



Office of the

Chief Medical
Health Officer

NORTH ISLAND
250.331.8591

Charmaine Enns
MD MHSc FRCPC
355-11th Street
Courtenay, BC V9N 1S4

CENTRAL ISLAND
250.739.6304

Sandra Allison
MD MPH CCFP FCFP FRCPC

Mike Benusic
MD MPH FRCPC

3rd Floor, 6475 Metral Drive
Nanaimo, BC V9T 2L9

COWICHAN AREA
250.737.2020

Shannon Waters
MD MHSc FRCPC
4th floor
238 Government St
Duncan, BC V9L 1A5

SOUTH ISLAND
250.519.3406

Richard Stanwick,
CMHO
MD MSc FRCPC FAAP

Murray Fyfe
MD MSc FRCPC

Dee Hoyano
MD FRCPC CCFP

1837 Fort Street
Victoria, BC V8R 1J6

After Hours On Call
1.800.204.6166

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COVID-19 Vaccination Update #2: Adverse Events

What is an AEFI?

An adverse event following immunization (AEFI) is an unwanted health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine. These range from expected mild side effects such as injection site pain, to severe events like encephalitis that may only be coincidentally related.

What AEFIs should be reported?

In general, the following events **should** be reported:

- Serious events: life threatening or resulting in death; requiring hospitalization; resulting in a residual disability; associated with congenital malformation
- Event requiring urgent medical attention
- A significant event that you are unsure whether is related to the vaccine or not
- Note: A causal relationship between receipt of a vaccine and an AEFI does not need to be proven to be reported. This may be determined by public health on review.

In general, the following events should **not** be reported:

- Local injection site reactions (including delayed local injection site reactions, which have been reported to occur 7-9 days after Moderna immunization, and were seen in 0.8% of participants in Moderna trials - see 'safety' at bit.ly/3tc3rXa)
- Non-specific systemic reactions
- Events that have another obvious cause (for example, co-existing conditions)

A detailed table of reportable AEFIs with temporal criteria can be found on page 7 of the BCCDC AEFI guide: bit.ly/39b8E9I

Why should an AEFI be reported?

Reporting an AEFI allows for guidance for further vaccinations to individual patients, is a requirement under the Public Health Act (bit.ly/3r33kv2), and is essential for post-marketing surveillance - of which for COVID-19 vaccines is updated federally at bit.ly/2MPi1mE. So far, reported AEFIs for COVID-19 vaccines are in the general expected incidence and types.

How are AEFIs reported?

Clinical management and reporting of an AEFI is the responsibility of the vaccine provider (if an immediate event occurs) or the treating health care professional (if client seeks subsequent care). Providing individualized guidance for future vaccinations and population surveillance of AEFIs is the responsibility of public health.

AEFI reporting for COVID-19 vaccine follows the same guidelines and process established by the BCCDC for all vaccines, available at bit.ly/2MEbwDp. For submitted AEFIs, guidance will be provided directly to the client and to the primary care provider if a MHO recommendation is required.

Resources:

- Island Health COVID-19 Vaccine Page (for public): bit.ly/3rfNOfl
- Island Health COVID-19 Vaccination Resources for Medical Staff: bit.ly/2LbpKLq
- BCCDC COVID-19 Immunization Program Q+A for Health Care Professionals: bit.ly/3sQotKN
- NACI Recommendations on the use of COVID-19 Vaccines: bit.ly/368Fx5c