# Alberta COVID-19 Immunization Policy

Effective February 2021 Revised August 2021

Alberta

Ministry of Health, Government of Alberta February 2021 Alberta COVID-19 Immunization Policy

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# I. INTRODUCTION

The Alberta COVID-19 Immunization Policy (ACIP) sets out the requirements for the delivery of the COVID-19 Immunization Program.

The COVID-19 Immunization Program supports the provincial and federal program goal: To minimize serious illness and overall deaths while minimizing societal disruption due to the COVID-19 pandemic.

The COVID-19 Immunization Program objectives are to:

- Provide a safe and effective COVID-19 vaccine for all Albertans for whom the vaccine is licensed and recommended;
- Allocate, distribute and administer COVID-19 vaccine as efficiently, equitably and effectively as possible; and,
- Monitor the safety and effectiveness of COVID-19 vaccines.

#### II. REQUIREMENTS FOR PARTICIPATION IN THE COVID-19 IMMUNIZATION PROGRAM

Health practitioners must be compliant with the <u>Immunization Regulation</u>, Alberta Health immunization policies and the following requirements:

- Immunization Regulation
  - All immunization events must be reported electronically to the Provincial Immunization Repository (Imm/ARI).
  - Follow the strict storage and handling requirements for the vaccines.
  - Report adverse reactions following immunizations as they become aware.
  - Vaccine inventory must be reconciled in the Alberta Vaccine Inventory System daily.
- Follow the wastage mitigation strategies provided for:
  - <u>AHS</u>
  - <u>Community Pharmacies</u>
  - Physicians
  - Follow the product monographs for information that includes:
    - Storage and Handling;
    - Vaccine preparation; and
    - Timeframe for use once thawed, reconstituted and/or vial punctured.
  - Must have protocols in place for the management of anaphylaxis.
- Provide each client with complete informed consent (includes an overview of the vaccine, a discussion on the risks/benefits, side effects and verifying immunization history to determine if the client has received COVID-19 vaccine).
- Offer the client an immunization record.
- Include information to each client on participation in CANVAS active surveillance process for adverse events following immunization.
- Alberta Health Services is primary responsible for immunization outreach services.
- COVID-19 vaccine should be administered on site in the pharmacy or clinic setting due to handling, storage and transport requirements. Immunization outreach by community pharmacies is being considered on a case-by-case basis.
- COVID-19 vaccine must not be transferred between pharmacies or physician clinics unless directed by Alberta Health.
  - Transferring vaccine increases risks of cold chain excursions.

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• Vaccine inventory cannot be tracked when transfers occur.

# III. CLIENT ELIGIBILITY

Albertans 12 years of age and older are eligible for a primary series of COVID-19 vaccines (two doses for all vaccines currently used in Alberta). Non-Alberta residents who live, work, go to school or travel in the province are also eligible to receive vaccine. Individuals without an active Alberta Health Care number must book an appointment with Alberta Health Services by calling Health Link 8-1-1.

A **third dose** may be required to provide stronger protection for those who have a suboptimal or waning immune response to vaccines.

#### Additional dose for immunocompromised individuals

It is recommended a third dose of the COVID-19 vaccine be offered to individuals with certain immunocompromising conditions. An mRNA vaccine should be administered as the third dose except in the event of contraindication or refusal.

Specific Immunocompromising conditions that make an individual eligible for a third dose:

- solid organ transplant recipients pre-transplant and post-transplant
- hematopoietic stem cell transplants recipients pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs)
- individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention).
- individuals on anti-CD20 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab).
- o individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.
- Dose 3: <u>at least 8 weeks</u> after the second dose

#### Additional dose for all residents of seniors congregate living facilities

Applicable congregate settings include all private and public long-term care facilities, licensed supportive living facilities and seniors' lodges including First Nations elder care lodges.

An mRNA vaccine should be administered as the third dose except in the event of contraindication or refusal.

Dose 3: <u>at least 5 months</u> after the second dose

#### Additional doses for travel

Receiving an additional dose for travel purposes is not considered clinically necessary. Although in Canada, anyone who has received two doses of a Health Canada-approved vaccine is considered fully immunized, this is not the case in all jurisdictions. Additional doses of mRNA COVID 19 vaccine are available to Albertans who have received a vaccine series that is not currently recognized in a jurisdiction to which they are travelling. This includes complete AZ/Covishield series or a mixed series.

- Dose 3: <u>at least 28 days</u> after the second dose
- Dose 4 if needed: <u>at least 28 days</u> after the third dose

A number of health practitioners are administering COVID-19 vaccine across the province. Each health practitioner may be offering vaccine to different priority groups depending on geographical location and

type of vaccine available. This will be communicated through <u>Alberta Health</u>, <u>Alberta Health Services</u>, <u>Alberta Medical Association</u> and <u>Alberta Blue Cross</u>.

#### IV. REPORTING IMMUNIZATIONS TO IMM/ARI

As of January 1, 2021, the Immunization Regulation requires health practitioners to ensure a report respecting immunizations is electronically submitted to the Provincial Immunization Repository (Imm/ARI) within 7 days in accordance with the Immunization Data Submission and Response Guidelines.

# For COVID-19 vaccine, immunization events must be reported daily to inform the Alberta Health daily immunization report.

Required reporting can be accomplished through immunization web services, Immunization Direct Submission Mechanism (IDSM) or Alberta Blue Cross (ABC) claims.

- Alberta Health is working with vendors to integrate immunizing partner's point of care systems for to the Provincial Immunization Repository (Imm/ARI).
- Providers can register to access the IDSM by following these instructions.
- For pharmacists: COVID-19 immunizations, are batched into Imm/ARI through the ABC claims data that pharmacists submit, (Immunization Direct Submission Mechanism is for privately funded vaccine only.

#### Reason Codes listed in order of priority:

Reason Codes	Descriptor	Pin (Pharmacy use)
03	Health Care Workers not including LTC/DSL	10000003 (Pfizer/BioNTech 20000003 (Moderna) 50000003 (AstraZeneca)* 80000003 (COVISHIELD)*
44	LTC/DSL Staff	N/A
22	LTC/DSL Resident	N/A
70	Other congregate care living settings (e.g. senior lodges, corrections, group homes)	10000070 (Pfizer/BioNTech 20000070 (Moderna) 50000070 (AstraZeneca)* 80000070 (COVISHIELD)*
02	Advanced age (65+)	10000002 (Pfizer/BioNTech 20000002 (Moderna) 50000002 (AstraZeneca)* 80000002 (COVISHIELD)*
66	Other Risk (Individuals 12** years to 64 years of age with underlying health conditions, see appendix for details)	10000066 (Pfizer/BioNTech 20000066 (Moderna) 50000066 (AstraZeneca)* 80000066 (COVISHIELD)*
72	12** years to 64 years of age	10000072 (Pfizer/BioNTech 20000072 (Moderna) 50000072 (AstraZeneca)* 80000072 (COVISHIELD)*
73	COVID-19 in-school immunization program	N/A
74	COVID-19 additional dose for travel	10000074 (Pfizer/BioNTech 20000074 (Moderna)
98	Research (AH approved)	10000098 (Pfizer/BioNTech 20000098 (Moderna) 50000098 (AstraZeneca)

\* Pfizer and Moderna (mRNA) vaccines are preferentially recommended for all eligible individuals, however, AstraZenaca/COVISHIELD vaccine may be considered for individuals 18 years of age and older for whom mRNA vaccines are contraindicated (e.g. anaphylaxis to PEG), individuals who decline mRNA COVID-19 vaccine, or as a second dose for individuals who have received AstraZeneca/COVISHIELD to complete a two dose series.

\*\* Pfizer and Moderna vaccine are the only vaccines licensed for 12-17 year olds.

## V. REPORTING ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI):

Health practitioners shall ensure that adverse events following immunization are reported to Alberta Health Services within 3 days of becoming aware.

**<u>Passive Surveillance</u>**: Passive AEFI surveillance systems rely on the client voluntarily reporting an AEFI for further investigation and reporting.

- As part of informed consent, clients are provided information on expected reactions following immunization and are encouraged to call Health Link or their health practitioner if there are events outside the expected reactions.
- As per the <u>Immunization Regulation</u> these events are to be reported to the AHS Provincial AEFI team, which determines if the events meet the reporting criteria for submitting the AEFI to Alberta Health.

<u>Active Surveillance</u>: Active AEFI surveillance involves proactively collecting data from clients who have received the vaccine through phone calls or surveys. The <u>CANVAS – COVID Study</u> is optional, and usually takes less than one minute to complete online. The initiative includes three email surveys sent to clients; one 8 days after dose 1, the second 8 days after dose 2, and the third six months later.

Enrollment should occur at the time of immunization and clients should be provided with the attached QR code from the printable poster which can be scanned or by provided the link: <u>https://canvas-covid.ca/</u>



COVID Vaccine QR Handout\_18DEC2020

The <u>Active Surveillance and Reporting of Adverse Events following COVID-19 Immunization</u> policy includes case definitions and reporting requirements for COVID-19 vaccine, the process for 'active and passive surveillance' of AEFIs following COVID-19 vaccine, and the list and description of <u>adverse events</u> of special interest to be monitored following COVID-19 immunization. The COVID-19 policy is a supplement to the current Adverse Events Following Immunization (AEFI) Policy.

See <u>Alberta Health Services information</u> on how to report an adverse event following immunization.

# VI. VACCINE STORAGE AND HANDLING:

The requirements for the storage, handling and transportation of all COVID-19 vaccines are outlined in the:

- Alberta Vaccine Storage and Handling for COVID-19 Vaccine.
- Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine
- Product monographs
  - Pfizer-BioNTech COVID-19 vaccine
  - o Moderna COVID-19 vaccine
  - o <u>AstraZeneca/COVISHIELD- COVID-19 Vaccine</u>

#### **Temperature Excursions**

- Health practitioners must report temperature excursions to the vaccine manufacturer within 24 hours.
  - The <u>Alberta Vaccine Storage and Handling for COVID-19 Vaccine</u> includes manufacturer contact information (including after hours).

• Any vaccine that is determined not viable, must be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.

## VII. ALBERTA VACCINE INVENTORY (AVI) MANAGEMENT SYSTEM

The AVI Management System is the administrative system that supports the vaccine inventory management within the Alberta Immunization Program and is integral to the management of the COVID-19 Immunization Program. It is a secure online information system used by Alberta for the ordering, receiving and reconciliation of vaccines in the province.

All immunizing partners, must receive the COVID-19 vaccine they have been shipped in AVI and are required to reconcile inventory using AVI <u>daily</u> by 9 pm.

All vaccine delivery sites must have at least one provider (up to 2) who will be responsible for AVI. Access and <u>training</u> will be provided by Alberta Health.

#### VIII. WASTAGE MITIGATION STRATEGIES

It is imperative that every effort is made to reduce COVID-19 vaccine wastage. In addition to following the storage and handling requirements, other strategies to reduce COVID-19 vaccine wastage include:

- Appointments must be arranged based on the available vaccine doses.
- Providers should work in advance to develop an evolving on-call or standby list of individuals who will be called to receive immunization with any remaining doses at the end of the day.
  - The remaining doses should be allocated in a fair and equitable manner and remain consistent with the sequencing criteria for Alberta's vaccine eligibility.
- Follow the wastage mitigation strategies provided for:
  - <u>AHS</u>
  - <u>Community Pharmacies</u>
  - Physicians

#### IX. VACCINE PREPARATION

Each COVID-19 vaccine has unique preparation requirements that health practitioners must be aware of.

#### Pfizer

- COVID-19 vaccine (mRNA) Pfizer ultra-frozen vaccine
- Pfizer-BioNTech COVID-19 vaccine (Product Monograph)
- The S.T.E.P.S. to Pfizer-Biotech COVID-19 vaccination
- Information about Low Dead-Volume Syringes and/or needles for Pfizer-BioNTech COVID-19
  vaccine

#### Moderna

- <u>COVID-19 Vaccine (mRNA) Moderna frozen vaccine</u>
- Moderna COVID-19 vaccine (Product Monograph)
- Moderna COVID-19 Vaccine Storage & Handling

#### AstraZeneca/COVISHIELD

<u>COVID-19 Vaccine – AstraZeneca/COVISHIELD</u>

<u>AstraZeneca/COVISHIELD COVID-19 vaccine (Product Monograph)</u>

## X. VACCINE ORDERING, ALLOCATIONS AND DISTRIBUTION

Advanced purchase agreements with the Government of Canada are in place with seven COVID-19 vaccine manufacturers, and they have secured ~200 million doses of vaccine with options for another ~200 million doses if needed. A National Allocation Framework was developed to ensure allocation is on a per-capita basis until such time as there is enough COVID-19 vaccine supply to resume the FPT allocation process using the established Vaccine Supply Working Group (VSWG) framework.

COVID-19 vaccines enter the province in various logistical distribution routes. Depending on vaccine type and storage and handling requirements, the vaccines can be distributed:

- From the manufacturer directly to the location immunizations are being offered.
- From the manufacturer directly to a third party distributor for further distribution (for example, pharmacy wholesale distributors that ship the vaccine to pharmacies).
- From the manufacturer to the Provincial Vaccine Deport for further distribution.

Allocations are based on the health practitioners ability to administer the vaccine within the timeframes allowed based on the type of vaccine and the amount of vaccine available. Instructions on how health practitioners will receive the vaccine will be communicated through Alberta Health in partnership with Alberta Health Services, Indigenous Services Canada, Alberta Blue Cross and Alberta Medical Association.

# XI. EDUCATION/TRAINING RESOURCES

Alberta Health:

- The Alberta COVID-19 Immunization Policy
- <u>COVID-19 vaccine biological pages;</u>
  - <u>COVID-19 Vaccine (mRNA) Pfizer ultra-frozen vaccine</u>
  - COVID-19 Vaccine (mRNA) Moderna frozen vaccine
  - <u>COVID-19 Vaccine AstraZeneca/COVISHIELD</u>
- Alberta Vaccine Storage and Handling for COVID-19 Vaccine
- Active Surveillance and Reporting of Adverse Events following COVID-19 Immunization (AEFI)
  Policy
- <u>COVID-19 Vaccine Questions and answers for public and health care practitioners</u>
- <u>COVID-19 immunization: Guidance during the COVID-19 pandemic</u>
- Alberta Inventory System (AVI) training must be complement for those health practitioners not already using AVI

Alberta Health Services:

- Health Professional Immunization Information COVID-19
  - COVID-19 Immunization Orientation- <u>PowerPoint</u> | <u>Recording Session</u>
  - <u>COVID-19 Immunization Demonstration</u>

<u>COVID-19 Vaccine Fact Sheet</u>

Pharmacies:

Alberta Blue Cross pharmacy COVID-19 immunization

Physicians:

• Alberta Medical Association community physician vaccine distribution plan

National resources:

- The <u>National Advisory Committee on Immunization (NACI) Recommendations on the use of</u> <u>COVID-19 vaccine</u>
- Health Canada taking further action to confirm the benefit-risk profile of the AstraZeneca vaccine
- NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults
- <u>COVID-19 for health professionals: Vaccines</u>
- COVID-19 Vaccination Information Resources: Tool Kit for Health Care Providers

Manufacturer resources:

- COVID-19 vaccine product monographs;
  - Pfizer-BioNTech COVID-19 vaccine
  - Moderna COVID-19 vaccine
  - <u>AstraZeneca/COVISHIELD- COVID-19 Vaccine</u>
- Pfizer- BioNTech COVID-19 Vaccine Information for Canadian Health Care Professionals
- Important Safety Information on AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of <u>Thrombosis with Thrombocytopenia</u>