Health Care Professional Town Hall: COVID-19 vaccination: Adverse Events Following Immunization (AEFIs)

Thursday, June 24, 2021

The webinar will begin at 5 p.m.
If you run into technical difficulties, please email Javier.rincon@halton.ca

Agenda

- Update on COVID-19 vaccination in Halton

- Adverse Events Following Immunization (AEFIs)
  - What they are
  - How to report
  - Specific AEFIs

- Questions and Answer session

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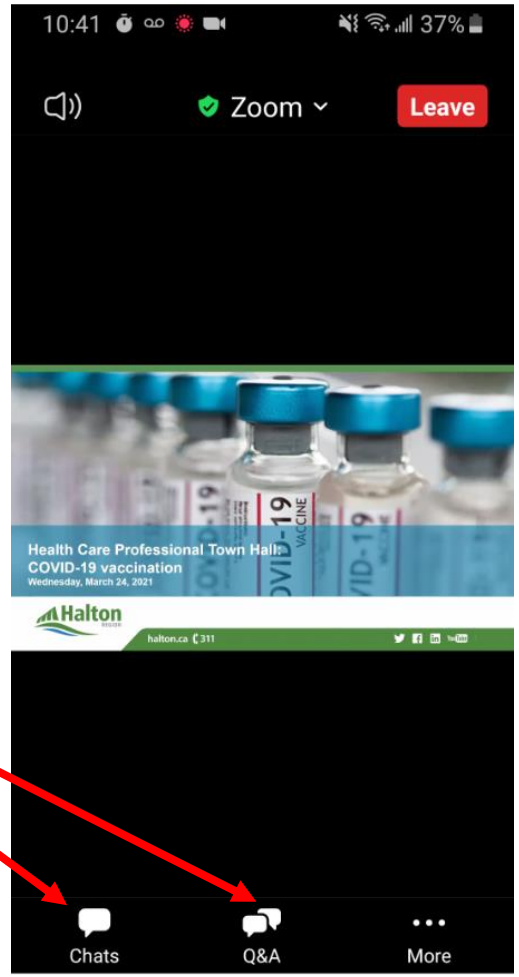
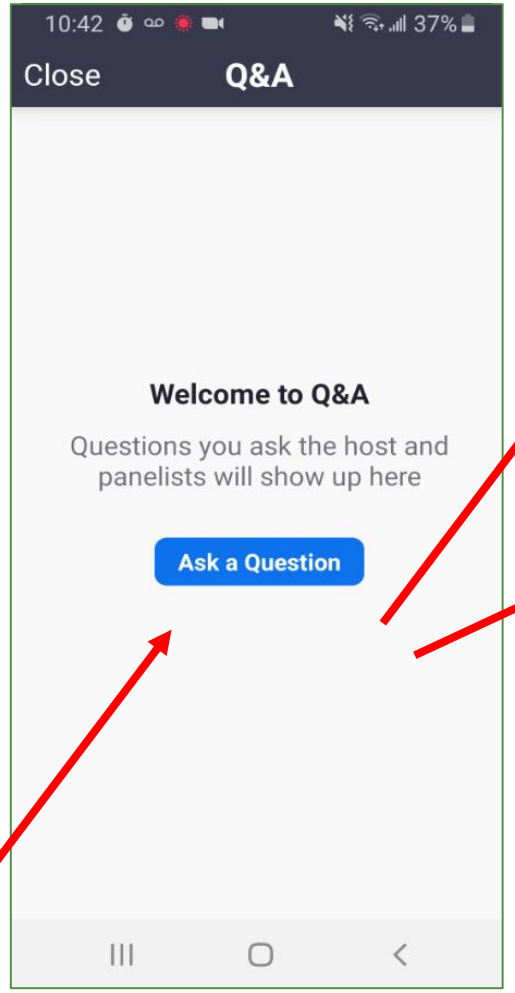
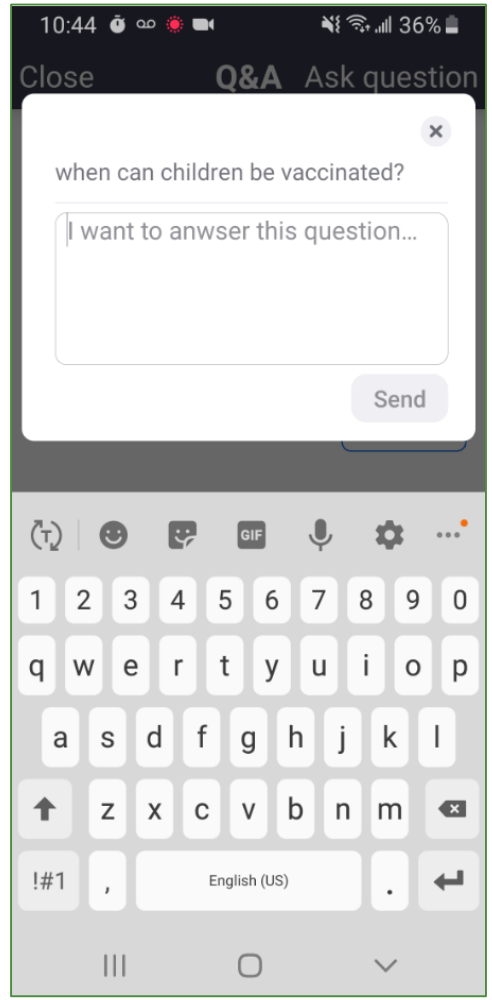




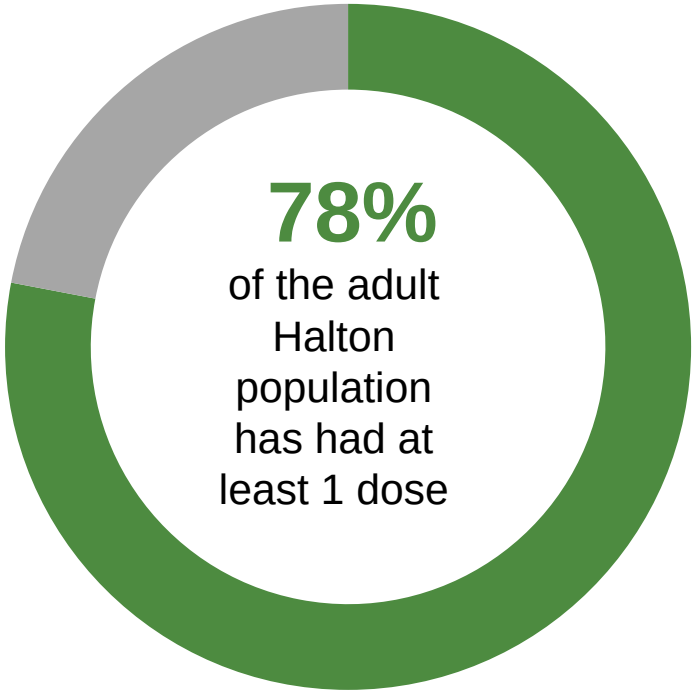


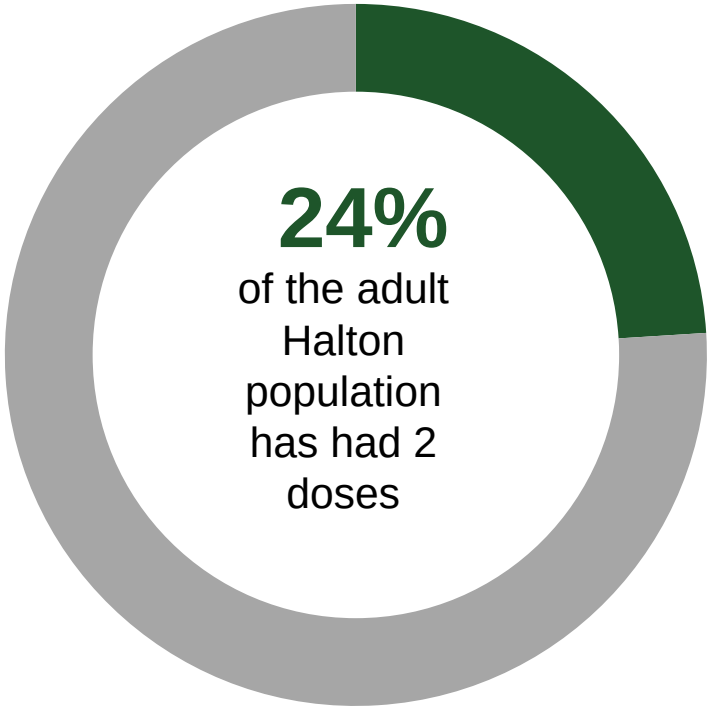
Use the Q&A function to ask, vote or comment on a question

Vaccine Rollout Progress and Update

COVID-19 Vaccination coverage

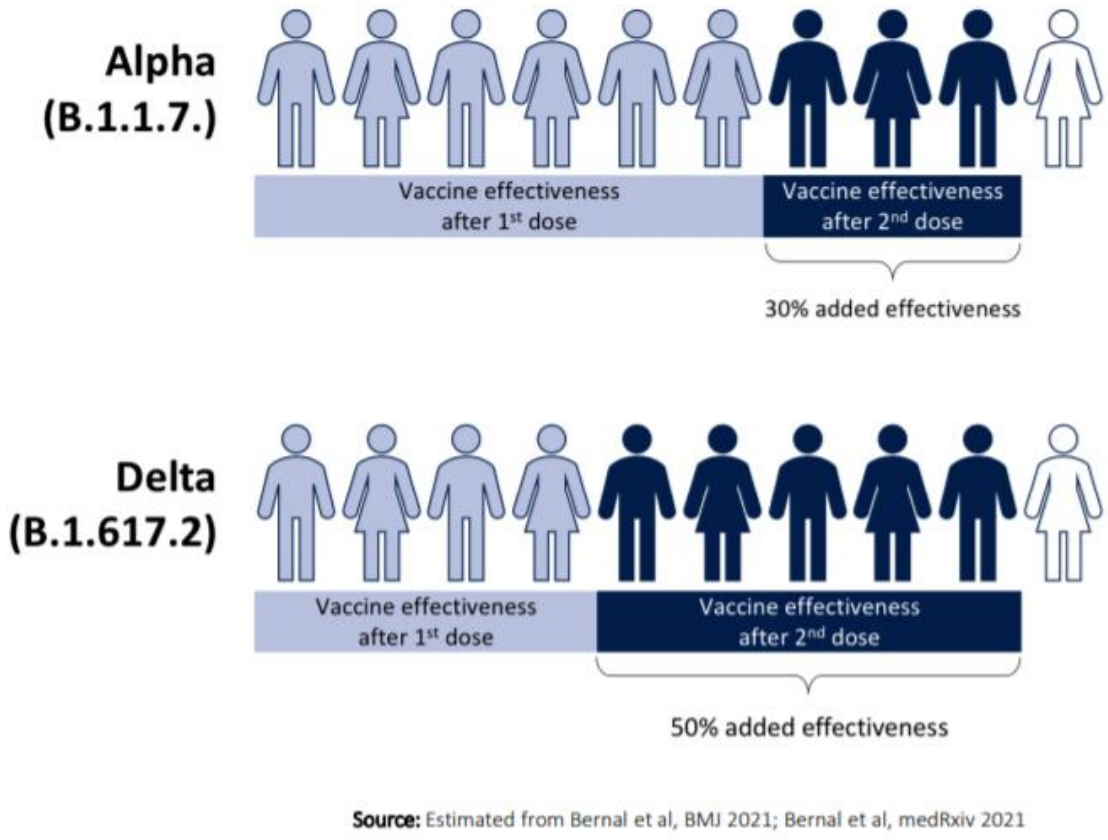
As of end of day on June 22, 2021:





COVID-19 Delta variant

- Delta variant will likely be the dominant variant by early summer
- Vaccine effectiveness against the Delta variant is improved by two doses
- Halton is part of a provincial strategy to target Delta hotspots with accelerated two-dose coverage
- Pfizer and Moderna are both mRNA vaccines are interchangeable
  - It is more important to get fully vaccinated than wait for a specific product



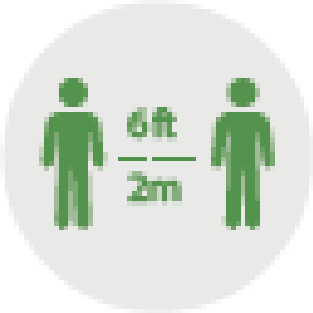
SOURCE: Ontario Science Advisory Table, Update on COVID-19 Projections, June 10, 2021

Continue public health measures

Get fully vaccinated against COVID-19

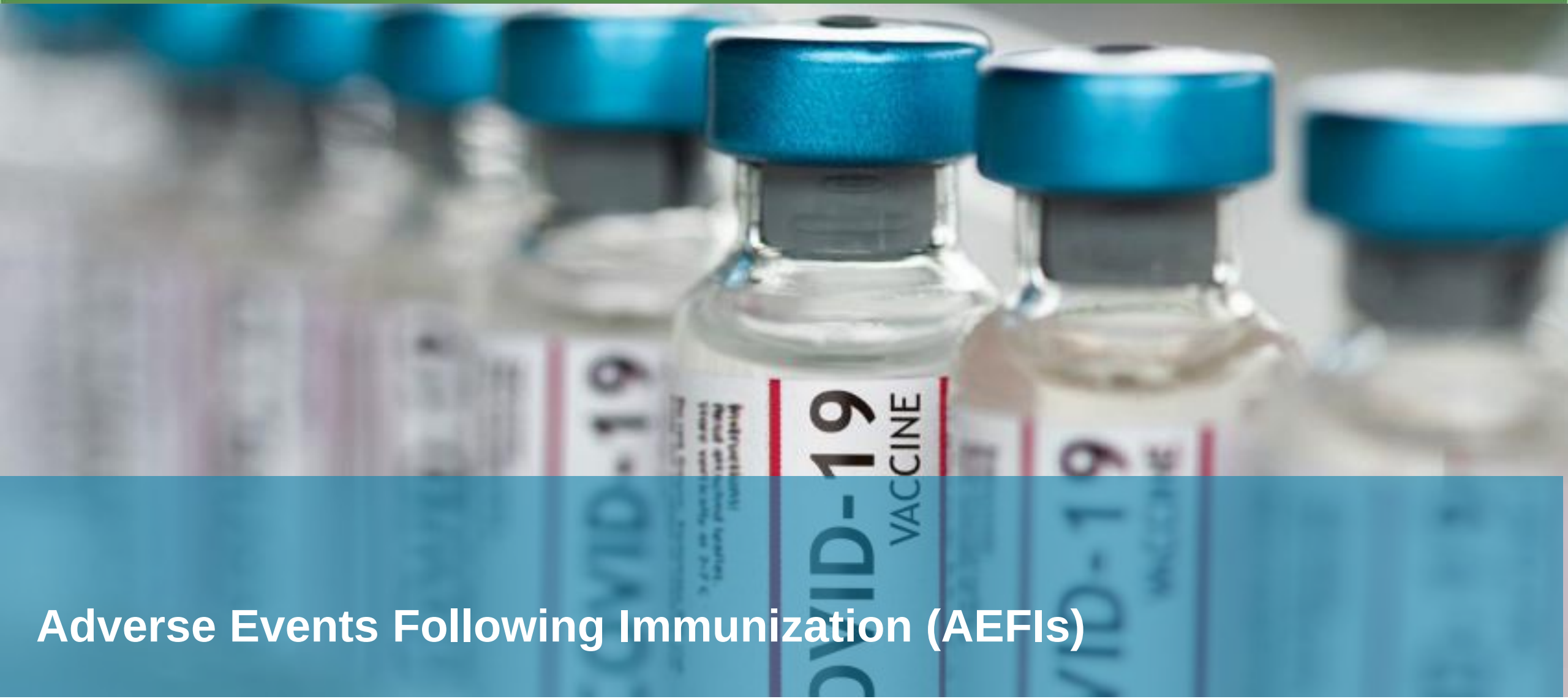
Stay home and get tested if you are not feeling well

Wash your hands with soap and water



Maintain 2 metres **physical distance** from others

Wear a mask when physical distancing is not possible



Adverse Events Following Immunization (AEFIs)

What is an AEFI? Why do we track them?

- An adverse event following immunization (AEFI):
  - an unwanted or unexpected health effect that happens after someone receives a vaccine
  - may or may not be caused by the vaccine
- Part of the local, provincial, national and international surveillance system to monitor vaccine safety:
  - Generate and test hypotheses about AEFIs, especially in specific populations which may have been excluded or under-represented from controlled studies
  - Rapidly identify any problems with specific vaccine lots/brands
  - Estimate rates of AEFIs in real world settings

What is not an AEFI?

- Excludes side effects:
  - Known to be associated with vaccine
  - Typically mild and short-term
  - Events clearly attributed to other causes
- Excludes:
  - 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

Assessing causality from AEFI reports can be challenging

- Vaccines are given to a large number of mostly healthy people to prevent disease.
  - Any change in health status temporally associated with vaccine is easily attributed to the vaccine, even if the health event was going to occur anyway
- Many health events have no known specific cause (e.g. autoimmune disorders) or have many known contributing causes (e.g. MI, stroke)
- The baseline rate of many health events are difficult to track, especially if subclinical cases are common (e.g. diarrheal illness, early pregnancy loss)

AEFI Reporting Trends in Halton

- Prior to COVID pandemic, Halton Public Health typically received 25-35 confirmed AEFI reports per year
- From January 2021 to current, Halton Public Health has received over 865 reports of possible AEFIs related to COVID-19 vaccines
- Of these 865 reports, 239 have been confirmed AEFIs among Halton residents, meeting the case definition
- 11 confirmed non-COVID vaccine AEFIs in 2021
- Reports come through various channels - HCP reporting, clients self-reporting through 311/intake lines

AEFIs in Halton

Table 1: Summary of AEFIs reported among Halton residents, by vaccine product, as of June 22, 2021

	Pfizer-BioNTech	Moderna	AstraZeneca	All products combined
Total number of AEFI reports	139	58	42	**239**
Number of non-serious reports	136	56	35	**227**
Number of serious reports	3	2	7	**12**
Doses administered	340,299	77,526	30,491	**448,316**
Total reporting rate per 100,000 doses administered	40.8	74.8	137.7	**53.3**
Total serious reporting rate per 100,000 doses administered	0.9	2.6	23.0	**2.7**

AEFI adverse reactions

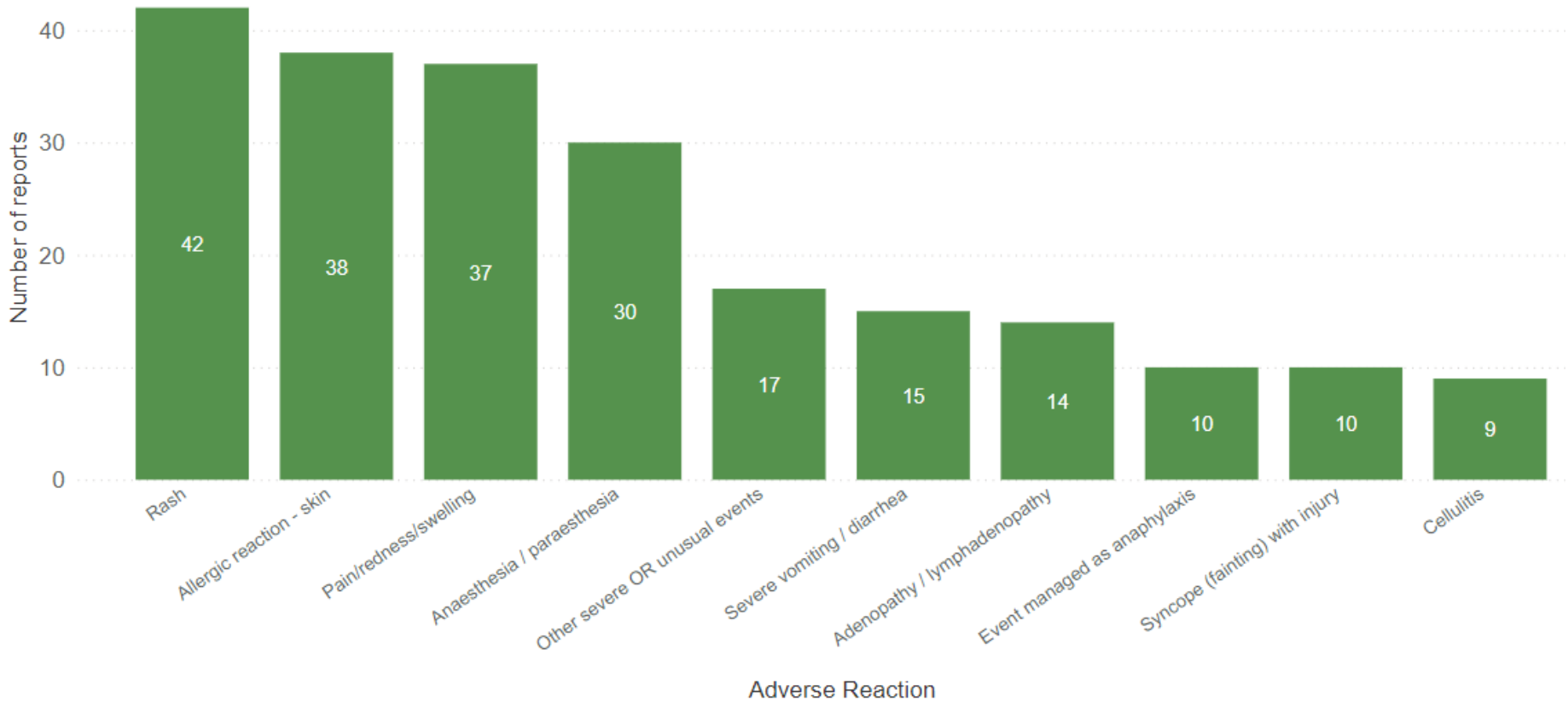
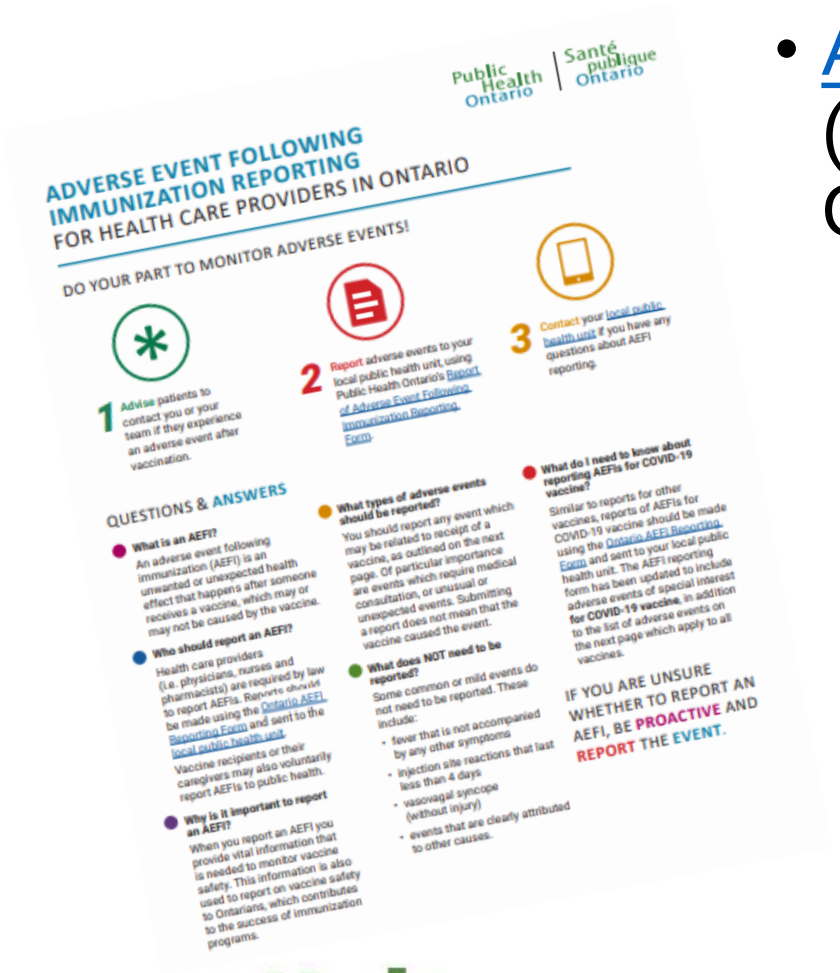


Figure 1: Top ten adverse reactions reported among Halton AEFI cases, as of June 22, 2021

Help identifying AEFIs



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ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING FOR HEALTH CARE PROVIDERS IN ONTARIO

DO YOUR PART TO MONITOR ADVERSE EVENTS!

1 Advise patients to contact you or your team if they experience an adverse event after vaccination.

2 Report adverse events to your local public health unit, using Public Health Ontario's Report of Adverse Event Following Immunization Reporting Form.

3 Contact your local public health unit if you have any questions about AEFI reporting.

QUESTIONS & ANSWERS

What is an AEFI?
An adverse event following immunization (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.

Who should report an AEFI?
Health care providers (i.e. physicians, nurses and pharmacists) are required by law to report AEFIs. Reports should be made using the Ontario AEFI Reporting Form and sent to the local public health unit.
Vaccine recipients or their caregivers may also voluntarily report AEFIs to public health.

Why is it important to report an AEFI?
When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information is also used to report on vaccine safety to Ontarians, which contributes to the success of immunization programs.

What types of adverse events should be reported?
You should report any event which may be related to receipt of a vaccine, as outlined on the next page. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

What does NOT need to be reported?
Some common or mild events do not need to be reported. These 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.

What do I need to know about reporting AEFIs for COVID-19 vaccine?
Similar to reports for other vaccines, reports of AEFIs for COVID-19 vaccine should be made using the Ontario AEFI Reporting Form and sent to your local public health unit. The AEFI reporting form has been updated to include adverse events of special interest for COVID-19 vaccine, in addition to the list of adverse events on the next page which apply to all vaccines.

IF YOU ARE UNSURE WHETHER TO REPORT AN AEFI, BE PROACTIVE AND REPORT THE EVENT.

- AEFI fact sheet, (Public Health Ontario)
  - Table lists types of adverse events that should be reported, including estimated timelines between vaccination and onset of symptoms

TYPES OF ADVERSE EVENTS TO REPORT

The table below lists the types of adverse events that you should report to your local public health unit. For each event there are estimated timelines between vaccination and onset of symptoms (i.e., temporal criteria). Other events not listed below can also be reported if they are clinically significant. If you are unsure, be proactive and report.

Adverse event type	TEMPORAL CRITERIA for Non-live vaccines	TEMPORAL CRITERIA for Live vaccines
Injection site reactions	**Non-live vaccines**	**Live vaccines**
Pain or redness or swelling lasting 4 days or more OR extending beyond the nearest joint	0 to 2 days	0 to 7 days
Infected abscess	0 to 7 days	0 to 7 days
Sterile abscess	0 to 7 days	0 to 7 days
Nodule	0 to 7 days	0 to 7 days
Cellulitis	0 to 7 days	0 to 7 days
Systemic reactions	**Non-live vaccines**	**Live vaccines**
Rash	0 to 7 days	0 to 42 days
Adenopathy/lymphadenopathy	0 to 7 days	0 to 42 days
Severe vomiting/diarrhea	0 to 3 days	0 to 42 days
Parotitis	N/A	0 to 30 days
Hypotonic-hyporesponsive episode (HHE); under 2 years of age only	0 to 2 days	0 to 2 days
Persistent crying/screaming; under 2 years of age only	0 to 3 days	0 to 3 days
Allergic reactions	**Non-live vaccines**	**Live vaccines**
Event managed as anaphylaxis (i.e., epinephrine administered)	0 to 24 hours	0 to 24 hours
Oculorespiratory Syndrome (ORS)	0 to 24 hours	0 to 24 hours
Allergic skin reaction (e.g., hives)	0 to 2 days	0 to 2 days
Neurologic events	**Non-live vaccines**	**Live vaccines**
Convulsions/seizure	0 to 3 days	0 to 42 days
Encephalopathy/encephalitis	0 to 42 days	0 to 42 days
Meningitis	0 to 15 days	0 to 42 days
Anaesthesia/paraesthesia	0 to 42 days	0 to 42 days
Paralysis	0 to 42 days	0 to 42 days
Myelitis/transverse myelitis	0 to 42 days	0 to 42 days
Acute disseminated encephalomyelitis (ADEM)	0 to 42 days	0 to 42 days
Guillian Barré Syndrome (GBS)	1 to 8 weeks	1 to 8 weeks
Bell's palsy	0 to 3 months	0 to 3 months
Other events of interest*	**Non-live vaccines**	**Live vaccines**
Arthritis/arthralgia	0 to 30 days	0 to 42 days
Intussusception	N/A	0 to 42 days
Thrombocytopenia	0 to 42 days	0 to 42 days
Syncope (fainting) with injury	0 to 30 minutes	0 to 30 minutes
Kawasaki disease	0 to 42 days	0 to 42 days
Other severe/unusual events	Reportable regardless of timeline	Reportable regardless of timeline

*Other adverse events of special interest for COVID-19 vaccine have been added to the Ontario AEFI Reporting Form, please refer to the form for a complete list of types of adverse events to report.

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For questions about AEFI reporting, contact your **local public health unit**.
PublicHealthOntario.ca/VaccineSafety

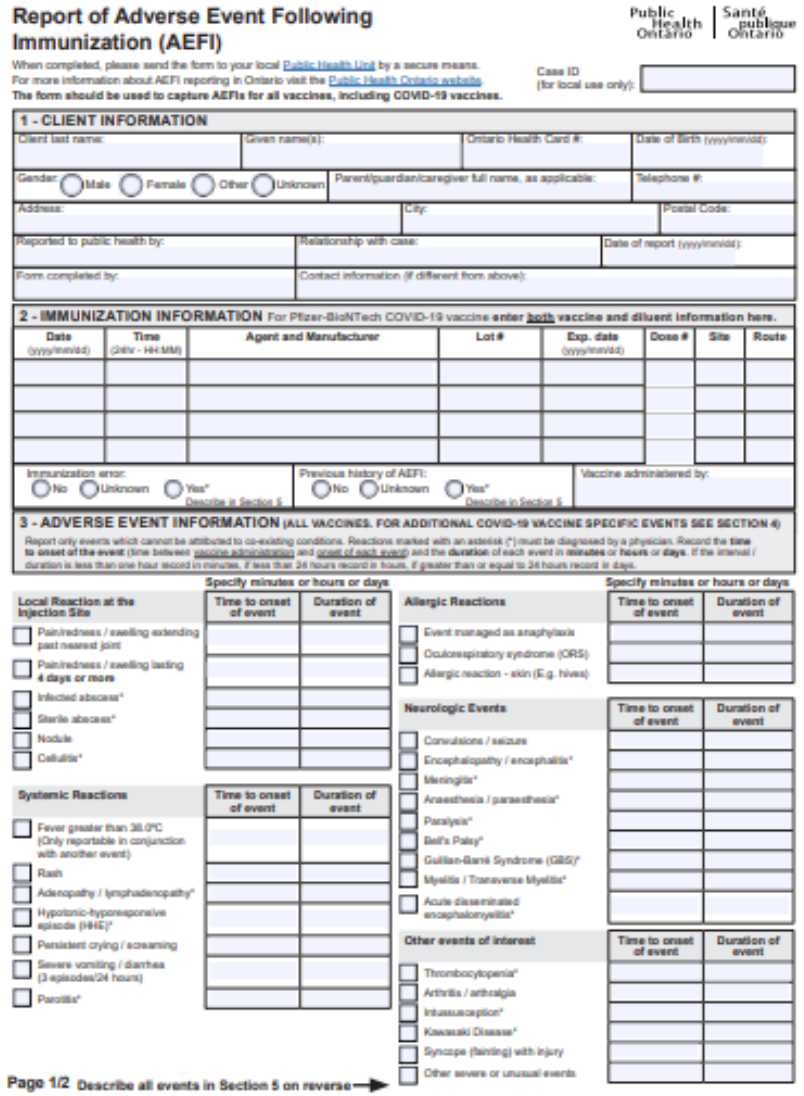
Ontario

Halton REGION

How to report AEFIs following COVID-19 vaccine

1. Complete Ontario AEFI reporting form (Ministry of Health) – 3 page form updated in May 2021

2. Fax to 905-465-3403 or Email to AEFI@halton.ca



Report of Adverse Event Following Immunization (AEFI)

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When completed, please send the form to your local Public Health Unit by a secure means.
For more information about AEFI reporting in Ontario visit the Public Health Ontario website.
The form should be used to capture AEFIs for all vaccines, including COVID-19 vaccines.

Case ID (for local use only):

1 - CLIENT INFORMATION

Client last name: | Given name(s): | Ontario Health Card #: | Date of Birth (yyyy/mm/dd):

Gender: Male Female Other Unknown | Parent/guardian/caregiver full name, as applicable: | Telephone #:

Address: | City: | Postal Code:

Reported to public health by: | Relationship with case: | Date of report (yyyy/mm/dd):

Form completed by: | Contact information (if different from above):

2 - IMMUNIZATION INFORMATION For Pfizer-BioNTech COVID-19 vaccine **enter both vaccine and diluent information here.**

Date (yyyy/mm/dd)	Time (24hr - HH:MM)	Agent and Manufacturer	Lot #	Exp. date (yyyy/mm/dd)	Dose #	Site	Route

Immunization error: No Unknown Yes* Describe in Section 5 | Previous history of AEFI: No Unknown Yes* Describe in Section 5 | Vaccine administered by:

3 - ADVERSE EVENT INFORMATION (ALL VACCINES. FOR ADDITIONAL COVID-19 VACCINE SPECIFIC EVENTS SEE SECTION 4)

Report only events which cannot be attributed to co-existing conditions. Reactions marked with an asterisk (*) must be diagnosed by a physician. Record the **time to onset of the event** (time between vaccine administration and onset of each event) and the **duration** of each event in **minutes** or **hours** or **days**. If the interval / duration is less than one hour record in minutes, if less than 24 hours record in hours, if greater than or equal to 24 hours record in days.

Specify minutes or hours or days

Local Reaction at the Injection Site	Time to onset of event	Duration of event
Pain/redness / swelling extending past nearest joint		
Pain/redness / swelling lasting 4 days or more		
Infected abscess*		
Sterile abscess*		
Nodule		
Cellulitis*		

Systemic Reactions	Time to onset of event	Duration of event
Fever greater than 38.0°C (Only reportable in conjunction with another event)		
Rash		
Adenopathy / lymphadenopathy*		
Hypotonic-hyporesponsive episode (HHE)*		
Persistent crying / screaming		
Severe vomiting / diarrhea (3 episodes/24 hours)		
Parotitis*		

Specify minutes or hours or days

Allergic Reactions	Time to onset of event	Duration of event
Event managed as anaphylaxis		
Oculorespiratory syndrome (ORS)		
Allergic reaction - skin (E.g. hives)		

Neurologic Events	Time to onset of event	Duration of event
Convulsions / seizure		
Encephalopathy / encephalitis*		
Meningitis*		
Anaesthesia / paraesthesia*		
Paralysis*		
Bell's Palsy*		
Guillain-Barré Syndrome (GBS)*		
Myelitis / Transverse Myelitis*		
Acute disseminated encephalomyelitis*		

Other events of interest	Time to onset of event	Duration of event
Thrombocytopenia*		
Arthritis / arthralgia		
Intussusception*		
Kawasaki Disease*		
Syncope (fainting) with injury		
Other severe or unusual events		

Page 1/2 **Describe all events in Section 5 on reverse**

What to report?
(Adverse Event Following Immunization)

Local reaction at injection site

- Pain/redness/swelling extending past nearest joint
- pain/redness/swelling lasting >4 days
- Infected abscess
- Sterile abscess
- Nodule
- Cellulitis

Systematic reactions

- Fever >38.0°C (only with another event)
- Rash
- Adenopathy/lymphadenopathy
- Hypotonic-hyporesponsive episode (HHE)
- Persistent crying/screaming
- Severe vomiting/diarrhea (3 episodes/24 hrs)
- parotitis

Allergic reactions

- Event managed as anaphylaxis
- Oculorespiratory syndrome (ORS)
- Allergic reaction – skin (e.g. hives)

Neurologic Events

- Convulsions/seizures
- Encephalopathy/encephalitis
- Meningitis
- Anaesthesia/paresthesia
- Paralysis
- Bell's Palsy
- Guillian-Barre Syndrome (GBS)
- Myelitis/Transverse Myelitis
- Acute disseminated encephalomyelitis

Other events of interest

- Thrombocytopenia
- Arthritis/arthralgia
- Intussusception
- Kawasaki Disease
- Syncope with injury
- Other severe or unusual events

What is an AESI?
(Adverse Events of Special Interest)

Vaccine-associated enhanced disease (VAED)	Multisystem inflammatory syndrome in children or adults (MIS-C/A)
Acute respiratory distress syndrome (ARDS)	Acute cardiovascular injury
Coagulation disorders	Acute kidney injury
Acute liver injury	Anosmia, ageusia
Chilblain – like lesions	Single Organ Cutaneous Vasculitis
Erythema multiforme	Acute pancreatitis
Rhabdomylysis	Subacute thyroiditis

What to report vs not report

What to report
Events requiring medical consultation or unusual/unexpected events
Injection site reactions >4 days or extending beyond nearest joint
Systematic reactions (rash, severe vomiting)
Allergic reactions (severe hives, anaphylaxis)
Neurologic events
Other events of interest

What not to report
Fever, without any other symptoms
Injection site reactions lasting <4 days
Vasovagal syncope (without injury)
Events clearly attributed to other causes

What to expect after reporting an AEFI

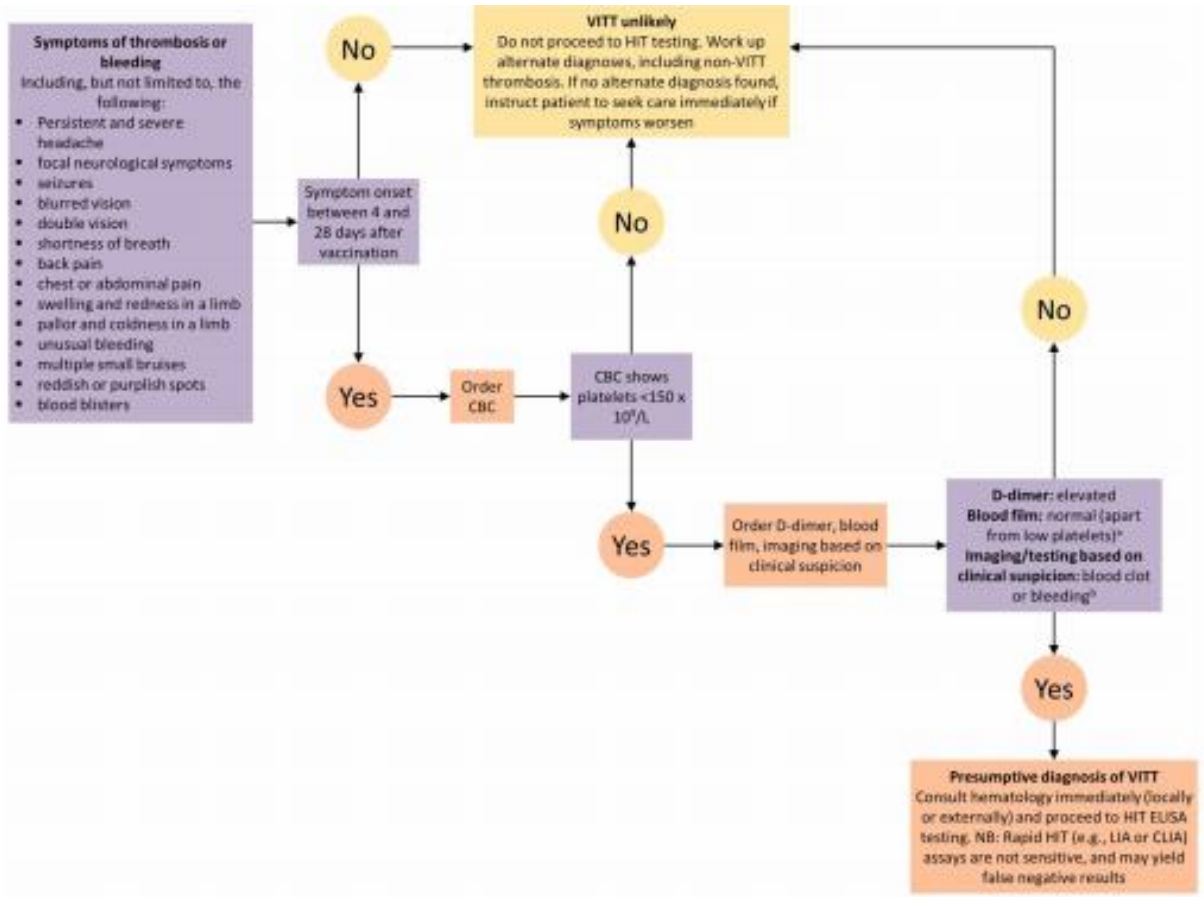
- Review by Medical Officer of Health or Associate Medical Officer of Health
- Public Health may call HCP for further details
- AEFI status and categorization determined
- Communication to HCP regarding final determination and immunization schedule moving forward
- Reported to Public Health Ontario and then Public Health Agency of Canada
- AEFI reporting enables:
  - Post-market vaccine surveillance locally, provincially, nationally
  - Reporting of AEFIs to HCPs and the public (e.g. PHO's Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario and the Vaccine Safety Surveillance Tool)

Specific AEFIs of interest following COVID-19 vaccination

VIIT (Vaccine-induced Immune Thrombocytopenia)

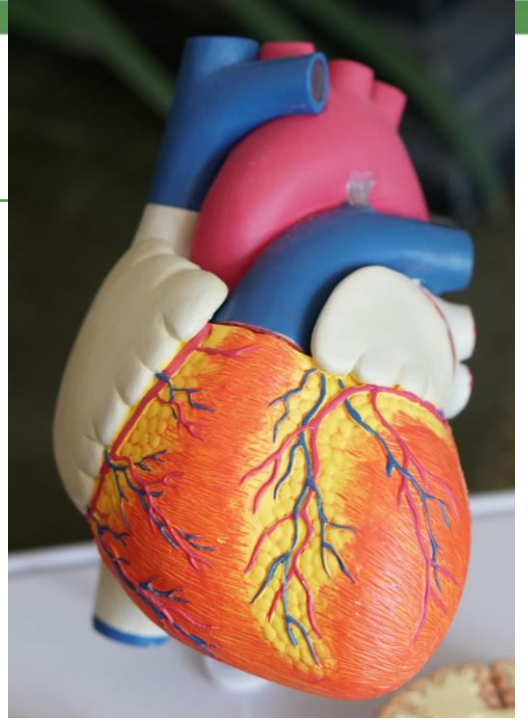
Symptoms of thrombosis

- Persistent, severe headache
- Focal neurological symptoms
- Seizures
- Blurred vision
- Double vision
- Shortness of breath
- Back pain
- Chest or abdominal pain
- Swelling and redness in a limb
- Pallor and coldness in a limb
- Unusual bleeding
- Multiple small bruises
- Reddish or purplish spots
- Blood blisters



[Ontario COVID-19 Science Advisory Table, May 10, 2021](#).

Myocarditis and pericarditis



Symptoms of myocarditis/pericarditis

- Chest pain
- Shortness of breath
- Arrhythmias
- Feeling of having a rapid or abnormal heart rhythm

- More common:
  - Males, 12-29 y.o.
  - after 2nd dose
- Usually within 1 week of vaccination
- Usually recover with conservative treatment
- No change in vaccine recommendations, at this time

Reports of myocarditis/pericarditis after COVID-19 vaccination FAQ for health-care providers (source: Sick Kids)

Changes to menstrual cycle and impact on fertility

Menstrual Cycle

- Anecdotal reports of changes to menstrual cycle
- Possible that immunomodulatory effects of vaccine have impact, but would be temporary. Persistent changes to menstrual cycle should be investigated for other causes

Fertility

- No evidence of impact on fertility in men or women
- No plausible cross-reactivity between spike protein antibodies and syncytin-1
- In Pfizer trial, no difference in conception rate between vaccine and placebo
- In contrast, strong evidence of worse outcomes from COVID-19 during pregnancy

What about…

- Herpes simplex virus (HSV) flare, Shingles?
  - No evidence of relationship, not a contraindication to vaccine
  - Concerns may have been prompted by a case series of herpes zoster in people with inflammatory rheumatic disease
  - Six cases of HZ within 14 days of immunization, one case of HZ ophthalmicus. Control group consisted of healthy vaccine recipients
  - Does not appear to be a greater rate than expected for this group.
- Second dose symptoms – Why are they worse? How long after vaccination can they start (3-5 days?)
  - Increased side effects following the second dose in a multi-dose series is typical. The immune system is primed to respond to the second dose
  - AZ is different in that side effects appear to be greater following the first dose compared to the second

Any expected AEFIs from mixing platforms?

- UK Com-COV trial preliminary findings that heterologous vaccination schedules related to increased side effects (both Pfizer – AZ and AZ – Pfizer)
- Increased systemic reactogenicity: fever chills, fatigue, headache, joint pain, malaise, and muscle ache
- Spanish CombivacS trial did not find a difference

All side effects short-lived, no serious adverse events reported
NACI recommends mRNA second dose for those with AZ first dose

Questions?

Email doctors@halton.ca
Call 311

halton.ca/COVIDvaccines


ME
THANK YOU
THANK YOU
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STAY 6 FEET AWAY

AEFIs demographics

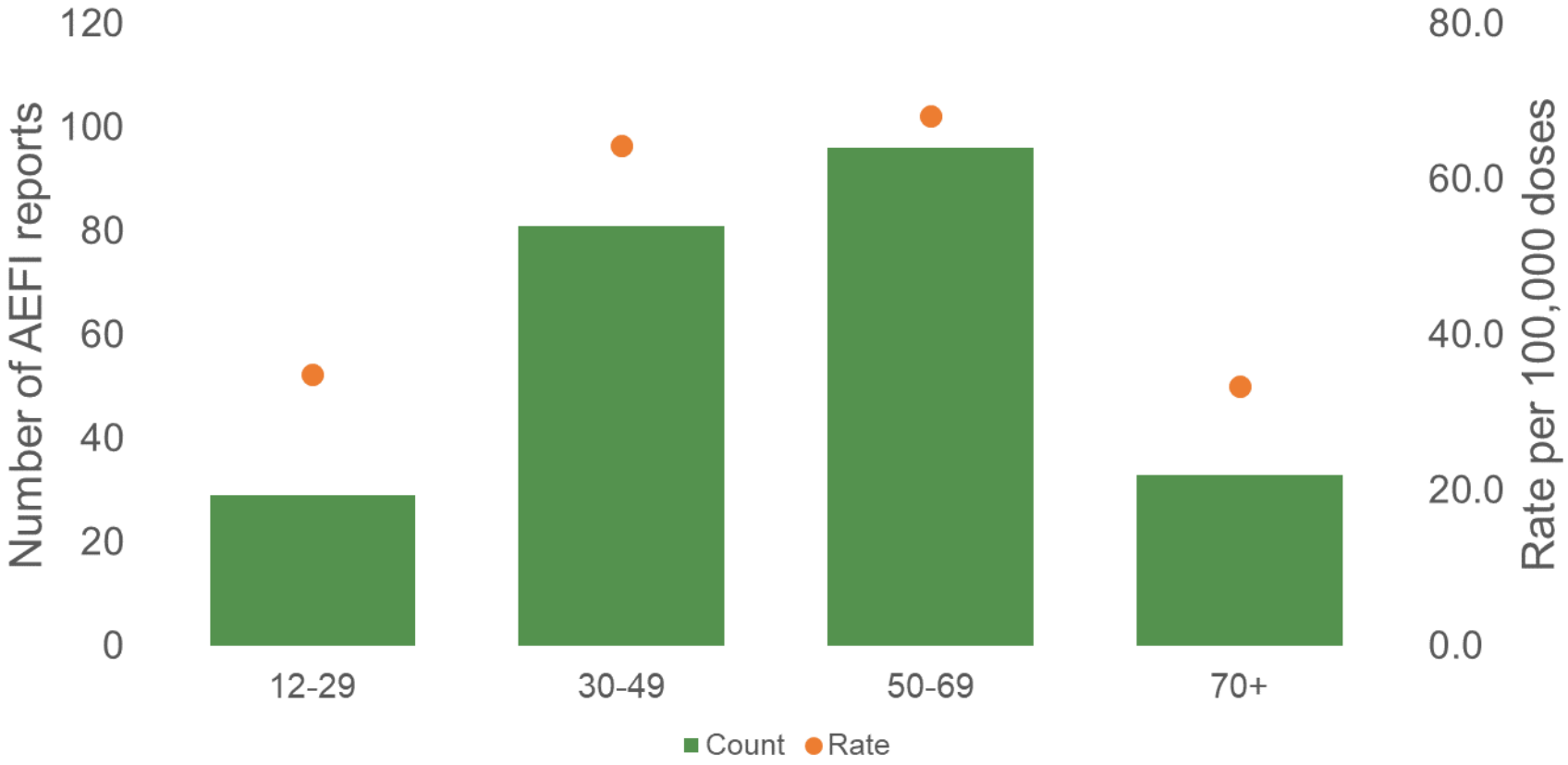

Figure 2: Number and age-specific rate of AEFI reports in Halton residents, as of June 22, 2021