Vaccine Safety - What can we learn from Administrative Data Linkages

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Land Acknowledgement

I acknowledge that this work was carried out on the traditional, ancestral, and unceded territory of the Coast Salish Peoples, including the territories of the xwməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), Stó:lō and Səl̓ílwətaʔ/Selilwitulh (Tsleil-Waututh) Nations.

Today, I am joining from the city of Halifax, located in Mi’kma’ki, the ancestral and unceded territory of the Mi’kmaq people. The people of the Mi’kmaw Nation have lived on this territory for millennia, and we acknowledge them as the past, present and future caretakers of this land.
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Introduction

• Data from healthcare encounters are captured in various datasets

• Integration of health encounter data \(\rightarrow\) longitudinal medical history
  • Health surveillance systems
  • Assessment of care gaps
  • Intervention effectiveness evaluation
  • Pharmacovigilance

• Integrated data used for vaccine safety monitoring
BC COVID-19 Cohort (BCC19C)

**COVID-19 Related Data**
- COVID-19 Case Surveillance: 2020 onward
- COVID-19 Hospital Census (PCMS): 2020 onward
- COVID-19 Lab Tests & Sequencing: 2020 onward
- COVID-19 Vaccinations: 2020 onward

**Population/Demographic**
- Chronic Disease Registry: 2008 - 2019/20
- Client Roster: 2008 onward
- Health System Matrix: 2018/19
- Population Grouper Data: 2008 onward
- Socioeconomic Census Data (DA-level): 2016
- Vital Statistics: 2008 onward

**Administrative/Laboratory**
- Emergency Department Visits (Health Authority, NACRS): 2020 onward
- Hospitalizations (DAD): 2008 onward
- Medical Visits (MSP): 2008 onward
- Medications (PharmFall): 2008 onward
- Influenza Lab Tests: 2008 onward
- Private and Public Lab Tests (PLIS): 2020 onward
- #11 Call Data (respiratory related): 2014 onward

**Refresh Cycles**
- Daily
- Weekly
- Monthly
- Yearly
- Census Year

**Data Stewards**
- Regional Health Authority
- Provincial Health Services Authority
- Ministry of Health
- Statistics Canada

DA = Dissemination Area; DAD = Discharge Abstracts Database; MSP = Medical Services Plan;
NACRS = National Ambulatory Care Reporting System; PCMS = Provincial COVID-19 Monitoring Solution;
PLIS = Provincial Laboratory Information Solution

*contain data for entire BC population*
Vaccine Safety Studies Using BCC19C

• Estimation of background rates

• Observed Versus Expected Rates of Myocarditis After SARS-CoV-2 Vaccination

• Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Coronavirus Vaccine

• Assessment of Myocarditis Following mRNA COVID-19 Booster Vaccination Among Adult Recipients
Observed Versus Expected Rates of Myocarditis After SARS-CoV-2 Vaccination

• **Design:** Observational study using data from the BC COVID-19 Cohort from Dec. 15, 2020, to Mar. 10, 2022

• **Primary exposure:** Any dose of an mRNA vaccine against SARS-CoV-2

• **Primary outcome:** Hospitalization or emergency department visit for myocarditis or myopericarditis within 7 and 21 days postvaccination

• **Analysis:** Myocarditis rates per 100,000 mRNA vaccine doses, expected rates of myocarditis cases and observed to-expected ratios
Observed and Expected Myocarditis Rates and OE Ratios Using 7-day Risk Window in British Columbia

99 incident cases of myocarditis within 7 days (0.97 cases/100,000 vaccine doses; observed v. expected ratio 14.81)
Myocarditis Rates Following 2\textsuperscript{nd} Vaccine Dose Using 7-day Risk Window by Age, Sex and Vaccine Product
Summary

• Absolute rates of myocarditis following mRNA vaccines were low

• Highest observed-to-expected ratio was seen after the second dose among males aged 18–29 years

• Highest rate observed among males aged 18–29 years who received the mRNA-1273 vaccine

• Findings support the preferential use of the BNT162b2 vaccine over the mRNA-1273 vaccine for people aged 18–29 years
Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Vaccines

- **Objective:** To compare the risk of myocarditis, pericarditis between recipients of BNT162b2 and mRNA-1273 vaccines

- **Data source:** British Columbia COVID-19 Cohort (BCC19C)

- **Exposure:** Second dose of an mRNA vaccine

- **Outcome:** Diagnosis of myocarditis, pericarditis, or myopericarditis during a hospitalization or an emergency department visit within 21 days of the second vaccination dose

- **Analysis:** Multivariable logistic regression to assess the association between vaccine product and the outcomes of interest
Myocarditis Study Population and Participant Enrollment Flowchart

Participants aged ≥18 years, received 2nd dose of mRNA COVID vaccination between Dec 15, 2020, and Sept 9, 2021 (n = 3,204,555)

Exclusion Criteria
- Administered out of BC either first dose or second dose (n = 109,012)
- Had myocarditis history within 1 year before vaccination (n = 129). Among these, 1 individual had post-vaccination event

Fulfilled the eligibility criteria (n = 3,095,414)

Received BNT162b2 (n = 2,223,454)
- Developed myocarditis within 21 days postvaccination (n = 28)
- Did not develop myocarditis within 21 days postvaccination (n = 2,223,426)

Received mRNA-1273 (n = 871,960)
- Developed myocarditis within 21 days postvaccination (n = 31)
- Did not develop myocarditis within 21 days postvaccination (n = 871,929)

Myocarditis rate
- 12.6; 95% CI: 8.4-18.2
- 35.6; 95% CI: 24.1-50.5
Rate of Myocarditis Per 1 Million Doses by Vaccine Product, Sex, and Age Group (Years)
Overall and Stratified Logistic Regression Results (Adjusted Odds Ratios With 95% CIs)

- mRNA-1273 vs BNT162b2 at Age ≥40 y
- mRNA-1273 vs BNT162b2 at Age 18-39 y
- mRNA-1273 vs BNT162b2 at Sex = Female
- mRNA-1273 vs BNT162b2 at Sex = Male
- mRNA-1273 vs BNT162b2 Overall

Summary

Comparative risk of myocarditis/pericarditis following second doses of BNT162b2 and mRNA-1273 coronavirus vaccines

Myocarditis and pericarditis following mRNA COVID-19 vaccines is rare.

People who received Moderna Spikevax were 2–3 times more likely to experience myocarditis or pericarditis than people who received Pfizer BioNTech.

The association between Moderna Spikevax and myocarditis was stronger for men aged 18–39.


Assessment of Myocarditis Following mRNA COVID-19 Booster Vaccination Among Adult Recipients

- **Objective:** To estimate the rate of myocarditis following the mRNA COVID-19 booster vaccination dose of the mRNA vaccine

- **Data source:** British Columbia COVID-19 Cohort (BCC19C)

- **Exposure:** Booster (third) dose of an mRNA vaccine

- **Outcome:** Diagnosis of myocarditis, pericarditis, or myopericarditis during a hospitalization or an emergency department visit within 7 days of the second and booster vaccination doses

- **Analysis:** Myocarditis rates, rate ratios and risk difference between 2nd and 3rd dose
Myocarditis Events Post 2\textsuperscript{nd} and Booster Doses, Rates/Million Doses During a 7-day Risk Window

- **Overall**: Rate/1,000,000 doses, Dose 2: 17.92, 95%CI: 13.74 – 22.97
  - Booster: 6.08, 95%CI: 3.32 - 10.21

### Rates per Vaccine and Age Group

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>18-29 Males</th>
<th>30-39 Males</th>
<th>Female</th>
<th>Male 18-29</th>
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</table>
Summary

• Linked administrative data are an important tool for vaccine safety surveillance

• Myocarditis following mRNA vaccines is rare

• People who receive Moderna Spikevax were 2-3 times more likely to experience myocarditis than people who received Pfizer BioNTech following 2nd dose

• The rate and association between Moderna Spikevax and Myocarditis was strongest among males 18-29 years following 2nd dose

• Rate of myocarditis following booster dose was lower than following second dose and there was no difference between Moderna Spikevax and Pfizer BioNTech
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Disclaimer

• All inferences, opinions, and conclusions drawn in this presentation are those of the author(s), and do not reflect the opinions or policies of the BC Ministry of Health and Data Steward(s).
Thank you!

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