

Episode #39 – COVID-19 Vaccines: Part 1 June 25, 2021

Evidence and knowledge related to SARS-CoV-2 and vaccines is rapidly evolving. The information contained in this Keynotes and Resources is current to June 25, 2021.

Naming SARS-CoV-2 variants

The World Health Organization (WHO) is assigning new labels for variants it has designated as variants of interest (VOI) or variants of concern (VOC) to make it easier for the public to say and remember the growing number of variants.

For instance, under the new system, the B.1.1.7 variant, first identified in the United Kingdom (UK), will be known as Alpha. The B.1.351 variant, initially identified in South Africa, will be called Beta. The P.1 variant initially found in Brazil will go by Gamma, while the B.1.617.2 first noted in India will be called Delta.

The new names do not replace existing nomenclature systems for naming and tracking SARS-CoV-2 genetic lineages by GISAID, Nextstrain, and Pango because these convey important scientific information and will continue to be used by scientists and in research. WHO is making the change in an attempt to avoid fueling stigma toward nations where new variants arise. [1]

SARS-CoV-2 variants of interest (VOI)

Variants are viruses that have changed or mutated. Variants are common with coronaviruses and variants of SARS-CoV-2 have been emerging and circulating globally throughout the COVID-19 pandemic.

A SARS-CoV-2 variant is a VOI if its genome has mutations associated with changes in epidemiology, antigenicity,[1] or virulence, or changes that potentially have a negative impact on available diagnostics, vaccines, therapeutics, or public health measures; and either:

- Has been identified to cause community transmission, multiple COVID-19 cases/clusters, or has been detected in multiple countries; OR
- Is assessed to be a VOI by WHO; OR
- Is assessed to be a VOI by the Canadian SARS-CoV-2 Variant Surveillance Group (CSVSG) [2] [3]

[1] Antigenicity is the ability to be specifically recognized by the antibodies generated as a result of an immune response to the given substance.

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Variants of interest [2]

WHO label	Pango lineage	GISAID clade/lineage	Nextstrain clade	Earliest documented samples	Date of designation
Epsilon	B.1.427/B.1.429	GH/452R.V1	20C	USA, Mar-2020	Mar 5, 2021
Zeta	P.2	GR/484K.V2	20B/S.484K	Brazil, Apr-2020	Mar 17, 2021
Eta	B.1.525	G/484K.V3	21D	Multiple countries, Dec-2020	Mar 17, 2021
Theta	P.3	GR/1092K.V1	21E	Philippines, Jan-2021	Mar 24, 2021
Iota	B.1.526	GH/253G.V1	21F	USA, Nov-2020	Mar 24, 2021
Kappa	B.1.671.1	G/452R.V3	21B	India, Oct-2020	Apr 4, 2021
Lambda	C.37	GR/452Q.V1	20D	Peru, Aug-2020	Jun 14, 2021

SARS-CoV-2 variants of concern (VOC)

A SARS-CoV-2 variant becomes a VOC when it has demonstrated an association with one or more of the following changes at a level of global public health significance:

- Increase in transmissibility or detrimental change in COVID-19 epidemiology;
- Increase in virulence or change in clinical disease presentation;
- Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics; OR
- Is assessed to be a VOC by WHO; OR
- Is assessed to be a VOC by CSVSG [2][3][4]

Variants of concern [2]

WHO label	Pango lineage	GISAID clade/lineage	Nextstrain clade	Earliest documented samples	Date of designation	Transmissibility
Alpha	B.1.1.7	GRY (formerly GR/501Y.V1)	20I (V1)	UK, Sep-2020	Dec 18, 2020	+55% increase [5]
Beta	B.1.351	GH/501Y.V2	20H (V2)	South Africa, May-2020	Dec 18, 2020	+50% increase [6]
Gamma	P.1	GR/501Y.V3	20J (V3)	Brazil, Nov-2020	Jan 11, 2021	1.7-2.4 times more transmissible [7]
Delta	B.1.617.2	G/452R.V3	21A	India, Oct-2020	VOI: Apr 4, 2021 VOC: May 11, 2021	+60% increase [8]

Cumulative number of cases involving VOC*

Location	B.1.1.7 (Alpha)	B.1.351 (Beta)	P.1 (Gamma)	B.1.617.2 (Delta)
Canada [9]	218,753	1,962	16,319	Not available
Ontario [10]	142,393	1,154	4,256	916

*As of June 21, 2021

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Overview of vaccines[2]

Vaccines have transformed public health, especially since national programs for immunization were established. In countries with high vaccine program coverage, many of the diseases that were previously responsible for the majority of childhood illnesses and deaths have essentially disappeared.

Overwhelming evidence demonstrates the benefits of immunization as one of the most successful and cost-effective health interventions known. Over the past several decades, immunization has achieved numerous milestones, such as the eradication of smallpox, a significant triumph. Vaccines have saved countless lives, reduced the global incidence of polio by 99%, and decreased illness, disability, and death from diphtheria, tetanus, whooping cough, measles, *Haemophilus influenzae* type b disease (Hib), and epidemic meningococcal A meningitis.

Further progress has been made with the development of vaccines against pneumococcal disease and rotavirus diarrhea as well as vaccines which prevent diseases such as liver and cervical cancer. [11]

Since WHO declared the COVID-19 outbreak a pandemic in March 2020, SARS-CoV-2 has claimed more than 3.8 million lives globally with upwards of 178 million confirmed cases. [12]

The pandemic has impacted every aspect of life, causing global economies to stall, changing the way people work and interact, and stretching healthcare systems to the limit. Governments internationally have had to implement public health measures to curb the spread of the virus.

COVID-19 vaccination offers a means to transition out of the pandemic. Without vaccines, natural herd immunity would not be sufficient to restore society to some form of normalcy without sustaining countless more fatalities. Without access to vaccines, strict behavioural measures would have to remain for the foreseeable future.

To safely achieve herd immunity against SARS-CoV-2, a substantial proportion of a population will need to be vaccinated to lower the overall amount of virus able to spread in the whole population. Typically, herd immunity is achieved when 70% to 90% of the population is immune through natural infection or vaccination. [13] One of the aims of working to achieve herd immunity is to keep vulnerable populations who cannot get vaccinated (e.g., due to history of anaphylaxis after vaccine administration), those ineligible for immunization (e.g., infants and children too young to be immunized), and those who may exhibit an impaired immune response despite vaccination (e.g., people with advanced age or compromised immune systems) safe and protected from the virus. [14] [15]

Fortunately, the start of 2021 saw numerous vaccines given emergency approval and begin their roll out in countries across the globe. As of June 2021, over 2.6 billion

[2] Refer to Episode #15 for more information on vaccines

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vaccine doses have been administered worldwide, with over 24 million and 12 million administered in Canada and Ontario, respectively. [12] [16] [17]

Vaccine immunology

Vaccines contain antigens that are either derived from a pathogen (e.g., measles, mumps, rubella) or manufactured to represent components of the pathogen (e.g., HPV vaccine) to safely induce an immune response that confers protection against infection and/or disease on subsequent exposure to the pathogen. [18]

Administration of a vaccine antigen triggers an inflammatory reaction that is initially mediated by the innate immune system and subsequently expands to involve the adaptive immune system[3] through the activation of T cells[4] and B cells[5]. While the majority of vaccines provide protection through the induction of humoral immunity[6] (primarily through B cells), some vaccines, such as Bacille Calmette-Guérin (BCG)[7] and live herpes zoster vaccines, act principally by inducing cell-mediated immunity[8] (primarily through T cells). Many vaccines probably work through both, although humoral immunity is the basis most often used as a marker of how well a vaccine works.

Long-term immunity requires the persistence of antibodies, or the creation and maintenance of antigen-specific memory cells (priming) that can rapidly reactivate to produce an effective immune response upon subsequent exposure to the same or similar antigen. [19]

COVID-19 vaccines[9]

Globally, there are 124 candidate vaccines and 363 trials underway, with 8 clinical trials occurring in Canada. To date, 18 vaccines have been authorized across multiple countries. [20]

Types of COVID-19 vaccines in Canada

The types of COVID-19 vaccines currently authorized for use in Canada are messenger RNA (mRNA) vaccines and non-replicating viral vector vaccines. These vaccines use various technologies to allow for the SARS-CoV-2 spike protein to be expressed in vaccine recipients. This protein is expressed on the surface of the SARS-CoV-2 virus

[3] Adaptive immune system or acquired immune system is the second line of defense in the immune system that specifically responds to the initial exposure to a pathogen or vaccine.
[4] T cells or T lymphocytes are a type of white blood cell developed in the lymphoid organ of the immune system that are involved in cell-mediated immunity.
[5] B cells or B lymphocytes are white blood cells that produce antibodies and are part of the adaptive immune response.
[6] Humoral immunity or antibody-mediated immunity is the immune response involving activation of B lymphocytes and production of antibodies in response to a pathogen.
[7] Bacille Calmette-Guérin (BCG) is a vaccine for tuberculosis (TB) disease.
[8] Cell-mediated immunity or cellular immunity is a cellular immune response that involves the activation of phagocytes, antigen-specific cytotoxic T lymphocytes, but does not involve the production of antibodies.
[9] Refer to Episode #28 for more information on COVID-19 vaccines.

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and is a major target for binding and neutralizing antibodies[10] as well as cell-mediated immune responses.

Messenger RNA (mRNA) vaccines
COVID-19 vaccines that use mRNA platforms contain modified nucleotides that code for the SARS-CoV-2 spike protein. A lipid nanoparticle formulation delivers the mRNA into the recipient's cells. Once inside the cytoplasm of a cell, the mRNA provides instructions to the cell's protein production machinery to produce the trans-membrane spike protein antigen that becomes anchored on the cell's external surface. The mRNA does not enter the nucleus of the cell and does not interact with, or alter, human DNA. The immune system is engaged by both the transmembrane spike protein and immune receptors carrying spike antigens to induce humoral and cellular immune responses. The mRNA, lipid nanoparticle, and spike protein are degraded or excreted within days to weeks from time of immunization. mRNA vaccines are not live vaccines and cannot cause infection in the host. [21]

Non-replicating viral vector vaccines
COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells. The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease (i.e., they are non-replicating). Once inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell. Both the AstraZeneca vaccine and the Janssen vaccine are adenovirus vector vaccines. The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd). The Janssen vaccine uses a modified human adenovirus serotype 26 vector (Ad26). [21]

COVID-19 vaccines authorized in Canada
COVID-19 vaccination began in Canada the week of December 13, 2020. Presently, there are five COVID-19 vaccines authorized for use by Health Canada: Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine, COVISHIELD COVID-19 vaccine, and Janssen COVID-19 vaccine. Four are currently being administered.

Among those vaccinated in Canada, most have received the Pfizer-BioNTech vaccine. Although the Janssen COVID-19 vaccine has not yet been administered in Canada, some Canadian residents have been vaccinated with it in other countries. To date, the Pfizer-BioNTech vaccine is the only COVID-19 vaccine authorized by Health Canada for children 12 years and older. More vaccines will likely be authorized in the future. [16]

Pfizer-BioNTech COVID-19 vaccine (Tozinameran or BNT162b2)
- Authorized for use in Canada on December 9, 2020 for ages 16 and up. On May 5, 2021, the authorization was expanded to include 12- to 15-year-olds
- Vaccine type: messenger RNA (mRNA) vaccine

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- Two doses are required: a single dose and then a second dose 21 days later; administered via intramuscular (IM) injection into the deltoid muscle
- Clinical studies showed that, beginning 1 week after the second dose, the Pfizer-BioNTech COVID vaccine was 95% effective in protecting trial participants aged 16 and above against COVID-19 and 100% effective in participants 12 to 15 years old
- It takes about 2 weeks to develop significant protection against COVID-19. For the greatest protection, the second dose is needed
- At present, there is no evidence for an additional booster after the 2-dose series
- As of June 21, 2021, this vaccine has been approved for use in a total of 89 countries [22] [23] [24]

Moderna COVID-19 vaccine (mRNA-1273)

- Authorized for use in Canada on December 23, 2020 for ages 18 and up
- Vaccine type: mRNA vaccine
- Two doses are required: a single dose and then a second dose 28 days later; administered via intramuscular (IM) injection into the deltoid muscle
- Based on studies in about 30,000 participants, the Moderna COVID-19 vaccine was 94.1% effective in preventing COVID-19 beginning 2 weeks after the second dose
- It takes about 2 weeks to develop significant protection against COVID-19. For the greatest protection, the second dose is needed
- At present there is no evidence for an additional booster after the 2-dose series
- As of June 21, 2021, this vaccine has been approved for use in a total of 53 countries [25] [26] [24]

AstraZeneca and COVISHIELD COVID-19 vaccine (ChAdOx1-S)

- Health Canada authorized two manufacturers of the ChAdOx1-S vaccine: AstraZeneca (brand name AstraZeneca COVID-19 Vaccine) and Verity Pharmaceuticals and Serum Institute of India in collaboration with AstraZeneca (brand name COVISHIELD Vaccine) on Feb 26, 2021 for ages 18 years and older
- AstraZeneca COVID-19 Vaccine and COVISHIELD are ChAdOx1-S recombinant vaccines developed by AstraZeneca and Oxford University
- Vaccine type: non-replicating viral vector (adenovirus vector vaccine using chimpanzee adenovirus [ChAd])
- Two doses are required: a first dose and then a second dose 4 to 12 weeks later; administered via IM injection into the deltoid muscle
- AstraZeneca COVID-19 vaccine showed an effectiveness of about 62% in preventing symptomatic COVID-19 disease beginning 2 weeks after the second dose
- It takes about 2 weeks to develop significant protection against COVID-19. For the greatest protection, the second dose is needed
- At present there is no evidence for additional boosters after the 2-dose series
- As of June 20, 2021, AstraZeneca COVID-19 Vaccine and COVISHIELD are approved in a total of 115 and 43 countries, respectively [24] [27]

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Janssen (Johnson & Johnson) COVID-19 vaccine (Ad26.COV2.S)

- Authorized for use in Canada on March 5, 2021 for ages 18 years and older
- Vaccine type: non-replicating viral vector (adenovirus vector vaccine using human adenovirus serotype 26 vector [Ad26])
- Single dose: administered via IM injection into the deltoid muscle
- Based on studies in about 43,000 participants, the Janssen COVID-19 vaccine was 66% effective in preventing symptomatic COVID-19 disease beginning 2 weeks after vaccination
- It takes about 2 weeks to develop significant protection against COVID-19
- At present there is no evidence for additional boosters after the 1-dose series
- Canada received an initial shipment of this vaccine on April 28, 2021; however, Health Canada did not release the shipment for distribution because of multiple areas of concern noted in an inspection by US Food and Drug Administration (FDA) of the Emergent BioSolutions facility in Baltimore, Maryland. On June 11, 2021, Health Canada announced that the quarantined shipment would not be released for distribution because they were unable to determine if the shipment meets Health Canada's rigorous quality standards. To ensure the safety of any future vaccine supply from this facility, Health Canada is planning an onsite inspection, expected to take place in summer 2021. Until this inspection has been completed, Canada will not be accepting any product or ingredients made at this site.
- As of June 20, 2021, this vaccine has been approved for use in a total of 52 countries [24] [28] [29]

COVID-19 vaccines authorized in Canada [21] [30] [31]

	Pfizer-BioNTech COVID-19 Vaccine	**Moderna COVID-19 Vaccine**	**AstraZeneca COVID-19 / COVISHIELD Vaccine**	**Janssen COVID-19 Vaccine**
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)
Contain live virus	No	No	No	No
Date authorized in Canada	December 9, 2020 (ages 16 years and older); May 5, 2021 (12 years and older)	December 23, 2020	February 26, 2021	March 5, 2021
Approved ages	12 years and older	18 years and older	18 years and older	18 years and older
Dose	0.3 mL (30 mcg of mRNA)	0.5 mL (100 mcg of mRNA)	0.5 mL (5 x 1010 viral particles)	0.5 mL (5 x 1010 viral particles)
Schedule	2 Doses, 3 weeks apart	2 Doses, 4 weeks apart	2 Doses, 4 to 12 weeks apart*	1 Dose
Extended interval	16 weeks after 1st dose	16 weeks after 1st dose	16 weeks after 1st dose	Not applicable

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	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 / COVISHIELD Vaccine	Janssen COVID-19 Vaccine
Administration route	Intramuscular	Intramuscular	Intramuscular	Intramuscular
Diluent	Yes	No	No	No
Overall efficacy rate (clinical trial data)	95.0%	94.1%	59.9%	66.9%
Highly effective preventing hospitalizations	Yes	Yes	Yes	Yes
Efficacy rate against severe disease	>1-14 days after dose 2: 75-100%	14 days after dose 2: 100%	After dose 2: 100%	28 days after dose: 85.4%
Effective protecting against symptomatic disease	Yes	Yes	Yes	Yes
Efficacy against VOC	B.117: 70-94%, 14-21 days after 2nd dose	B.117: 85.7%, 15 days after 2nd dose	B.117: 65-74% after 1st dose	B.135: 81.7% against severe disease after 28 days

*The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks

Cumulative percent (number) of COVID-19 vaccines administered [16]

Location	Status	Pfizer-BioNTech	Moderna	AstraZeneca	COVISHIELD	Combination**
Canada*	At least one dose	46.88% (17,815,261)	11.63% (4,419,453)	4.57% (1,735,187)	0.90% (340,236)	0.57% (216,048)
	Partially vaccinated	28.49% (10,828,383)	6.64% (2,524,501)	3.15% (1,198,384)	0.59% (222,893)	Not available
	Fully vaccinated	7.29% (2,769,798)	2.01% (763,905)	0.16% (59,049)	0.01% (3,845)	0.57% (216,048)
Ontario	At least one dose	47.13% (6,944,483)	10.80% (1,590,960)	4.46% (656,568)	0.60% (88,121)	0.90% (133,299)
	Partially vaccinated	38.11% (5,615,506)	8.54% (1,257,877)	4.43% (653,032)	0.59% (87,247)	Not available
	Fully vaccinated	9.02% (1,328,977)	2.26% (333,083)	0.02% (3,536)	0.01% (874)	0.90% (133,299)

*As of June 12, 2021 **Includes people who completed their vaccination series with more than one product

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Extended dose intervals

In March 2021, the National Advisory Committee on Immunization (NACI)[11] released guidance on COVID-19 vaccines recommending the interval between the first and second dose be extended up to 4 months. [32] This recommendation was based on the importance of maximizing vaccination within the context of limited vaccine supply and significant community transmission. To make this decision NACI considered:

- Recent studies of COVID-19 vaccine efficacy and effectiveness
- Real world effectiveness demonstrating sustained high-level protection after the first dose of the COVID-19 vaccine
- Immunological principles and vaccine science
- Public Health Agency of Canada (PHAC) modelling data that examined different strategies to prevent the greatest numbers of symptomatic disease, hospitalizations, and deaths
- The Ethics, Equity, Feasibility, and Acceptability (EEFA) Framework[12]
- Vaccine supply projections [33]

NACI's recommendation was adopted in Ontario with a limited number of exceptions. For example, individuals with an immunocompromising medical condition or on immunosuppressive therapies, who were in the vaccine authorized age group would receive the second dose (of a 2-dose series) at the interval stipulated in the product monograph. These individuals included:

- Transplant recipients (including solid organ transplants and hematopoietic stem cell transplants);
- Individuals with malignant hematologic disorders or non-hematologic malignant solid tumors that are receiving stable, active treatment (chemotherapy, targeted therapies, immunotherapy), excluding individuals receiving solely hormonal therapy and/or radiation therapy;
- Individuals undergoing hemodialysis or peritoneal dialysis; and
- Individuals who are taking or imminently initiating an anti-CD20 agent (e.g., rituximab, ocrelizumab, ofatumumab).

Also, individuals in the 70 plus age group who have recently received their first dose are recommended to receive their second dose at the product monograph. [33]

Extending the interval of the second dose of a COVID-19 vaccine maximizes vaccine supply to immunize the largest number of people as quickly as possible. Principles of

[11] The National Advisory Committee on Immunization (NACI) is a national external advisory committee of experts in fields such as pediatrics, infectious diseases, immunology, epidemiology, and public health. NACI has provided guidance on the use of vaccines to the Government of Canada since 1964. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/naci-membership-representation.html

[12] The EEFA Framework facilitates the systematic consideration of factors critical for comprehensive immunization program decision-making and successful implementation of recommendations. Its use empowers organizations to review and balance all of the available evidence and transparently summarize their rationale for appropriate, timely recommendations. [56]

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immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. [21]

COVID-19 vaccine interchangeability

On June 17, 2021, NACI updated their recommendations on the use of COVID-19 vaccines, which included recommendations on the interchangeability of COVID-19 vaccines in a vaccine series. NACI recommended that:

- Individuals who received a first dose of an mRNA vaccine (Pfizer-BioNTech, Moderna) should be offered the same mRNA product for their second dose. If the same product is not readily available[13], or the product used for the first dose is unknown, another mRNA vaccine is considered interchangeable and should be used to complete the series.

- When the first dose in a COVID-19 vaccine series is the AstraZeneca/ COVISHIELD vaccine, either the AstraZeneca/COVISHIELD vaccine or an mRNA vaccine product may be offered for the subsequent dose to complete the series. However, an mRNA vaccine **is now preferred** as the second dose for individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, based on emerging evidence of a potentially better immune response from this mixed vaccine schedule and to mitigate the potential risk of vaccine-induced immune thrombotic thrombocytopenia (VITT) associated with viral vector vaccines.

- People who received two doses of AstraZeneca/COVISHIELD vaccine can rest assured that the vaccine provides good protection against infection and very good protection against severe disease and hospitalization. [34]

Regardless of which product is offered, a complete two-dose series is important for protection; the previous dose should be counted, and the series need not be restarted. [21]

In providing these recommendations, NACI considered the increasing availability of mRNA vaccines (Pfizer-BioNTech, Moderna) in Canada; emerging evidence suggesting better immune responses when a first dose of the AstraZeneca vaccine is followed by a second dose of the Pfizer-BioNTech mRNA vaccine; the risk of vaccine-induced immune thrombotic thrombocytopenia (VITT) associated with viral vector vaccines (AstraZeneca, Janssen) but not associated with mRNA vaccines (Pfizer-BioNTech, Moderna); and principles of ethics, equity, feasibility, and acceptability. [34]

For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine). Recommendations on extended intervals apply to mixed vaccine schedules. [21]

[13] Readily available i.e., easily available at the time of vaccination without delay or vaccine wastage.

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Emerging evidence indicates that mixed COVID-19 viral vector and mRNA vaccine schedules with dosing intervals between 4 and 12 weeks have acceptable safety profiles that may be associated with short-term increased systemic reactogenicity,[14] which is potentially increased with shorter intervals between vaccines.

Shaw et al. (2021) analyzed the combination of AstraZeneca and Pfizer-BioNTech vaccines as first and second doses in the UK. The study found that people in the mix-and-match groups experienced higher rates of common vaccine-related side effects, such as fever, chills, fatigue, headache, joint pain, malaise, and muscle ache than did people who received two doses of the same vaccine. Most who reported symptoms described them as mild. There were no hospitalizations due to the symptoms, and most of this increase in reactogenicity was observed in the 48 hours after immunization. The study suggests that mixing COVID-19 vaccines is safe, despite more mild-moderate symptoms. The short-term increase in reactogenicity may have been due to the shorter intervals between vaccines. [21] [35] [36]

Preliminary results from Spain's CombivacS clinical trial found the presence of IgG antibodies in the bloodstream was between 30 and 40 times higher in people who received the follow-up Pfizer dose after their first dose of AstraZeneca than in a control group who only received one AstraZeneca dose. Also, the presence of neutralizing antibodies rose sevenfold after a Pfizer dose, significantly more than the doubling effect observed after a second AstraZeneca dose. Mild side effects were common, and similar to those seen in standard COVID-19 vaccine regimens (e.g., headache, malaise, chills). None of the side effects were deemed severe. [36] [37] [38]

Evidence from research in Germany indicates that humoral and cellular immune responses (including responses against VOCs) increase when the Pfizer-BioNTech vaccine is administered as the second dose after AstraZeneca vaccine with an interval of 8 to 12 weeks. Also the responses are equivalent to or greater than immune responses following a homologous two-dose schedule of the AstraZeneca or Pfizer-BioNTech vaccine. [21] [39]

Booster doses and re-immunization

Currently, there is no evidence for booster doses of COVID-19 vaccine after a vaccine series is complete. Given the emergence of VOC against which vaccine effectiveness may be decreased, additional vaccine doses may be necessary. [21]

Vaccine availability

The Government of Canada has stated COVID-19 vaccines will be available to everyone in Canada who is recommended to get the vaccine by federal, provincial, and territorial public health bodies. Doses of the vaccines have been distributed in Canada in phases, which began in December 2020. Assuming the continued supply of safe and effective vaccines, it is expected there will be enough vaccines to immunize everyone

[14] Reactogenicity represents the physical manifestation of the inflammatory response to vaccination, and can include injection-site pain, redness, or swelling at the injection site, as well as systemic symptoms, such as fever, myalgia, or headache.

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for whom vaccines are approved and recommended. The government anticipates this will be accomplished by September of 2021. [40]

Vaccine safety

Health Canada only approves a vaccine if it is supported by very robust scientific data and evidence. Before authorizing a vaccine, Health Canada assesses:

- Scientific and clinical evidence, including results of clinical trials, to determine if a vaccine product is safe, effective, and manufactured to the highest quality
- Safety and efficacy of the vaccine to determine that there are no concerns, the vaccine can trigger an adequate immune response to protect against disease and the benefits outweigh the risks
- Manufacturing process to make sure the manufacturer can carry out the necessary quality controls for the vaccine

After approval, Health Canada and the Public Health Agency of Canada (PHAC) continue to monitor the ongoing safety and effectiveness of all approved vaccines in Canada. [41]

Side effects of the COVID-19 vaccines

Similar to medications and other vaccines, the COVID-19 vaccines can cause side effects. During the clinical trials, common side effects similar to other vaccines were reported (e.g., redness and pain at the injection site). These side effects do not pose a health risk. In clinical trials, most of these side effects were mild to moderate and on average did not last longer than three days after vaccination. [42]

Summary of side effects [26] [23] [43]

Vaccine	**Very common side effects** (may affect more than 1 in 10 people)	**Common side effects** (may affect 1 to less than 10 in 100 people)	**Uncommon side effects** (may affect up to 1 in 100 people)
Moderna	Pain at injection site Lymphadenopathy/ Axillary swelling and tenderness Fatigue Headache Muscle pain Joint pain	Localized redness and swelling at injection site (very common after 2nd dose) Chills (very common after 2nd dose) Nausea and/or vomiting (very common after 2nd dose)	Fever (very common after 2nd dose)
Pfizer-BioNTech	Pain at injection site Fatigue Headache Muscle pain Chills Fever (common after 1st dose for adults)	Localized redness or swelling at injection site Joint pain (very common after 2nd dose) Diarrhea Nausea and/or vomiting (uncommon after 1st dose in adults)	Enlarged lymph nodes

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Vaccine	**Very common side effects** (may affect more than 1 in 10 people)	**Common side effects** (may affect 1 to less than 10 in 100 people)	**Uncommon side effects** (may affect up to 1 in 100 people)
AstraZeneca and COVISHIELD	Pain, tenderness, warmth at injection site Fatigue Chills (common after 2nd dose) Headache Muscle pain Nausea (common after 2nd dose) Joint pain Fever/ Feverish	Localized redness, swelling, and pruritis Induration Vomiting (uncommon after 2nd dose)	Enlarged lymph nodes

Some people have reported adverse events (side effects) after being immunized with a COVID-19 vaccine in Canada. These adverse events are not necessarily related to the vaccine. For example, they may be:

- Anxiety about immunization
- An allergic reaction to another substance
- Related to a pre-existing condition
- Coincidental [44]

Managing vaccine side effects

A cool, damp cloth where the injection was given may help with soreness. Oral analgesics or antipyretics may be considered for the management of side effects (e.g., pain or fever, respectively), if they occur after vaccination. [45]

Note: NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. [21]

Serious adverse effects

Serious adverse effects after receiving the vaccine are rare. Individuals should be advised to contact their healthcare provider or seek medical attention if they experience worrisome side effects or side effects that do not seem to be going away after a few days.

Individuals who develop serious adverse reactions within three days of receiving the vaccine, should seek medical attention right away or call 911 if they are severely unwell. Serious adverse reactions include:

- Hives
- Swelling of the face or mouth
- Trouble breathing
- Serious drowsiness

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- High fever (over 40°C)
- Convulsions or seizures
- Other serious symptoms (e.g., “pins and needles” or numbness)

If individuals have received a viral vector COVID-19 vaccine (e.g., AstraZeneca/ COVISHIELD vaccine) and develop any of the following symptoms within 42 days after receiving the vaccine, they should seek immediate medical attention:

- Shortness of breath
- Chest pain
- Leg swelling or pain
- Persistent abdominal pain
- Skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under the skin)
- Sudden onset of severe headaches or persistent or worsening headaches
- Blurred vision, double vision or dizziness
- Confusion or seizures
- Difficulty speaking or moving a part of the body [21] [31]

Adverse events following immunization (AEFIs)

Public Health Ontario (PHO) leads the provincial surveillance of adverse events following any immunization (AEFIs). An AEFI is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine. [46]

Importance of reporting AEFIs

Provincial reporting of AEFIs is an important component of the overall safety assessment of any vaccine. This type of surveillance, commonly called post-marketing or post-licensure surveillance, allows for monitoring of the vaccines throughout implementation in the context of “scaled up” vaccine production and expansion of the population receiving the vaccine.

Individual case reports of AEFIs represent an important source of data as they have the potential to generate signals of adverse events not previously recognized in clinical studies which can be further evaluated. This is particularly important for rare adverse events which may not have been evident in clinical trials due to limited sample size.

In Ontario, passive vaccine safety surveillance relies on reporting of AEFIs by health care providers, vaccine recipients, or their caregivers to their local public health unit (PHU). AEFI reports received by PHUs are investigated, assessed and documented according to provincial surveillance guidelines, as required by the Ontario Public Health Standards (OPHS). PHO conducts provincial surveillance of AEFIs and provides advice and support for local PHUs in the investigation and management of AEFI reports. All provincially reported AEFIs that meet the confirmed case definition are reported by PHO to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) at the Public Health Agency of Canada (PHAC). [47]

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In Ontario, healthcare professionals (i.e., physicians, nurses, and pharmacists) are required by law to report AEFIs to their local PHU using the "Report of Adverse Event Following Immunization (AEFI)" form,[15] available from PHO. Public health units investigate AEFIs and provide support to immunizers, individuals, and their families. Vaccine recipients or their caregivers may also voluntarily report AEFIs to public health. [46] [48]

Events that do not need to be reported

Some common or mild events do not need to be reported after any type of immunization, include:

- Fever that is not accompanied by any other symptoms
- Injection site reactions that last less than 4 days
- Vasovagal syncope (without injury)
- Events that are clearly attributed to other causes [48]

Reportable adverse events[16]

Types of adverse events after any type of immunization that should be reported include:

- Reactions at injection sites, such as pain or redness or swelling lasting 4 days or more or extending beyond the nearest joint; infected abscess, nodule, cellulitis
- Systemic reactions, such as rash, lymphadenopathy, severe vomiting or diarrhea, parotitis
- Allergic reactions, such as anaphylaxis and allergic skin reactions (e.g., hives)
- Neurologic events, such as seizures, encephalitis, meningitis, paraesthesia, paralysis, Guillain Barré Syndrome (GBS), Bell's palsy
- Other events of interest, such as arthritis, arthralgia,[17] intussusception,[18] thrombocytopenia,[19] syncope with injury, Kawasaki disease [47] [48]

Adverse events of special interest (AESIs) for COVID-19 vaccines

In addition to the list of adverse events which apply to all vaccines, PHO updated AEFI reporting to include adverse events of special interest (AESIs) for COVID-19 vaccine surveillance. Reporting AESIs for COVID-19 vaccines in the context of overall AEFI surveillance enables enhanced monitoring by pre-specifying events which may otherwise not be captured or readily analyzed from a passive surveillance system.

To date, PHAC and international health authorities, including the Brighton Collaboration[20] and WHO have identified a list of AESIs for COVID-19 vaccines. The AESIs were originally selected based on a theoretical rationale for a possible association with COVID-19 vaccines. For example, they include events that may occur

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[15] Report of Adverse Event Following Immunization (AEFI) form https://www.publichealthontario.ca/-/media/documents/a/2020/aefi-reporting-form.pdf?la=en

[16] Note that this list is not exhaustive.

[17] Arthralgia - joint pain.

[18] Intussusception is the infolding (telescoping) of one segment of the intestine within another usually resulting in a blockage of the intestine that can lead to death of the affected bowel tissue.

[19] Thrombocytopenia - low platelet (thrombocyte) count.

[20] Brighton Collaboration is a community aiming to promote and improve vaccine safety. https://brightoncollaboration.us/about/

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during the clinical course of SARS-CoV-2 infection or as a complication of infection. For this reason, collecting and documenting recent history of COVID-19 infection is an important component of the reporting process for all AESIs.

In addition, the AESI category of coagulation disorders, which also includes thrombotic events, is currently a focus of enhanced surveillance activity following the recognition of very rare immune mediated thrombotic events in association with low platelets that has been observed following the AstraZeneca vaccine. Given the rapidly evolving state of information related to COVID-19 disease and vaccines, AESIs and other documents will be updated as new information becomes available. [49]

AESIs for COVID-19 vaccine surveillance include:

Vaccine-associated enhanced disease (VAED) – An illness occurring in an individual who receives a vaccine and is subsequently infected with the pathogen that the vaccine is meant to protect against. VAED is reportable if the vaccine recipient:

- Develops laboratory confirmed SARS-CoV-2 infection after receiving the first or second dose of COVID-19 vaccine; AND
- Has severe and/or modified/unusual clinical symptoms compatible with COVID-19 infection; AND/OR
- Is hospitalized [49]

Multisystem inflammatory syndrome in children or adults[21] – Multisystem inflammatory syndrome in children/young adults under 21 years of age (MIS-C) or adults 21 years of age and older (MIS-A) is characterized by a hyperinflammatory response including persistent fever and multi-organ involvement (MIS-A may not be accompanied by fever). MIS-C and MIS-A are also rare complications of SARS-CoV-2 infection. [49]

Thrombosis with thrombocytopenia syndrome (TTS) and vaccine-induced immune thrombotic thrombocytopenia (VITT) – TTS is a condition characterized by the presence of acute venous or arterial thrombosis and new onset thrombocytopenia (i.e., blood clots and low platelets) and no known recent exposure to heparin. VITT refers to the clinical syndrome of TTS, in addition to laboratory tests that confirm platelet activation (i.e., anti-platelet 4 antibodies). [49]

VITT is an autoimmune thrombotic process that has been observed to occur approximately 4-28 days following vaccination with adenoviral vector vaccines. The first identification of this clinical syndrome occurred following AstraZeneca COVID-19 vaccine, although it has now also been identified in association with Janssen vaccine. VITT seems to be rare. The rate of VITT is estimated to be approximately 1 per 26,000 to 1 per 127,000 persons vaccinated with a first dose of AstraZeneca and/or COVISHIELD COVID-19 vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered. The frequency of VITT following a second dose of AstraZeneca vaccine is currently reported between 1 per 600,000 to 1 per 750,000 doses administered. [21] [31]

[21] Refer to Episode #33 for more information on MIS-C and MIS-A.

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There have been few reported cases of VITT with the Janssen vaccine, so it is difficult to calculate a precise rate, but the incidence of VITT appears to be approximately 1 case per 500,000 vaccine doses administered.

At this time, it is unknown if certain patients are more likely to develop VITT. Currently, there is no evidence that VITT is more common in people who have had blood clots before; people with a family history of blood clots; people on birth control or other hormones; people with autoimmune disease; people with low platelets or other platelet disorders; or pregnant people, because VITT does not develop through the same process as more common types of bleeding or clotting disorders. It may be possible, however, that people with a history of heparin induced thrombocytopenia (HIT) or cerebral sinus vein thrombosis (CSVT) with low platelets are at increased risk of VITT. For this reason, they should receive an mRNA vaccine (Pfizer or Moderna) rather than an adenoviral vector vaccine. [50]

VITT may present with venous clots (e.g., PE, DVT, portal vein thrombosis, CVST) or arterial clots (myocardial infarction, stroke), in association with new onset thrombocytopenia (i.e., platelet count < 150x 109 /L, with low platelets confirmed by peripheral smear). Symptoms of VITT may include severe or persistent headache, focal neurological symptoms, seizures, blurred or double vision, limb swelling, redness, pallor, or coldness. [49]

Acute cardiovascular injury – Refers to a broad spectrum of cardiac pathology including microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease, myocarditis, pericarditis, and cardiac arrhythmias. Myocarditis and pericarditis are of particular interest for AESI surveillance for COVID-19 vaccines. [49]

Cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines have been reported internationally (e.g., Europe, Israel, and US), more commonly after the second dose in a homologous 2-dose series of COVID-19 mRNA vaccines and more often in males, adolescents, and young adults. To date, an association between myocarditis/pericarditis and mRNA COVID-19 vaccines has not been confirmed. [21]

There have been a small number of reports of pericarditis/myocarditis following vaccination with a COVID-19 mRNA vaccine in Canada. However, Canada is not currently seeing higher rates than would be expected in the general population. To date, PHO has received reports of a small number of cases of myocarditis/pericarditis in the 12 to 17 age group in Ontario. [51]

There have been no reports of myocarditis or pericarditis following mRNA COVID19 vaccines when used as the second dose in a two-dose mixed schedule and therefore it is unknown at this time if there could be an association between myocarditis/pericarditis and mRNA vaccines used in mixed schedules. PHAC, Health Canada, and PHO are closely monitoring rare reports of potential myocarditis/pericarditis following a COVID-19 mRNA vaccine, including those among youth. [21] [52]

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Myocarditis and pericarditis both involve inflammation of the heart in response to an infection or another trigger. Symptoms can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. Symptoms can be accompanied by abnormal tests (e.g., electrocardiogram, serum troponins, echocardiogram). While myocarditis and periocarditis can be serious, cases that have been reported after receipt of COVID-19 mRNA vaccines have been generally mild and resolved well with medical care (e.g. non-steroidal anti-inflammatory drugs) and rest. [52]

Based on cases reported internationally, available information indicates that myocarditis and pericarditis occur:

- More often after the second dose
- Usually within 4 days after vaccination
- More often in adolescents and young adults (younger than about 25-30 years of age)
- More often in males than females. [21]

Acute respiratory distress syndrome (ARDS) – An acute illness characterized by progressive symptoms of dyspnea, tachypnea, and hypoxemia. ARDS is a manifestation of acute lung injury, commonly resulting from sepsis, trauma, and severe pulmonary infection. Clinically, it is characterized by diffuse alveolar damage with hypoxemia and poor lung compliance. Severe COVID-19 can also lead to ARDS. [49]

Coagulation disorder (including thrombotic events) – Coagulation disorders affect the body's ability to control blood clotting and can include both hemorrhagic (excessive bleeding) and thrombotic events (blood clots). Examples of specific diagnoses include thrombotic and thromboembolic events both venous (e.g., cerebral venous sinus thrombosis (CVST), pulmonary embolism (PE), deep venous thrombosis (DVT)) and arterial (e.g., ischemic stroke, myocardial infarction). This AESI grouping also includes haemorrhagic disease, bleeding disorders, other coagulation disorders (e.g., disseminated intravascular coagulation, hemolytic uremic syndrome, complement disorder). Severe COVID-19 has been associated with coagulation abnormalities that mimic other systemic coagulopathies associated with severe infections (e.g., disseminated intravascular coagulation (DIC) or thrombotic microangiopathy). [49]

Acute kidney injury – An acute impairment of kidney function characterized by a decline in urine output and an elevation of creatinine levels. [49]

Acute liver injury – An acute illness that occurs without preceding chronic liver disease. [49]

Acute pancreatitis – A condition involving acute inflammation of the pancreas. Acute pancreatitis typically presents as acute onset of severe and constant abdominal pain radiating to the back, that is associated with vomiting and fever. [49]

Anosmia and/or ageusia – A condition characterized by subjective loss of sense of smell (anosmia) and/or taste (ageusia) that is not associated with trauma, respiratory infections (e.g., influenza), or previously diagnosed medical condition manifesting as

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anosmia or ageusia. Smell and taste disorders may be attributable to a number of causes including, inflammatory conditions of the nasal sinuses, infections (e.g., SARS-CoV-2), head trauma, medication side effects, neurological disorders, and aging. [49]

Rhabdomyolysis – A condition involving damage and injury of skeletal muscles. Clinical presentation of rhabdomyolysis may range from an asymptomatic illness with incidental elevation in the creatinine kinase (CK), to symptomatic weakness, limb swelling, and myalgia (e.g., shoulders, thighs, back, calves) secondary to tissue necrosis.

Rhabdomyolysis is most commonly caused by direct physical trauma (e.g., electric shock, crush injury) but can also be caused by infections (e.g., influenza, HIV, cytomegalovirus, varicella zoster virus, herpes simplex virus), muscle ischemia (e.g., compartment syndrome), overexertion, prolonged bed rest, and medications (e.g., statins). [49]

Single organ cutaneous vasculitis – A syndrome characterized by clinical and histological features of small vessel vasculitis of the skin without systemic involvement. Cutaneous vasculitis (CV) encompasses a wide range of entities characterized by inflammation of cutaneous (skin) blood vessels, with the term “single-organ vasculitis” referring to vasculitis affecting arteries/veins of any size in a single organ, without features suggesting systemic vasculitis. Typically, cases manifest with a single crop of lesions consisting of palpable purpura (hemorrhagic papules), erythematous papules, urticarial lesions, vesicles, and hemorrhagic vesicles. Lesions are usually asymptomatic, or associated with burning, pain, or pruritus. Single organ cutaneous vasculitis may be challenging to distinguish from systemic vasculitis. [49]

Subacute thyroiditis (SAT) – A condition involving inflammation of the thyroid. SAT characteristically presents clinically as either a painful or painless swelling of the thyroid gland associated with signs and symptoms of either hyperthyroidism (thyrotoxicosis) or hypothyroidism.

Patients with the classic, painful (i.e., De Quervain thyroiditis) SAT, present with painful swelling of the thyroid which may initially be unilateral but usually spreads to involve the whole gland. Common systemic symptoms include a low-grade fever, malaise, fatigue, myalgia,[22] and arthralgia.[23] Disease symptomatology includes a painful thyroid gland typically extending over 1 to 2 weeks with continuing fluctuating intensity for 3 to 6 weeks. Laboratory investigation demonstrates a very high erythrocyte sedimentation rate (ESR), and elevated C-reactive protein (CRP) and thyroglobulin with thyroid function test (e.g., thyroid stimulating hormone (TSH), free thyroxine) abnormalities.

Painless subacute thyroiditis, also known as silent SAT occurs spontaneously due to an autoimmune process. It occurs following 4-10% of pregnancies, referred to as postpartum thyroiditis but also presents as Grave’s disease. The combination of thyroid enlargement without discomfort and positive anti-thyroid antibodies, associated with

[22] Myalgia – muscle pain
[23] Arthralgia – joint pain

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thyroid function test abnormalities, over a 9-12-month course is suggestive of painless SAT. [49]

Erythema multiforme – An acute immune-mediated dermatologic condition, with or without mucosal involvement characterized by the appearance of distinctive target lesions, with concentric colour variations, sometimes accompanied by oral, genital, and/or ocular mucosal erosions.

The clinical manifestations of erythema multiforme can vary and target lesions may not be present in all patients. The earliest lesions are typically round, erythematous, edematous papules surrounded by areas of blanching. The papules can enlarge and develop concentric alterations in morphologic features and colour, which results in the well-known target lesions. Lesions typically appear over three to five days and resolve over one to two weeks.

Erythema multiforme is most commonly caused by herpes simplex virus (HSV) infection and certain medications. Laboratory testing can be used to support infectious associations. Although usually self-limiting, in a subset of individuals frequent episodes of erythema multiforme over many years can lead to recurrent disease. [49]

Chilblain-like lesions – A cutaneous manifestation resembling chilblains characterized by erythematous, edematous, or blistering skin lesions that most commonly affect the toes and extremities.

Chilblain-like lesions are a dermatological finding that has been described in relation to COVID-19 disease. Chilblains (perniosis) are an inflammatory skin condition typically occurring as an abnormal vascular response to the cold, whereas chilblain-like lesions are attributed to inflammatory or embolic microvascular occlusion, occurring in the toes, feet, fingers, and/or hands. The lesions have been described as erythematous, purplish patches, and papules, sometimes evolving towards erosions, pigmentation, and scaling. Chilblain-like lesions have been reported to occur predominantly in younger, otherwise asymptomatic patients and may represent a post-viral or delayed-onset process, as developing lesions occur after the onset of other symptoms. [49]

Reported adverse events following COVID-19 vaccination in Canada

As of June 11, 2021, a total of 28,156,222 vaccine doses were administered in Canada. Adverse events (side effects) were reported by 7,408 people, which is approximately 3 people out of every 10,000 people vaccinated who reported 1 or more adverse events.

- Of the 7,408 individual reports, 5,483 were considered non-serious (0.021% of all doses administered) and 1,565 were considered serious (0.006% of all doses administered).
- Most adverse events are mild and included soreness at the site of injection or a slight fever. [53]

Serious adverse events are rare, but do occur. They included anaphylaxis, which has been reported 76 times for all COVID-19 vaccines across Canada. This is rationale for

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why individuals wait for a period of time after vaccination in case of an allergic reaction requiring treatment. [53]

All serious events undergo medical review to see if there are any safety issues needing further action. Cases of thrombosis with thrombocytopenia syndrome following vaccination with AstraZeneca/COVISHIELD COVID-19 vaccine continue to be monitored.

PHAC and Health Canada are aware of international reports and regulatory actions related to capillary leak syndrome and the AstraZeneca COVID-19 vaccine. Capillary leak syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood, and low blood levels of albumin. European Medical Agency's safety committee investigated six cases of capillary leak syndrome in people who had received AstraZeneca COVID-19 Vaccine. Most of the cases occurred in women within 4 days of vaccination. As of May 27, 2021, more than 78 million doses (combination of first and second doses) of AstraZeneca had been administered in the EU/EEA,[24] and UK. [53] [54]

One case of capillary leak syndrome has been confirmed in Canada. Health Canada is working with the manufacturers and international regulators to review information as it becomes available and will take appropriate action. [53]

Also, as part of ongoing COVID-19 vaccine safety efforts, PHAC and Health Canada are closely monitoring myocarditis and pericarditis in passive and active Canadian safety surveillance systems, including the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS),[25] the Canada Vigilance Program (CV),[26] the Canadian National Vaccine Safety Network (CANVAS)[27] and the Canadian Immunization Monitoring Program ACTive (IMPACT).[28] As well, PHAC and Health Canada are monitoring international reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines.

In Canada, there have been a small number of reports of pericarditis or myocarditis**,** following vaccination with a COVID-19 mRNA vaccine; however, it is important to note that adverse events occurring after vaccination are **not** necessarily related to the vaccine. Based on the few reports received, Canada is **not** currently seeing higher rates than would be expected in the general population. [55]

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[24] The European Union (EU) countries include Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. The European Economic Area (EEA) includes EU countries and also Iceland, Liechtenstein, and Norway. https://www.gov.uk/eu-eea

[25] CAEFISS https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

[26] CV https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html

[27] CANVAS https://cirnetwork.ca/network/national-ambulatory-network/

[28] IMPACT https://www.cps.ca/impact

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To date, no clear association has been established between myocarditis/pericarditis and mRNA vaccines, and to date, no regulatory action has been taken in Canada or internationally. Health Canada, PHAC, and the provincial and territorial health authorities will continue to monitor closely. Health Canada is also working closely with the manufacturers and international regulators to review information as it becomes available and will take appropriate action when needed. [53]

The benefits of vaccination greatly outweigh the risks, and many more illnesses and deaths would occur without vaccines. Vaccines prevent illness and disease, and save lives and livelihoods. Mass vaccination will protect people's lives and help Canada recover from the COVID-19 pandemic. [42]

Take home messages

The authorized COVID-19 vaccines in Canada have been shown to be safe and efficacious against symptomatic laboratory confirmed COVID-19, and protect against severe disease, hospitalization, and death due to COVID-19. Preventing the spread of COVID-19 remains extremely important, and COVID-19 vaccines continue to be recommended for all eligible individuals, including youth. Healthcare providers should encourage all eligible individuals to get vaccinated and to get a second dose of COVID-19 vaccine as soon as they are eligible. Clients should be reminded to continue to practice recommended public health measures for prevention and control of COVID-19 infection and transmission regardless of receipt of COVID-19 vaccine.

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