

National Advisory Committee on Immunization (NACI) Summary of Discussion (SOD)

Below are excerpts from the minutes of the NACI from December 7, 2020 – September 7, 2021

September 7, 2021

Discussion: Role of NACI in Booster Doses and Key Populations For Discussion

Following the presentation, NACI members discussed the implications of a recommendation for additional doses in key populations. Members deliberated on key questions surrounding optimal timing of booster doses for specific populations, and discussed the results of the Ethics Consultative Report and the equity/ethical principles therein.

Some additional information will be compiled by the NACI Secretariat to help inform discussions at a future meeting on the issue of additional doses/boosters for key populations.

August 10, 2021

Precautions Regarding Previous History of Myocarditis For Discussion/Decision

The presenter from PHAC provided feedback from various groups regarding the precautions to consider for individuals with a history of myocarditis/pericarditis including the Canadian Pediatric Society, Canadian Cardiovascular Society, and the Special Immunization Clinic.

After the presentation, the committee decided on the advice to be offered for people with a previous history of myocarditis not related to COVID-19 vaccination.

Discussion and Next Steps For Information

The presenter from the NACI secretariat provided an update on the NACI vote for the recommendation on mRNA COVID-19 Vaccines for Adolescents and outlined the next steps to the committee.

August 3, 2021

US Perspective: Myocarditis in Adolescents and Consideration on Pfizer and Moderna For Information

The presenter from the Centre for Disease Control provided an update on myocarditis/pericarditis following mRNA COVID-19 vaccines in the United States.

PHAC Safety Update For Information

The presenter from PHAC's Vaccine Safety section provided an update on myocarditis/pericarditis events in Canada following mRNA vaccine.

Epidemiological Perspective For Information

The Vaccine Safety Working Group Chair provided an epidemiological perspective of the myocarditis/pericarditis vaccine safety signal.

Immunizer perspectives: Myocarditis in Adolescents and Consideration on Pfizer and Moderna For Information

Presenters from the Special Immunization Clinic Network provided an overview of the work done by the network and cases of pericarditis and myocarditis following mRNA vaccine.

NACI Recommendation on mRNA COVID-19 Vaccines for Adolescents - Additional option For Discussion/Decision

NACI members discussed the emerging domestic and international myocarditis/pericarditis data in young adults, and implications for recommendations in the adolescent population, and how data should be communicated in the NACI statement. The committee voted on updated recommendations for use of mRNA vaccines in adolescents but consensus was not reached.

July 27, 2021

Myocarditis/Pericarditis and vaccines
Information/Discussion

The presenter from the Ottawa Health Institute provided a verbal overview on myocarditis and pericarditis following COVID-19 immunization in adults.

The presenter from SickKids Hospital in Toronto presented a case series on acute myocarditis following COVID-19 vaccination in adolescents and young adults.

July 20, 2021

Health Canada Update

Health Canada provided a regulatory update on COVID-19 vaccines in Canada, including Moderna's adolescent submission and safety update on myocarditis/pericarditis.

For Information

PHAC Safety Update

The PHAC Vaccine Safety section provided information on cases of myocarditis/pericarditis following COVID-19 vaccination in Canada.

For Information

July 13, 2021

Recommendations for individuals vaccinated abroad

The NACI Chair provided an update on the results of the electronic survey circulated to members regarding their preference on the various recommendations for individuals vaccinated abroad with non-Health Canada (HC) authorized COVID-19 vaccines. Outstanding issues were discussed and decided upon by the Committee.

For Decision

July 9, 2021

Presentation: COVID-19 Vaccine Guidance for Individuals Vaccinated Abroad

The NACI Secretariat provided an update on the recommendations for individuals vaccinated abroad with non-Health Canada authorized vaccines. An overview was provided on context and considerations related to individuals vaccinated in other countries with COVID-19 vaccines not authorized by Health Canada and coming to live, work and/or study in Canada, which was followed by an overview of current evidence and proposed approaches for recommendations on this issue.

For Information

Discussion: COVID-19 Vaccine Guidance for

Following the presentation, there was discussion with NACI members on the

Individuals Vaccinated Abroad	potential approaches for recommendations for individuals vaccinated abroad.
For Discussion	Following the meeting, the NACI Secretariat will follow up with members of the committee to decide on recommendations for the issue of vaccination abroad with non-HC authorized vaccines.

July 8, 2021

Ontario Safety Data Update	The presenter from the Public Health Ontario (PHO) Vaccine Safety team provided an update on provincial data on myocarditis and pericarditis following vaccination with a COVID-19 mRNA vaccine.
For Information	
Institut national de santé publique du Québec (INSPQ) Committee Update	The presenter from INSPQ provided an update on the risks and benefits of vaccinating people aged 12 to 39 with COVID-19 mRNA vaccines in in Quebec.
For Information	
Health Canada Update	Health Canada provided a verbal regulatory update on COVID-19 vaccines in Canada and an update regarding myocarditis and pericarditis and mRNA COVID-19 vaccination was provided.
For Information	
Presentation: Updates on mRNA COVID-19 Vaccines for Adolescents and Myocarditis/ Pericarditis	The NACI Secretariat provided an overview of updated data on what is currently known and unknown regarding myocarditis/pericarditis following mRNA COVID-19 vaccine in adolescents and young adults. The PHAC Vaccine Safety section provided an update on cases of myocarditis/pericarditis in Canada. The current and proposed NACI Recommendations for the use of mRNA COVID-19 vaccines in adolescents were presented.
For Information	

June 30, 2021

Presentation: COVID-19 Vaccine Guidance for Individuals Vaccinated Abroad	The NACI Secretariat provided a presentation on guidance for vaccination of individuals who received COVID-19 vaccines outside of Canada that are not authorized by Health Canada. An overview was provided on jurisdictional and international guidance on COVID-19 vaccines received abroad.
For Information	
Discussion: COVID-19 Vaccine Guidance for Individuals Vaccinated Abroad	Following the presentation, committee members discussed the World Health Organization (WHO) regulatory process for COVID-19 vaccines as well as evidence, acceptability and ethical considerations for this guidance. Committee members will reconvene this discussion and a decision on guidance following this meeting.
For Discussion	

June 29, 2021

Discussion: Dose schedule for previously infected	Following the presentations and updates provided, committee members discussed the evidence and its implications on NACI guidance for COVID-19 vaccination for individuals with previous SARS-CoV-2 infection. The NACI Secretariat will update the
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For Discussion	statement summarizing recent evidence on vaccination of individual with previously confirmed SARS-CoV-2 infection and recommendation will be updated to reflect discussion and decisions by the Committee.
Health Canada Regulatory Status Update For Information	Health Canada (HC) provided a verbal update on labelling modifications to the product monographs (PM) for COVID-19 vaccines.
PHAC Safety Update For Information	The PHAC Vaccine Safety section provided a verbal update on Canadian rates for myocarditis and pericarditis related to mRNA COVID-19 vaccination.

June 24, 2021

Presentation: Optimal Dosing Interval for COVID-19 Vaccine For Information	To help inform discussions at an upcoming meeting of Chief Medical Officers of Health, PHAC provided an overview of evidence on optimal dosing interval for COVID-19 vaccines for informal feedback from NACI members.
Discussion: Optimal Dosing Interval for COVID-19 Vaccine For Discussion	Following the presentation, NACI members provided feedback on optimal dosing intervals for homologous/heterologous COVID-19 vaccine schedules. NACI will continue to discuss optimal intervals as further evidence emerges.

June 15, 2021

Health Canada Regulatory Status Update For Information	Health Canada (HC) provided a brief regulatory status and safety update on COVID-19 vaccines in Canada, including updates on ongoing reviews of myocarditis/pericarditis and capillary leak syndrome (CLS).
PHAC Safety Update For Information	The PHAC Vaccine Safety section provided a verbal update on thrombosis with thrombocytopenia syndrome (TTS), myocarditis/pericarditis, Guillain-Barré Syndrome (GBS) and capillary leak syndrome (CLS) in Canada following COVID-19 vaccination.
Presentation: Update on Myocarditis/Pericarditis following mRNA COVID-19 vaccines For Information	The NACI Secretariat provided an update on myocarditis and pericarditis international evidence following mRNA COVID-19 vaccines.

June 9, 2021

Presentation: Epidemiological impact of adult COVID-19 vaccination program on adolescents and children in Israel For Information	The presenter from the Israel Ministry of Health provided an update on adolescent COVID-19 disease rates, and observed cases of myocarditis following Pfizer COVID-19 vaccination in Israel. Following the presentation, meeting participants were invited to ask questions to the presenter.
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Discussion on Myocarditis
For Discussion / Decision

Due to time constraints, the discussion on Myocarditis recommendations will be held at the next NACI meeting on June 15, 2021.

Introduction of New NACI Member and Liaisons
For Information

The NACI Chair provided an update on the new NACI voting member and liaison representatives. These new members were welcomed to the committee and introduced themselves, including a liaison representative for the Indigenous Physicians Association of Canada (IPAC); the Canadian Pharmacists Association (CPhA); and the Canadian Indigenous Nurses Association (CINA).

June 1, 2021

Health Canada

Regulatory Status Update

For Information

The presenter from Health Canada (HC) provided a regulatory update on COVID-19 vaccines.

PHAC Safety Update

For Information

The PHAC Vaccine Safety surveillance unit provided an update on international reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines and current myocarditis cases counts in Canada following COVID-19 vaccination, in relation to background rates. The presenter also provided a summary of Guillain-Barre Syndrome (GBS) cases following COVID-19 vaccination in Canada, in relation to background rates.

May 26, 2021

**Mixed schedules/
interchangeability update for
authorized COVID-19 vaccines**
For Information

NACI Secretariat provided an update on NACI's COVID-19 vaccine interchangeability recommendations, including an overview of safety studies on mixed schedules.

**Update on heterologous COVID-19
vaccine schedule study, Spain
(CombiVacS study)**
For Information

The presenter from The Carlos III Health Institute (ISCIII) in Madrid provided an update on the CombiVacS phase 2 randomized, multicenter, adaptive trial to evaluate the safety and immunogenicity of *Comirnaty* (Pfizer BioNTech) in subjects that had received one dose of *Vaxzeveria* (Oxford-AstraZeneca).

**Discussion on NACI mixed-
schedule / interchangeability of
authorized COVID-19 vaccines
recommendation**
For Discussion and Decision

Following the previous presentations, NACI discussed a recommendation on the interchangeability of the authorized COVID-19 vaccines (also referred to as "mixed vaccine schedules") in a two-dose primary series schedule for COVID-19 immunization in Canada. The committee came to a consensus on discretionary recommendations to allow interchangeability of authorized COVID-19 vaccines.

May 18, 2021

Health Canada Update:

Health Canada (HC) provided an update on the regulatory perspective

**Myocarditis International
Perspective**
For Information

regarding reports of myocarditis following Pfizer COVID-19 vaccination internationally.

May 4, 2021

**Presentation: Heterologous
COVID-19 vaccine schedule
study**
For Information

The presenter from the University of Oxford provided an update on interim COM-COV data comparing the safety of heterologous versus homologous prime/boost schedules administered at a 4 week interval.

**** See Attached Article ** Canada pausing distribution of Johnson & Johnson vaccine**

Last Updated Apr 30, 2021 at 8:48 pm EDT

Canada is pausing distribution of the recent shipment of the Johnson & Johnson COVID-19 vaccine after Health Canada learned part of them were manufactured at a Maryland facility that messed up the ingredients in 15 million doses bound for the U.S. market.

April 26, 2021

**Presentation: Janssen
Benefit-Risk
Recommendations**
For Information

NACI Secretariat provided an update on the current context for Janssen, an overview of the benefit-risk analysis, and the proposed NACI recommendations for the Janssen vaccine.

**Discussion: Janssen
Benefit-Risk
Recommendations**
For Discussion / Decision

Following the presentation, NACI members deliberated on the proposed NACI recommendations. Majority of voting members voted in favor of aligning the AstraZeneca and Janssen vaccines, recommending that use can be considered in individuals 30 years of age and older with informed consent, based on epidemiological context, and considering time to mRNA vaccine availability for each age group.

April 17, 2021

**Discussion on
AstraZeneca
recommendation**
For Discussion /
Approval

NACI discussed principles of ethics, equity, feasibility, and acceptability in relation to the AstraZeneca vaccine induced immune thrombotic thrombocytopenia safety signal. The committee voted in favour of a benefit-risk framework to inform jurisdictions and individuals about the relative benefits and risks of AstraZeneca vaccine while waiting for mRNA supply, which varies across age groups.

Those receiving the AstraZeneca vaccine
were to be told of the Risks Prior but I personally
know several people who were NEVER TOLD!

March 30, 2021 (?? Why is NACI still discussing in their meeting minutes the safety signal status and yet the CBC releases that NACI has changed the age range to those over 55 on March 29 ?? No decision is noted in the minutes prior on this.)

Discussion: AstraZeneca safety status and next steps, implications for Janssen update
For Discussion

The NACI Chair provided an update on the AstraZeneca safety signal status and next steps, and PHAC provided an overview of implications for the NACI Statement recommendations. Based on the presentation provided, the Committee discussed the implications of this information on current and upcoming NACI recommendations.

**** See Article from CBC **** Noting the recommendation by NACI to withdraw AstraZeneca

<https://www.cbc.ca/news/politics/astrazeneca-under-55-1.5968128>

CBC News · Posted: Mar 29, 2021 1:04 PM ET | Last Updated: March 29

"Canada's National Advisory Committee on Immunization (NACI) is recommending provinces pause the use of the AstraZeneca-Oxford COVID-19 vaccine on those under the age of 55 because of safety concerns — guidance most provinces said today that they would follow."

March 24-25, 2021

Presentation: Safety on AstraZeneca - European Medicines Agency (EMA) Review
For Information

PHAC provided an update on the recent AstraZeneca COVID-19 vaccine safety signal (risk of thrombosis and thrombocytopenia). The presentation covered summaries of the European Medicines Agency (EMA) statement (dated March 18, 2021), information from the Paul-Erich Institut in Germany, recommendations from Regulatory Agencies, and National Immunization Technical Advisory Groups (NITAGs).

Discussion: Safety of AstraZeneca
For Discussion

Based on the presentation provided, the Committee discussed the available evidence and implications for the current NACI recommendations and statement.

Presentation: Janssen Recommendations
For Information

PHAC highlighted key issues for discussion and provided an evidence summary to inform proposed changes to NACI COVID-19 vaccine recommendations.

March 16, 2021

Presentation: Janssen data updates and proposed recommendations
For Information

PHAC provided an update on NACI COVID-19 Guidance and recent evidence for Janssen viral vector vaccine.

Discussion on proposed Janssen recommendations
For Discussion / Decision

Based on the presentation provided, the Committee discussed the evidence and proposed recommendations on the use of the Janssen COVID-19 vaccine. Members agreed that further work on the recommendations is required and this will be brought to the next NACI meeting for discussion.

No evidence to suggest AstraZeneca's COVID-19 vaccine causing adverse events: Tam
(See full article attached)

*Why is Tam Not aware of risks at this point?
She sits on Board for the World Health Organization?*

<https://www.cbc.ca/news/politics/astrazeneca-naci-65-recommendation-1.5951305>

Canada's chief public health officer said today there is no evidence to suggest the AstraZeneca-Oxford COVID-19 vaccine is causing adverse events — and the vaccine's benefits outweigh any risks.

Dr. Theresa Tam told reporters at a media briefing that federal, provincial and territorial authorities are "continuously monitoring" vaccine safety after nearly a dozen European countries suspended the vaccine's use in response to concerns about blood clots.

"Health Canada is aware of reports of serious adverse events in Europe following immunization with the AstraZeneca vaccine, but wants to reassure Canadians that the benefits of the vaccine continue to outweigh its risks," she said.

"There is currently no indication that the vaccine caused the observed event."

To date, she added, "no unexpected vaccine safety issues have been identified in Canada."

February 8, 2021

**Public Health England (PHE)
Vaccine Effectiveness Data
Presentation**

The presenter provided an overview of data sources, limitations, risks of bias and preliminary vaccine effectiveness (VE) for the Pfizer BioNTech COVID-19 vaccine roll-out in the United Kingdom.

For Information

January 28, 2021

**AstraZeneca COVID-19 Vaccine
Recommendations**

- **Background Information**
- **Overall populations recommendation**
- **Administration and special population recommendations**

NACI Secretariat presented options for AstraZeneca COVID-19 Vaccine Recommendations. Members discussed public health factors and the implications of integrating AstraZeneca vaccine into the mRNA vaccine programs already underway in Canada.

Members reached consensus on appropriate ages and intervals, and discussed potential recommendations for populations and how this vaccine might be used in context of other available options in the event the AstraZeneca vaccine is authorised by Health Canada. NACI will consider recommendations on other clinical issues through later approvals.

For Approval

December 17, 2020

COVID-19 Vaccine

The NACI Secretariat presented the NACI evergreen Statement:

Recommendations- Moderna Update

For Approval

Recommendations on the use of COVID-19 Vaccines (Moderna Update) to members for their review. This included consideration of how to integrate Moderna vaccine into recommendations, in the event of regulatory authorisation, in addition to clarifications in the special population recommendations (pregnancy, breastfeeding, immunocompromised, autoimmune) in response to questions from jurisdictions and frontline immunizers. NACI approved proposed recommendations.

December 7, 2020

COVID-19 Vaccine Recommendations

For Approval

Proposed recommendations for COVID-19 vaccines, and specifically for the Pfizer-BioNTech COVID-19 vaccine, were presented to members. Recommendations were approved with adjustments. Recommendations covered topics such as recommended age groups, recommended dosing intervals, immunization of those previously infected with SARS-CoV-2, immunization of special populations (e.g. pregnancy, immunocompromised), and recommendations for continuity of public health measures in vaccine recipients.

Health Canada authorizes first COVID-19 vaccine

<https://www.canada.ca/en/health-canada/news/2020/12/health-canada-authorizes-first-covid-19-vaccine0.html>

Canada pausing distribution of Johnson & Johnson vaccine

by News Staff and The Canadian Press

<https://toronto.citynews.ca/2021/04/30/canada-is-pausing-distribution-of-johnson-johnson-vaccines/>

Posted Apr 30, 2021 6:22 pm EDT

Last Updated Apr 30, 2021 at 8:48 pm EDT

Canada is pausing distribution of the recent shipment of the Johnson & Johnson COVID-19 vaccine after Health Canada learned part of them were manufactured at a Maryland facility that messed up the ingredients in 15 million doses bound for the U.S. market.

The Emergent Biosolutions facility in Baltimore was recently cited by the U.S. Food and Drug Administration for violations including cleaning and sterilization failures, the potential for cross-contamination and failure to follow required protocols.

The FDA ordered the facility to stop making more J&J vaccine until the problems are corrected and the earlier mistake on the doses resulted in all 15 million being destroyed.

Health Canada had already cleared 1.5 million doses of the Oxford-AstraZeneca vaccine made at the facility, but did not think the Canadian J&J doses had any connection to that plant.

Now Health Canada says the drug substance that makes up part of the J&J vaccine was actually produced there and then shipped elsewhere for the vaccines to be finished.

Health Canada says it is seeking information from the FDA and J&J's pharmaceutical arm, Janssen, to determine if the 300,000 doses shipped to Canada meet required safety standards.

In a statement, Health Canada says those doses will only be released when "once Health Canada is satisfied that they meet the Department's high standards for quality, safety and efficacy."

A spokesperson for Health Minister Patty Hajdu said the government was made aware of the information late Friday – the same day that Health Canada decided to communicate it with Canadians.

The J&J vaccine has not been used in Canada so far, and the National Advisory Committee on Immunization hasn't yet provided guidance on how they think it should be used.

Why Canada is suspending use of AstraZeneca vaccine in people under 55

No reported cases of rare blood clots after vaccinations in Canada, but Health Canada still assessing risk

Adam Miller · CBC News · Posted: Mar 29, 2021 4:17 PM ET | Last Updated: March 29

<https://www.cbc.ca/news/health/canada-suspends-astrazeneca-vaccine-covid-19-1.5968657>

A change in advice has renewed apprehension around the AstraZeneca vaccine, which has been compounded by contradictory messages in Ontario. There's also concern the confusion will add to vaccine hesitancy. 3:14

Canada's vaccine advisory committee is recommending immediately suspending the use of the AstraZeneca-Oxford COVID-19 vaccine in Canadians under 55 following reports of rare but potentially fatal blood clots in Europe that appear to be connected to the shot.

The National Advisory Committee on Immunization (NACI) updated its guidelines to provinces and territories against the use of the vaccine for younger Canadians on Monday over safety concerns.

Health Canada said Monday that 300,000 doses of AstraZeneca vaccine have been administered and no cases of the rare blood clotting adverse events have been reported in Canada, but that it was aware of additional cases that have recently been reported in Europe.

Quebec, Ontario, Alberta, Saskatchewan, Manitoba, Newfoundland and Labrador and Prince Edward Island have all suspended the use of the vaccine for anyone below the age of 55. Other provinces and territories are expected to follow.

Dr. Isaac Bogoch, an infectious diseases physician and member of Ontario's COVID-19 vaccine task force said that the discovery of a potential connection with the vaccine to blood clots raised a "red flag" that "warrants further exploration."

"People should appreciate that not all blood clots are created the same," he said. "This is a very specific and particular method of blood clotting that likely has an association with the vaccine."

Risk of blood clots seems not to affect older age groups: NACI

NACI previously recommended earlier this month that Canadians over 65 not receive the shot, despite emerging evidence from around the world demonstrating its ability to prevent severe COVID-19 in older adults.

But that guidance changed on March 16 after more real-world data on the vaccine's effectiveness was reviewed by NACI, and CBC News broke the story revealing documents on the federal government's plans to allow those 65 and older to receive it.

"This vaccine has had all the ups and downs — it looks like a roller coaster," said Dr. Caroline Quach, chair of NACI and a pediatric infectious diseases expert. "The problem is because data are evolving, we are also evolving our recommendations."

Quach said the risk of rare blood clots appears to only occur in younger populations, which is why NACI recommended suspending the vaccine in those under 55.

"What we're doing is trying to contrast the risks and benefits," she said. "So if you have that vaccine versus having to wait for two months while COVID is ramping and you're at risk of catching it and having complications from it, I think that taking the vaccine is the best option at this point."

Quach added that the vaccine works well in preventing severe outcomes and death in older populations over 55, particularly in those over 70, and the risk of blood clots does not appear to be present in those age groups.

Dr. Supriya Sharma, Health Canada's chief medical adviser, discusses NACI's recommendation to pause the use of AstraZeneca's COVID-19 vaccine on those under the age of 55. 1:34

"What we need to have is continued confidence in our expert review panel that it's looking at these vaccines and deciding what is going to be best, safest and most effective for Canadians," said Alyson Kelvin, an assistant professor at Dalhousie University and virologist at the Canadian Center for Vaccinology in Halifax.

"This is a new vaccine to a new virus, it's really important that we're following all the data as closely as possible and as the vaccines are rolling out, we're understanding them more and reviewing what the guidance should be."

- Suspend AstraZeneca use for people under 55, vaccine committee recommends

Dr. Zain Chagla, an infectious diseases physician at St. Joseph's Healthcare Hamilton and an associate professor at McMaster University, said NACI is taking a calculated risk by recommending older Canadians still get the vaccine because they are at higher risk of severe outcomes from COVID-19.

"Scientifically, it makes sense," he said. "This isn't saying that everyone under 55 is going to get this complication. It's the slight risk of this complication seems to be more predisposed in this age group. But again, the raw numbers seem to be very, very low."

What led to Canada's decision to suspend AstraZeneca

The decision to halt the use of the vaccine in Canadians under 55 comes after the European Medicines Agency (EMA) investigated 25 cases of the rare blood clots out of about 20 million AstraZeneca shots given. It concluded on March 18 that the benefits from the vaccine far outweigh its possible risks, although a definitive link could not be ruled out.

But 18 of the cases in Europe were of an extremely rare type of blood clot called cerebral venous sinus thrombosis (CVST) — where veins that drain blood from the brain are obstructed and can potentially cause fatal bleeding.

The EMA said on March 18 at least nine deaths have been associated with the adverse events in Europe and the agency is continuing to investigate the situation.

- Health Canada changes AstraZeneca vaccine label to add information about blood clots

Germany's medical regulator told The Associated Press on Monday it had received reports of 21 cases of rare blood clots in people who had recently received AstraZeneca's coronavirus vaccine.

The Paul Ehrlich Institute also said that seven people affected by the blood clots have died. It added that of the 21 cases reported in Germany until March 25, 12 also involved an abnormally

"We are being fully transparent. Maybe it's too transparent, I don't know," says Dr. Caroline Quach-Thahn, Chair of the National Advisory Committee on Immunization. NACI issued guidance for the AstraZeneca vaccine for the third time, now recommending a pause for those under 55. 4:34

Nineteen of the 21 cases were in women ages 20 to 63, while two were in men ages 36 and 57. During the period covered by the reports, some 2.27 million first doses of the AstraZeneca vaccine were administered in Germany.

"You cannot ignore the blood clots that have been associated with AstraZeneca globally," said Bogoch. "It's not entirely clear what the true incidence of this is, but it does appear to be a rare event."

What Canadians need to know about the AstraZeneca vaccine

The federal health ministry said it would be requiring both manufacturers, AstraZeneca and India's Serum Institute, to conduct risk assessments by age and gender — but is requesting more data before deciding whether or not to change authorization of it in Canada.

Health Canada had previously updated the vaccine's label with information on the rare blood clotting events.

Canadian health officials said during a press conference Monday the specific syndrome is being called Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) and that they are in contact with European officials about it.

The National Advisory Committee on Immunization (NACI) updated its guidelines against the use of the vaccine for younger Canadians on Monday. (Dado Ruvic/Reuters)

"I do understand why Canadians might feel worried," said Canada's Deputy Chief Public Health Officer Dr. Howard Njoo.

"What I can say is that the chief medical officers of health of the provinces and territories take vaccine safety very seriously and we want Canadians to have confidence in these vaccines."

Officials added that Germany's Paul Ehrlich Institute reported VIPIT has an incidence rate of about one in 100,000, with a mortality rate of about 40 per cent, although more research is needed and that risk is reduced if treated early enough.

"Where the true rate is, we just don't know at this point in time," said NACI Co-Chair Dr. Shelley Deeks. "But we are continuing to follow the data, as it emerges."

Pausing the use of the AstraZeneca vaccine in people under the age of 55 was a precautionary measure, says Dr. Shelley Deeks of the National Advisory Committee on Immunization. Deeks also said that the NACI continues to revise guidance based on evidence. 12:00

Symptoms to watch for

The Public Health Agency of Canada released a statement on Monday saying that "there is no cause for concern" for Canadians who have already been vaccinated with AstraZeneca for more than 20 days, but that you should seek immediate medical attention in the rare event you develop the following symptoms four or more days after vaccination:

- Shortness of breath.
- Chest pain.
- Leg swelling.
- Persistent abdominal pain.
- Sudden onset of severe or persistent worsening headaches or blurred vision.
- Skin bruising (other than at the site of vaccination).

PHAC said decisions on the type of second dose that will be offered to those who have been vaccinated with AstraZeneca will be determined based on the "latest evidence and research."

Most of the complications in Europe occurred within 14 days of receiving the AstraZeneca shot, and the majority were in women under the age of 55. It's worth noting that CVST is typically more common in women, particularly during and after pregnancy, while on birth control and hormone replacement therapy.

Germany and Italy resumed vaccinations with the shot on March 19, but France opted to vaccinate only those over 55 with it after discovering several cases of CVST. Denmark and Norway have suspended the use of the vaccine altogether for at least three weeks, while Sweden has resumed the use of the vaccine in those over 65.

"The real question here is, how common is it, and are there identifiable risk factors for this? That way, we could probably continue to use this vaccine in people with very, very low risks of having a blood clot and selectively vaccinate people who would benefit," Bogoch said.

"If there is that risk, we would hopefully have better data to support who we could safely and selectively vaccinate with this product."

Benefits still outweigh risks, says vaccine maker

A spokesperson for AstraZeneca Canada said in a statement the company respects the decision by NACI but stressed that Health Canada's guidance to health care providers around the use of the vaccine remains unchanged.

"Regulatory authorities in the U.K., European Union, the World Health Organization and Health Canada have concluded that the benefits of using our vaccine to protect people from this deadly virus significantly outweigh the risks across all adult age groups," the statement read.

"Tens of millions of people have now received our vaccine across the globe. The extensive body of data from two large clinical data sets and real-world evidence demonstrate its effectiveness, reaffirming the role the vaccine can play during this public health crisis."

Chagla said NACI's decision will likely hurt confidence in the vaccine in the eyes of Canadians, especially among those over 55 who may be left "scratching their heads" as to why the vaccine is being recommended for their age group but not younger people.

"I, unfortunately, envision this vaccine is going to have a limited rollout in Canada moving forward," he said.

"Even if the dust starts settling, and it's a completely separate issue or it's much lower risk than expected, I don't think you're going to get many under 55-year-olds to get this vaccine anymore and that's the reality."