

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 Səlílwətaʔ/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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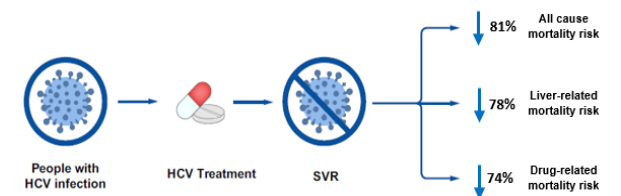
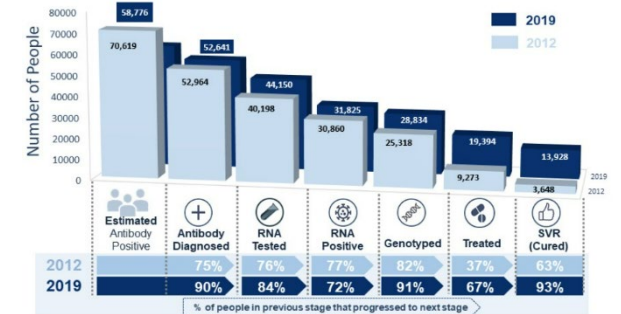


BC Immunization Forum 2023 Presenter Disclosure

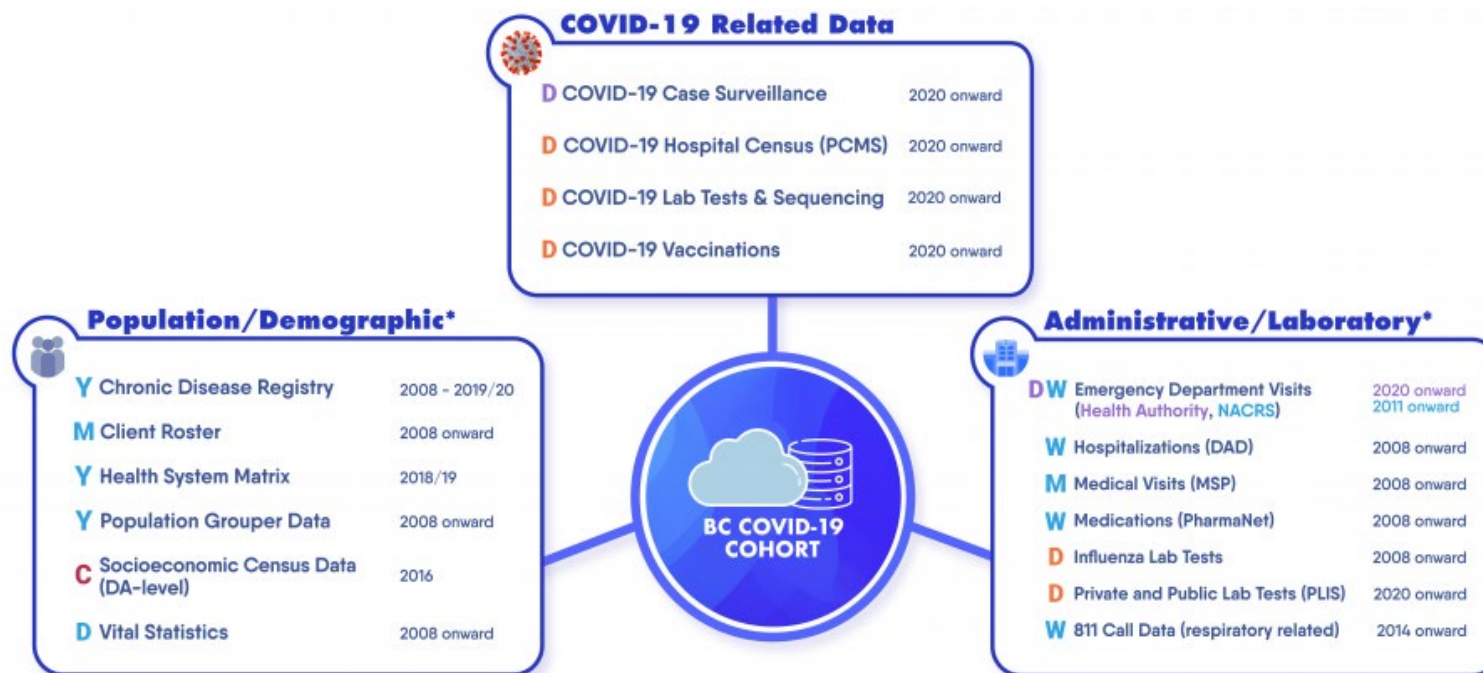
- [Naveed Janjua](#)
- **Relationships with financial sponsors:**
 - Memberships on advisory boards or speakers' bureau: [AbbVie](#), [Gilead](#)

Introduction

- Data from healthcare encounters are captured in various datasets
- Integration of health encounter data → 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)



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

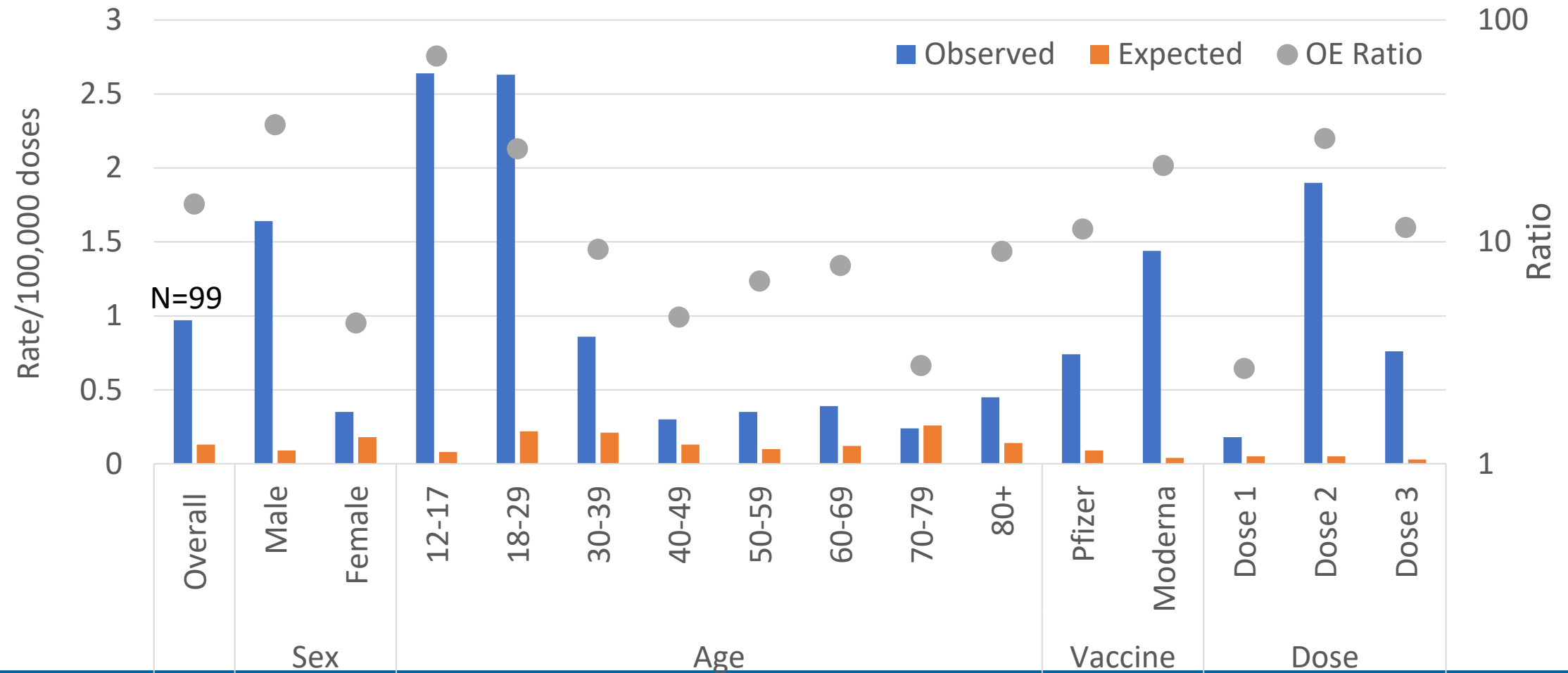
- Estimation of background rates
- Observed Versus Expected Rates of Myocarditis After SARS-CoV-2 Vaccination
- Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Coronavirus Vaccine
- Assessment of Myocarditis Following mRNA COVID-19 Booster Vaccination Among Adult Recipients

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

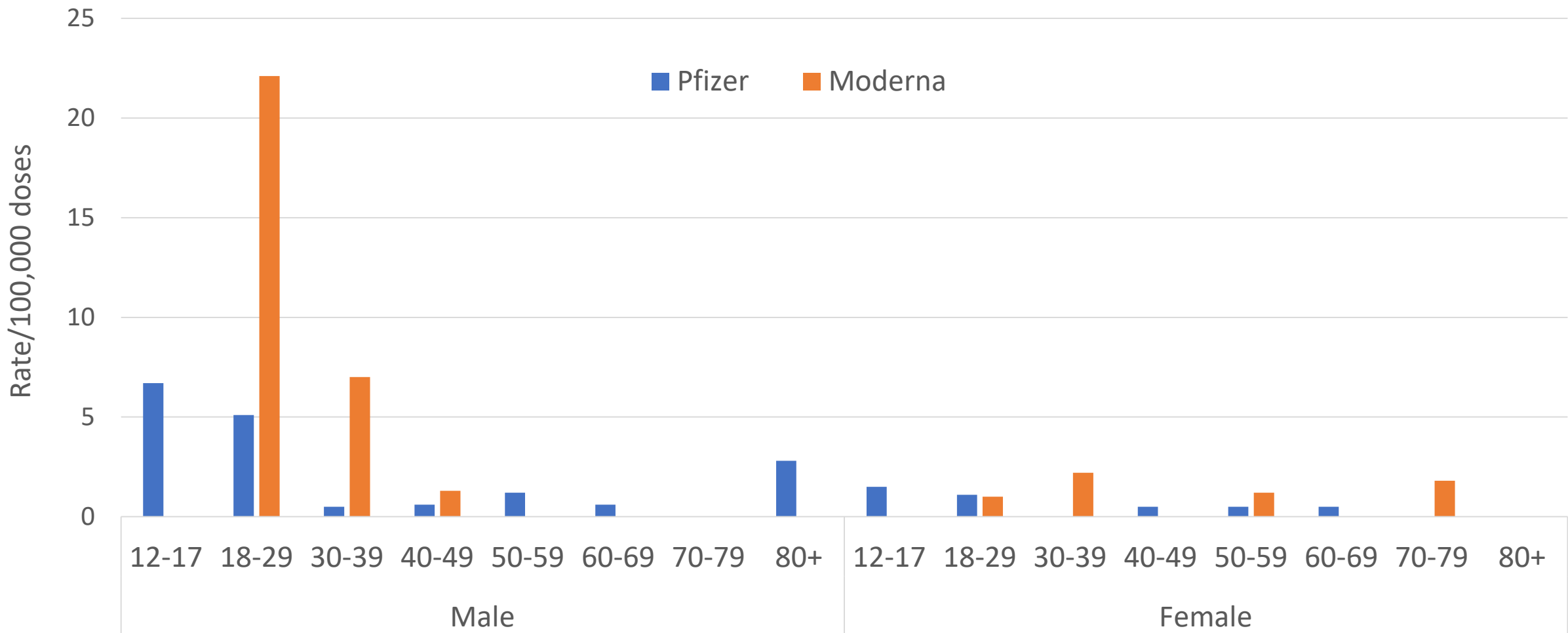
- **Design:** Observational study using data from the BC COVID-19 Cohort from Dec. 15, 2020, to Mar. 10, 2022
- **Primary exposure:** Any dose of an mRNA vaccine against SARS-CoV-2
- **Primary outcome:** Hospitalization or emergency department visit for myocarditis or myopericarditis within 7 and 21 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 2nd Vaccine Dose Using 7-day Risk Window by Age, Sex and Vaccine Product



Summary

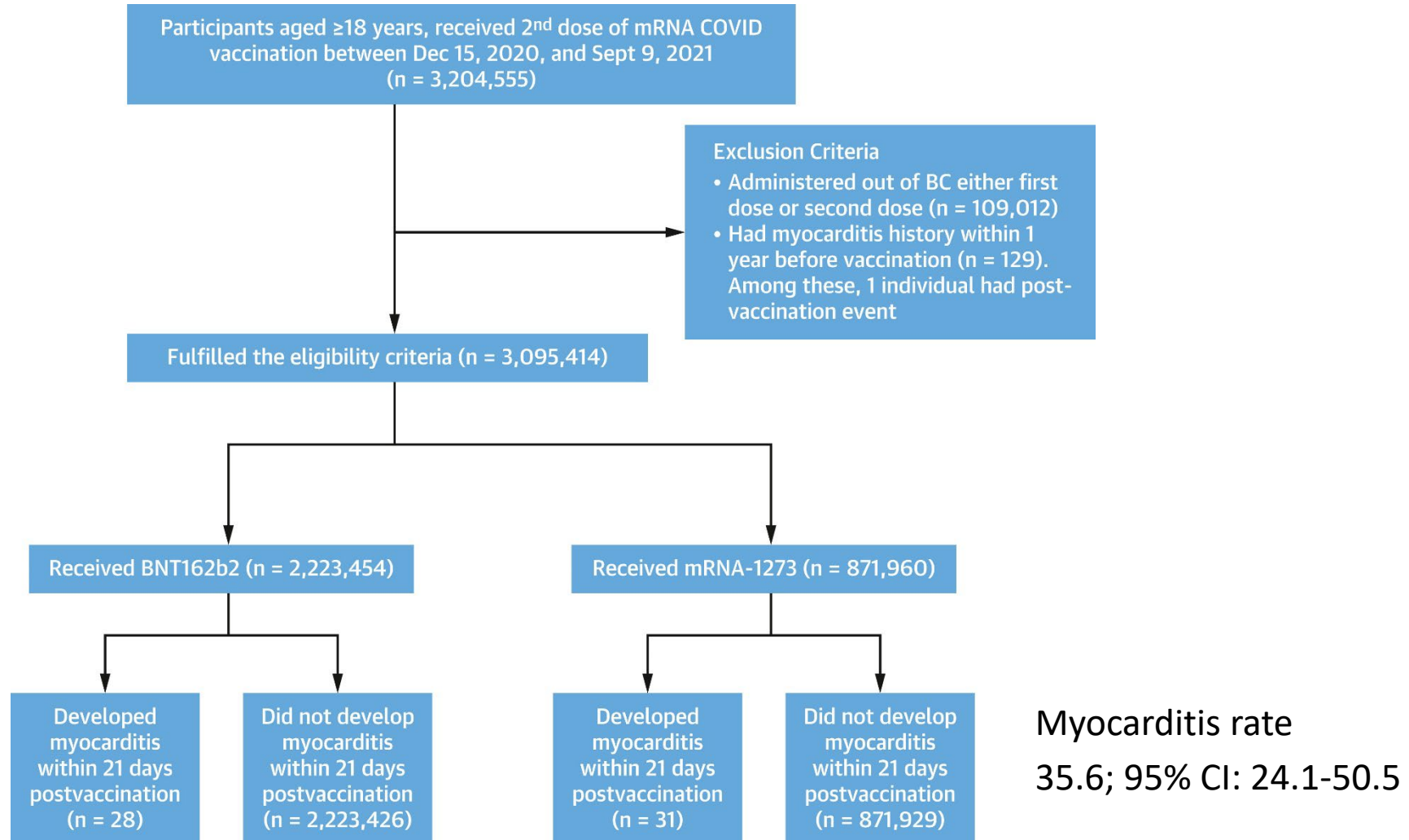
- Absolute rates of myocarditis following mRNA vaccines were low
- Highest observed-to-expected ratio was seen after the second dose among males aged 18–29 years
- Highest rate observed among males aged 18–29 years who received the mRNA-1273 vaccine
- Findings support the preferential use of the BNT162b2 vaccine over the mRNA-1273 vaccine for people aged 18–29 years



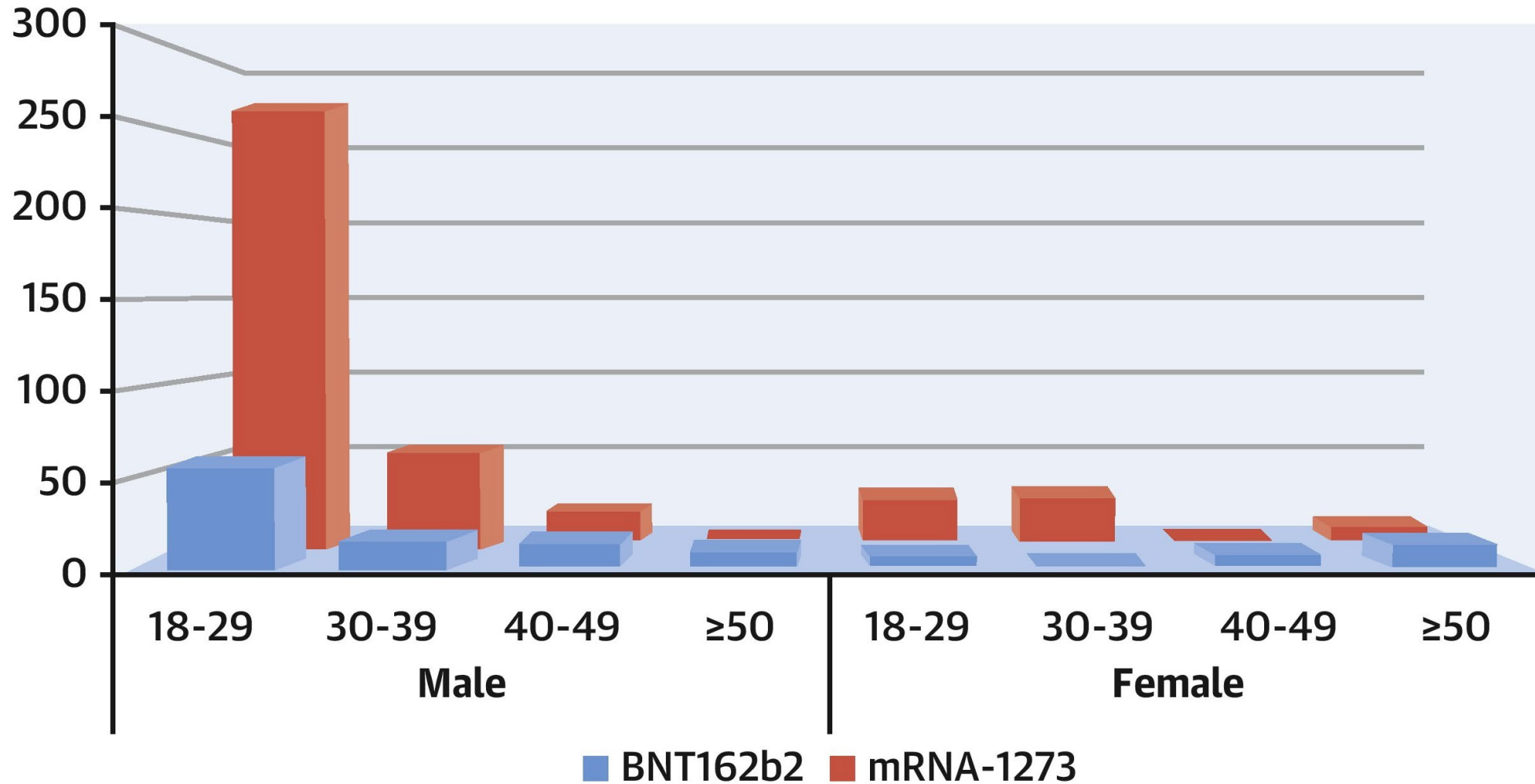
Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Vaccines

- **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

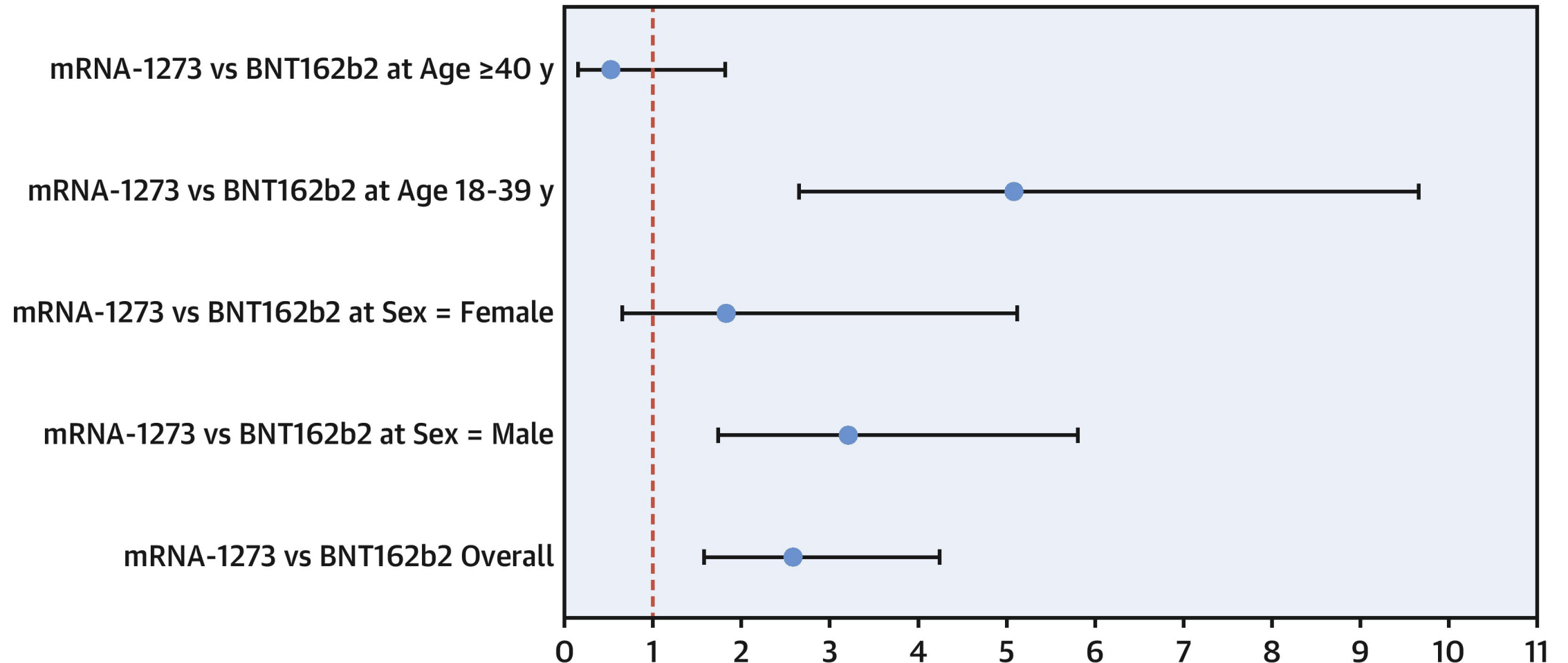
Myocarditis Study Population and Participant Enrollment Flowchart



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)



Naveed Z, et al. J Am Coll Cardiol. 2022;80(20):e2218505.

Summary

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



BNT162b2: Pfizer
BioNTech

mRNA-1273: Moderna
Spikevax



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.

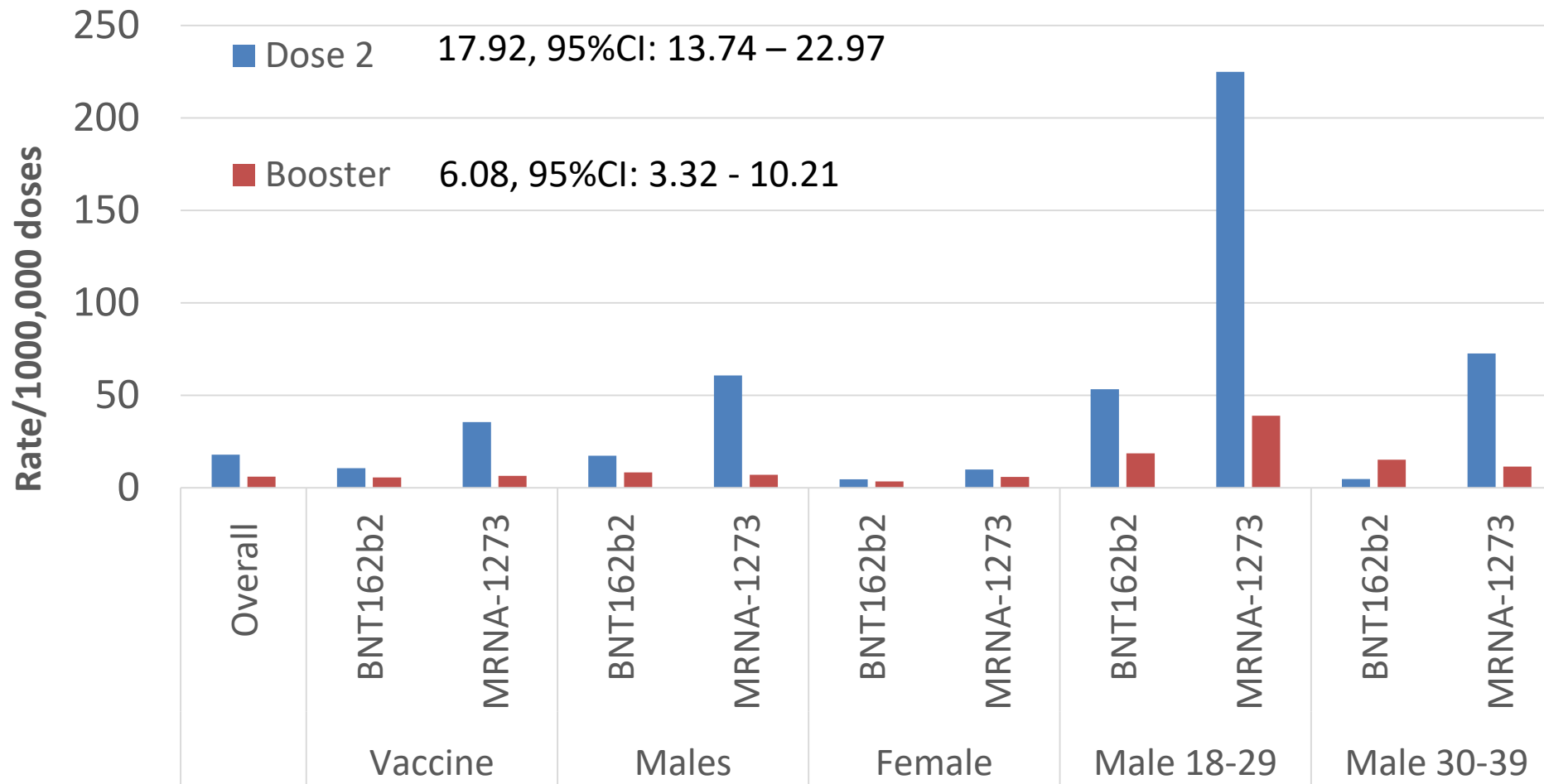


The association between Moderna Spikevax and myocarditis was stronger for men aged 18–39.

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 2nd and Booster Doses, Rates/Million Doses During a 7-day Risk Window





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).



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Thank you!

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