qualified paramedics the administration of vaccines.

If you have received additional orders or directives under another authority (e.g., Local Medical Officer of Health, local staff physician) it is advisable to confirm the authority under which this directive is being provided and understand the associated liability risks to your Organization. Additional areas for risk evaluation includes whether the delegate has the appropriate authority, training, order, and confirmation with their respective College.

Please connect with us at [riskmanagement@hiroc.com](mailto:riskmanagement@hiroc.com) to discuss your needs.

#### 4. Question: Who is currently authorized to administer SARS-CoV-2 vaccines in Ontario?

##### Answer:

In [Bulletin 15](#), we explored the Order by Ontario's Chief Medical Officer of Health (CMOH) issued on December 29, 2020. Furthermore, under the [Regulated Health Professions Act \(RHPA\)](#), regulated health professionals are allowed to administer vaccinations if they are authorized to do so under their health professional Act. For example, physicians are authorized to administer vaccinations under the [Medicine Act](#). The CMOH's Order allowed for additional health care professionals to administer SARS-CoV-2 vaccinations in certain circumstances.

Changes to [O. Reg. 107/96](#) under the RHPA allow registered and practical nurses, pharmacists, pharmacy interns, registered pharmacy students and pharmacy technicians to administer SARS-CoV-2 vaccines if the organization engaging the individual enters into an agreement with the Ministry of Health.

The CMOH Order dated December 29, 2020 also allows registered and practical nurses to administer SARS-CoV-2 vaccines if certain terms and conditions are met.

As indicated above, there may be situations where a local medical directive can authorize administration of the SARS-CoV-2 vaccine by other professionals employed by the health organization if:

- their professional College has indicated in writing that this is within their scope,
- all requirements for a delegation from a physician to that professional have occurred,
- the Subscriber has confirmed the qualifications or training of the professional to do so, and
- there is a specific medical order authorizing that professional to administer the vaccine.

For clarity, a local medical directive should not be a substitute for the CMOH's Order. The local directive should reference the CMOH Order for all other aspects of the delegation and then deal specifically with the proposed delegation. Physicians considering writing such "local" orders are advised to contact Canadian Medical Protective Association (CMPA) with any questions they may have.

**5. Question: Are there additional risks when considering whether students can administer SARS-CoV-2 vaccinations?**

**Answer:**

As indicated above, if physicians have questions related to the delegation of their authority to administer vaccine to students, we recommend that they seek advice from the Canadian Medical Protective Association (CMPA) and the College of Physicians and Surgeons of Ontario as it relates to medical students.

HIROC urges caution when it is proposed that there be a delegation to students and would recommend obtaining specific legal advice in this regard. In general, we understand that Subscribers have been advised by legal counsel that it is not advisable to have students administer vaccinations unless there is specific legal authority for them to do so. As always, legal advice is specific to the facts of each case and outlines a course of action that reflects unique and varied legal considerations.

The table below summarizes considerations for different groups of professionals.

As noted above it is important to understand and verify where the authority for vaccination is provided. Please connect with your legal counsel, professional colleges or with us at [riskmanagement@hiroc.com](mailto:riskmanagement@hiroc.com) to discuss your needs.

Profession	Within CMOH Order	Other route for authority	Requirements or Conditions
<b>Registered Nurse Registered Practical Nurse</b>	Yes	Yes	- Agreement with O. Reg 107/96 - CMOH Order (Dec. 29) under specific terms and conditions
<b>Nursing Student</b>	Not specified	Not specified	- Consult the CNO, - Consult CMPA, if considering delegation from a staff physician - Consult your legal counsel
<b>Pharmacists Pharmacy interns</b>	Yes	Not specified	- Agreement with O. Reg 107/96 - CMOH Order (Dec. 29) under specific terms and conditions - Application to MOH
<b>Medical Students</b>	Not specified	Not specified	- Consult CMPA, CPSO and your legal counsel
<b>Respiratory Therapists</b>	Not Specified	Not specified	- Consult the College of Respiratory Therapists

Profession	Within CMOH Order	Other route for authority	Requirements or Conditions
Paramedics	Not specified	Traditional delegation under an Emergency Health Services Medical Director that works with a regional Paramedic Service	- Paramedic Service Physician to consult CMPA, CPSO

**6. Question: Will the medications table within the CMOH order be updated to reflect the new dose interval for the vaccines?**

**Answer:**

To our knowledge, the medications table CMOH’s Order has not been updated. In a guidance document dated March 11, 2021, the Ministry of Health has provided guidance documents that speak to dose intervals, but these are not an update to legislation nor to the Order:

- [Administration of Pfizer BioNTech COVID-19 Vaccine](#)
- [Administration of Moderna COVID-19 Vaccine](#)
- [Administration of AstraZeneca and COVISHIELD COVID-19 Vaccines](#)

## Consent

**7. Question: We have patients and healthcare professionals who are advising that they believe they should receive the second vaccine dose at the interval time indicated when they signed the initial consent form. Is this correct? How should we deal with these situations?**

**Answer:**

The original consent form was developed based on the expert scientific evidence and official provincial and national direction available at the time. In the interim, the evidence and official direction has progressed based on evolving current knowledge.

As a result, we understand the recommended interval between doses one and two of the vaccination has changed provincially. Even where a different interval was contemplated when consent was obtained, the change in timing between interval doses does not invalidate the initial consent and does not require that doses be delivered in accordance with that interval.

Even in instances where a consent is meant to cover a series of treatments, for example chemotherapy, changes in clinical or other circumstances occurring between the dates of these



treatments can impact the timing and content of the treatment delivered. It is important, as is the case for the COVID-19 vaccine, to obtain a new consent in this instance. As indicated above, such an additional consent was contemplated and is required for the second dose of the SARS-CoV-2 vaccine.

We hope you will find this to be helpful. If you have any further concerns or questions regarding your insurance coverage, please contact Shahbaz Haque, Director of Insurance Services at [shaque@hiroc.com](mailto:shaque@hiroc.com), Risk Management support at [riskmanagement@hiroc.com](mailto:riskmanagement@hiroc.com), or myself at [cgaulton@hiroc.com](mailto:cgaulton@hiroc.com).

Sincerely,

Catherine Gaulton  
CEO, HIROC

PARTNERING TO CREATE THE SAFEST HEALTHCARE SYSTEM

