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COVID-19 vaccine program surveillance - Part Two: Monitoring vaccine impact and surveillance for special populations

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Disclosures

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- None of the presenters have potential conflicts of interest to declare.

Outline

- Overview of breakthrough cases
- Estimates of vaccine effectiveness
- Outline of the plans to monitor the effectiveness and the safety of COVID-19 vaccines in pregnancy

Learning Objectives

- Describe what is known about breakthrough cases of COVID-19 among vaccinated individuals in Ontario
- Discuss early estimates of vaccine effectiveness from Ontario
- Discuss the plans in place to monitor both the safety and the effectiveness of COVID-19 vaccines given in pregnancy



Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to May 15, 2021

Background and Methods

- Objective: to describe cases of COVID-19 following vaccination
- Data extracted from COVAX_{ON} and CCM were linked
 - Cases and vaccinations reported up to May 15, 2021
- Symptomatic post-vaccination cases are shown separately from combined estimates for symptomatic and asymptomatic post-vaccination cases

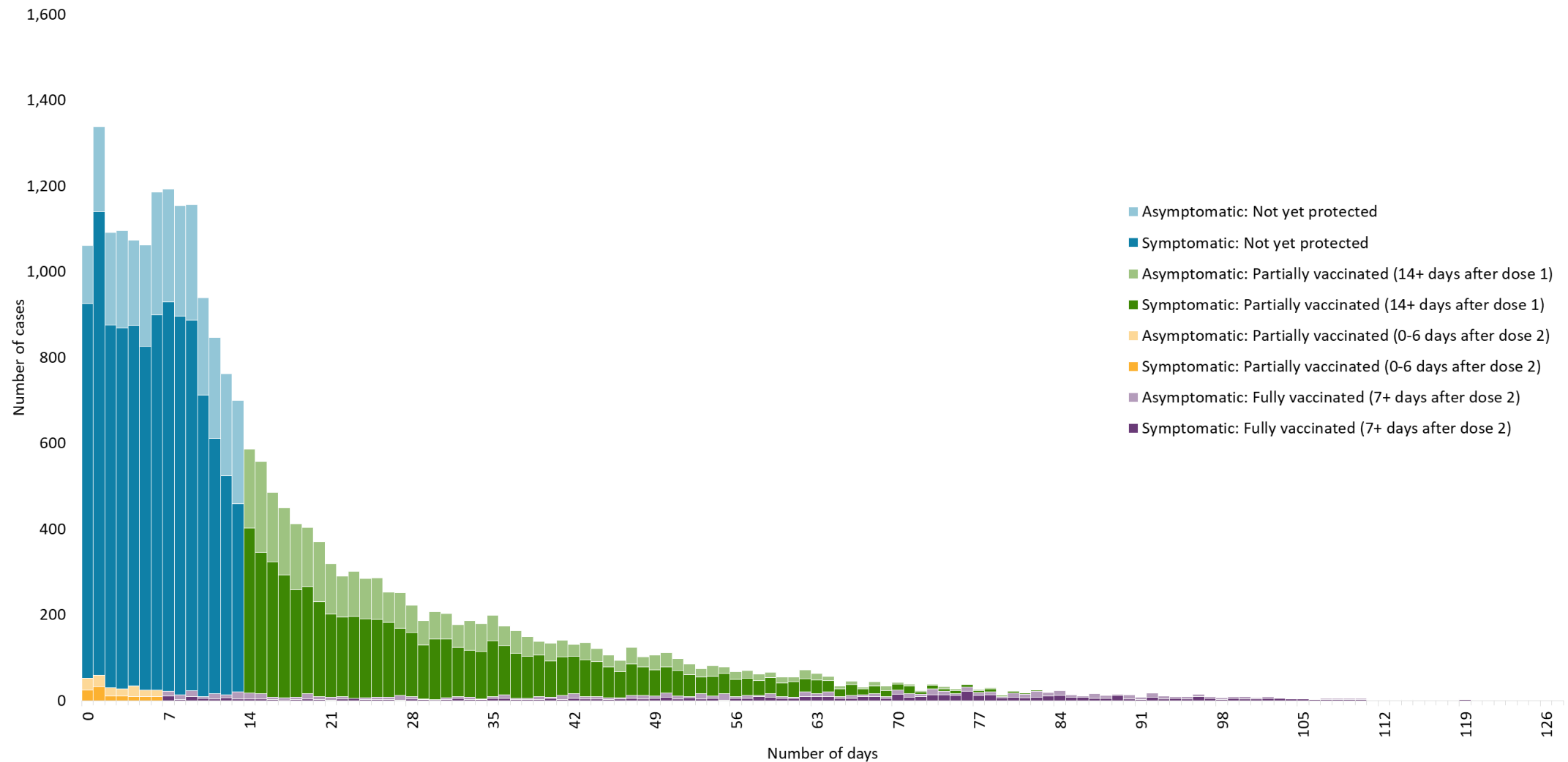
Case Definitions (modelled after proposed national definitions)

- **Case not yet protected from vaccination:**
 - Symptom onset date **0 to <14 days following the first dose** of a COVID-19 vaccine
- **Partially vaccinated case:**
 - Symptom onset date: **14 or more days following the first dose**
 - Or: **0 to <7 days after receiving the second dose**
- **Breakthrough (i.e., fully vaccinated) case:**
 - Symptom onset date **7 or more days following the second dose**

Highlights

- The number of partially vaccinated and breakthrough cases is **small**
 - Partially vaccinated cases
 - **2.6%** (9,703/366,696) of total COVID-19 cases since Dec 14, 2020
 - **0.15%** (9,703/6,638,361) of individuals vaccinated with ≥ 1 dose
 - Breakthrough (i.e., fully vaccinated) cases
 - **0.4%** (1,292/366,696) of total COVID-19 cases since Dec 14, 2020
 - **0.02%** (1,292/6,638,361) of individuals vaccinated with ≥ 1 dose

Figure 1. Confirmed symptomatic and asymptomatic post-vaccination cases of COVID-19 by number of days between dose administration and symptom onset



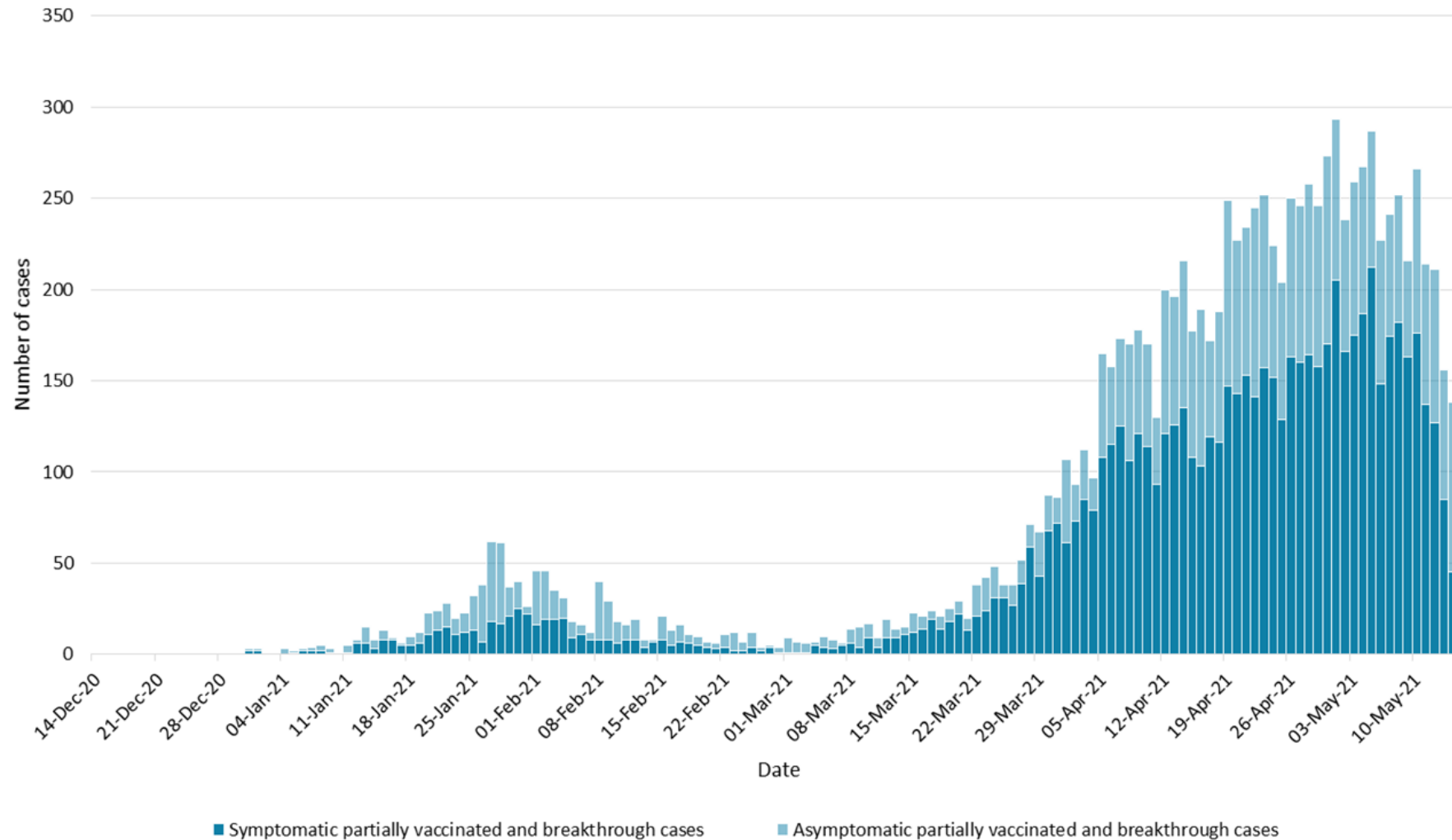
Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Table 1. Confirmed symptomatic post-vaccination cases of COVID-19

	Not yet protected: 0-13 days after dose 1	Partially vaccinated: 14-27 days after dose 1	Partially vaccinated: 28+ days after dose 1	Partially vaccinated: 0-6 days after dose 2	Partially vaccinated: Total	Breakthrough: 7-13 days after dose 2	Breakthrough: 14+ days after dose 2	Breakthrough: Total	Total
Symptomatic	11,055 (61.2%)	3,302 (18.3%)	2,986 (16.5%)	109 (0.6%)	6,397 (35.4%)	44 (0.2%)	557 (3.1%)	601 (3.3%)	18,053 (100.0%)
Asymptomatic	3,230 (44.7%)	1,809 (25.0%)	1,353 (18.7%)	144 (2.0%)	3,306 (45.7%)	77 (1.1%)	614 (8.5%)	691 (9.6%)	7,227 (100.0%)
Total	14,285 (56.5%)	5,111 (20.2%)	4,339 (17.2%)	253 (1.0%)	9,703 (38.4%)	121 (0.5%)	1,171 (4.6%)	1,292 (5.1%)	25,280 (100.0%)

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

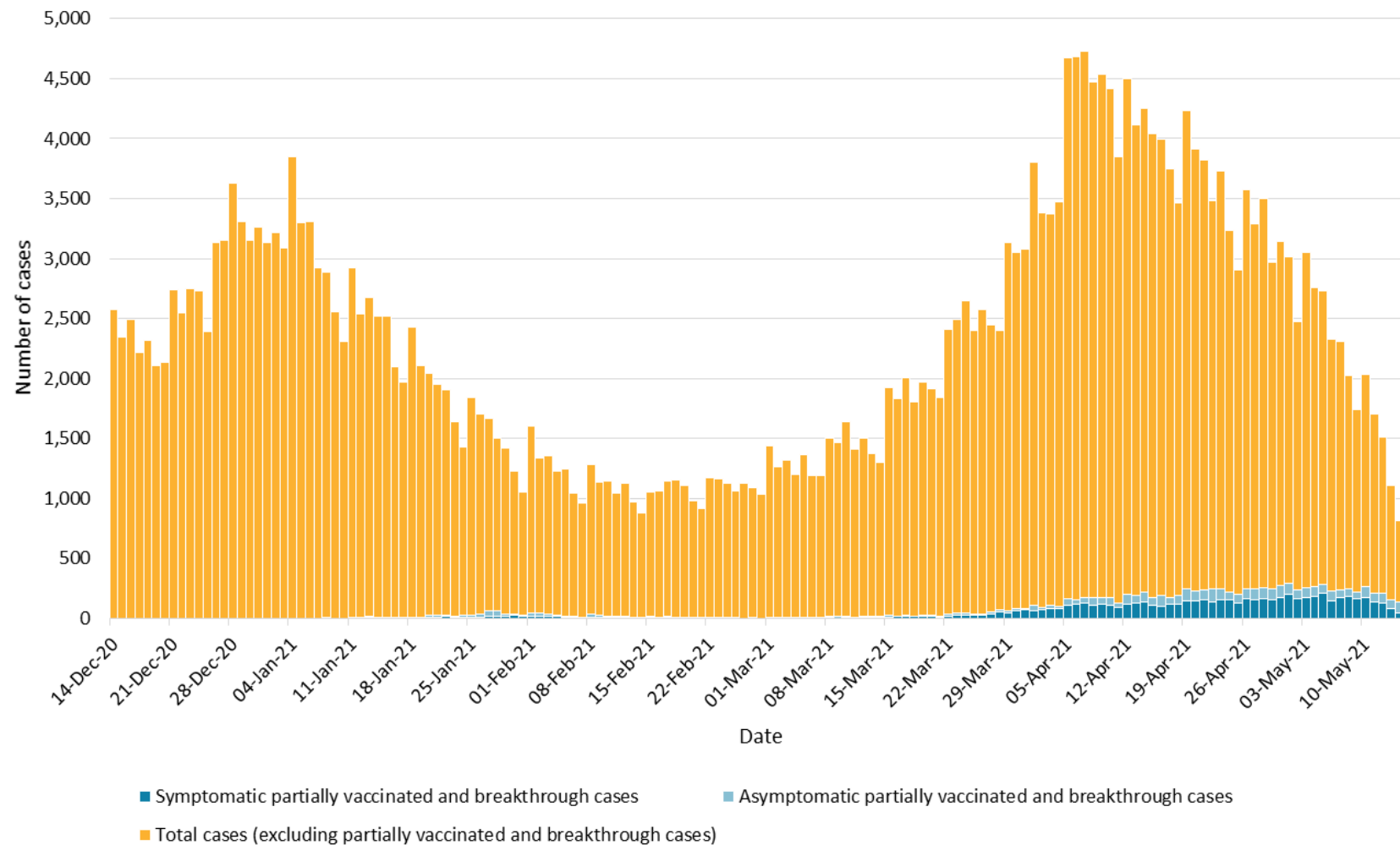
Figure 2a. Partially vaccinated and breakthrough confirmed cases of COVID-19 by symptom onset date*



*Symptomatic partially vaccinated and breakthrough cases are shown by symptom onset date. Asymptomatic partially vaccinated and breakthrough cases are shown by the first available of specimen collection or reported date, as an approximation of symptom onset date.

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Figure 2b. Confirmed cases of COVID-19 by symptom onset date*



*Symptomatic partially vaccinated and breakthrough cases are shown by symptom onset date. Asymptomatic partially vaccinated and breakthrough cases are shown by the first available of specimen collection or reported date, as an approximation of symptom onset date. COVID-19 cases that are not partially vaccinated or breakthrough cases (indicated with yellow bars) are showing using the first in time of symptom onset, specimen collection or reported date.

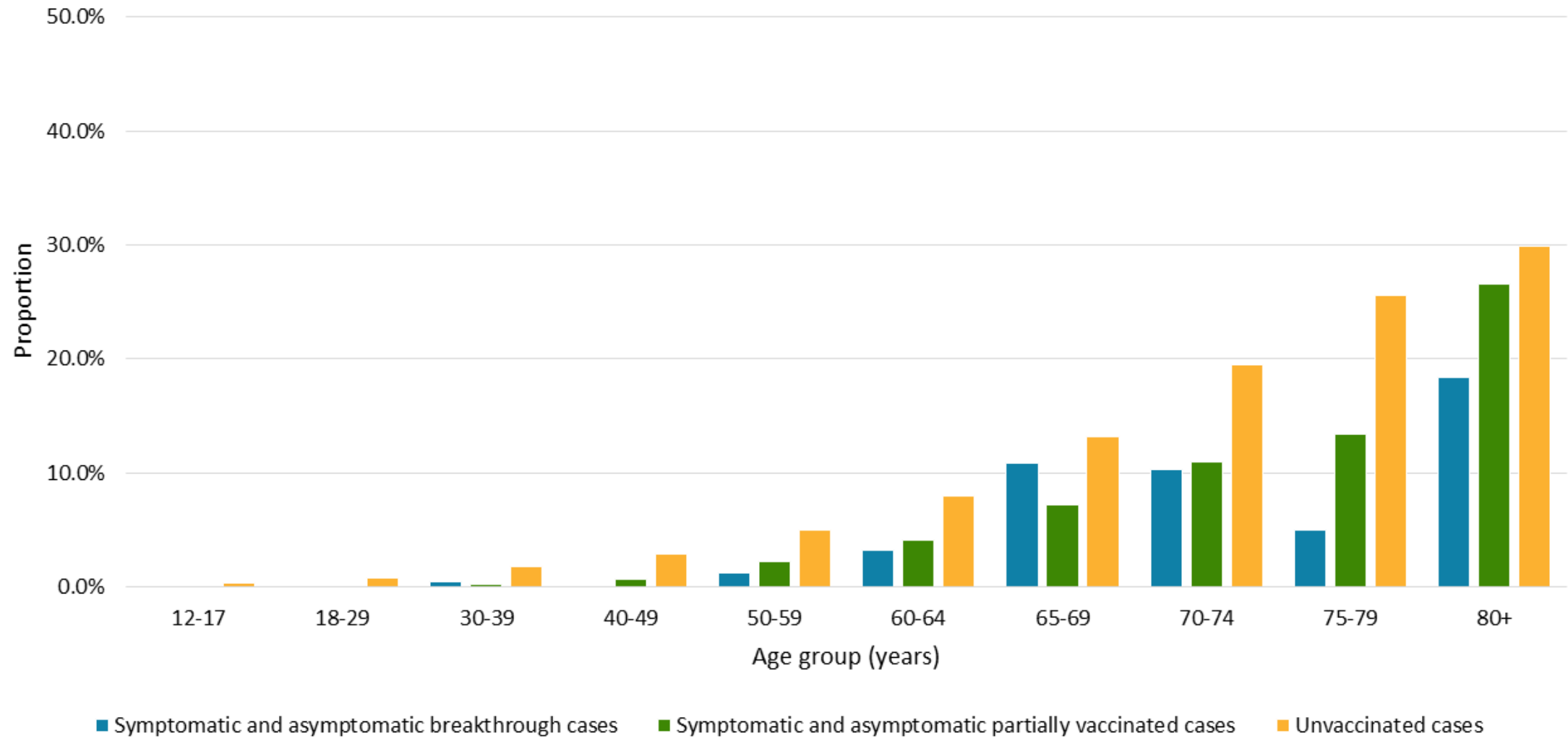
Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Table 2. Demographic characteristics of partially vaccinated, breakthrough, and all confirmed cases of COVID-19

Age group (years)	Symptomatic partially vaccinated cases: Number (% of all cases)	Symptomatic breakthrough cases: Number (% of all cases)	Symptomatic and asymptomatic partially vaccinated cases: Number (% of all cases)	Symptomatic and asymptomatic breakthrough cases: Number (% of all cases)	Symptomatic and asymptomatic partially vaccinated cases: Number (% of individuals with at least one dose)	Symptomatic and asymptomatic breakthrough cases: Number (% of individuals with at least one dose)
12-17	7 (<0.1%)	0 (0.0%)	11 (0.1%)	2 (<0.1%)	11 (0.04%)	2 (0.01%)
18-29	652 (0.7%)	86 (0.1%)	869 (1.0%)	163 (0.2%)	869 (0.12%)	163 (0.02%)
30-39	664 (1.1%)	117 (0.2%)	885 (1.5%)	198 (0.3%)	885 (0.12%)	198 (0.03%)
40-49	714 (1.3%)	124 (0.2%)	996 (1.9%)	214 (0.4%)	996 (0.11%)	214 (0.02%)
50-59	1,093 (2.1%)	107 (0.2%)	1,593 (3.0%)	240 (0.5%)	1,593 (0.12%)	240 (0.02%)
60-64	904 (4.6%)	47 (0.2%)	1,373 (7.0%)	126 (0.6%)	1,373 (0.18%)	126 (0.02%)
65-69	534 (4.1%)	24 (0.2%)	816 (6.3%)	46 (0.4%)	816 (0.12%)	46 (0.01%)
70-74	502 (5.4%)	13 (0.1%)	804 (8.6%)	29 (0.3%)	804 (0.14%)	29 (0.00%)
75-79	380 (6.0%)	14 (0.2%)	699 (11.0%)	40 (0.6%)	699 (0.17%)	40 (0.01%)
80+	947 (7.2%)	69 (0.5%)	1,657 (12.6%)	234 (1.8%)	1,657 (0.29%)	234 (0.04%)
Total	6,397 (1.7%)	601 (0.2%)	9,703 (2.6%)	1,292 (0.4%)	9,703 (0.15%)	1,292 (0.02%)

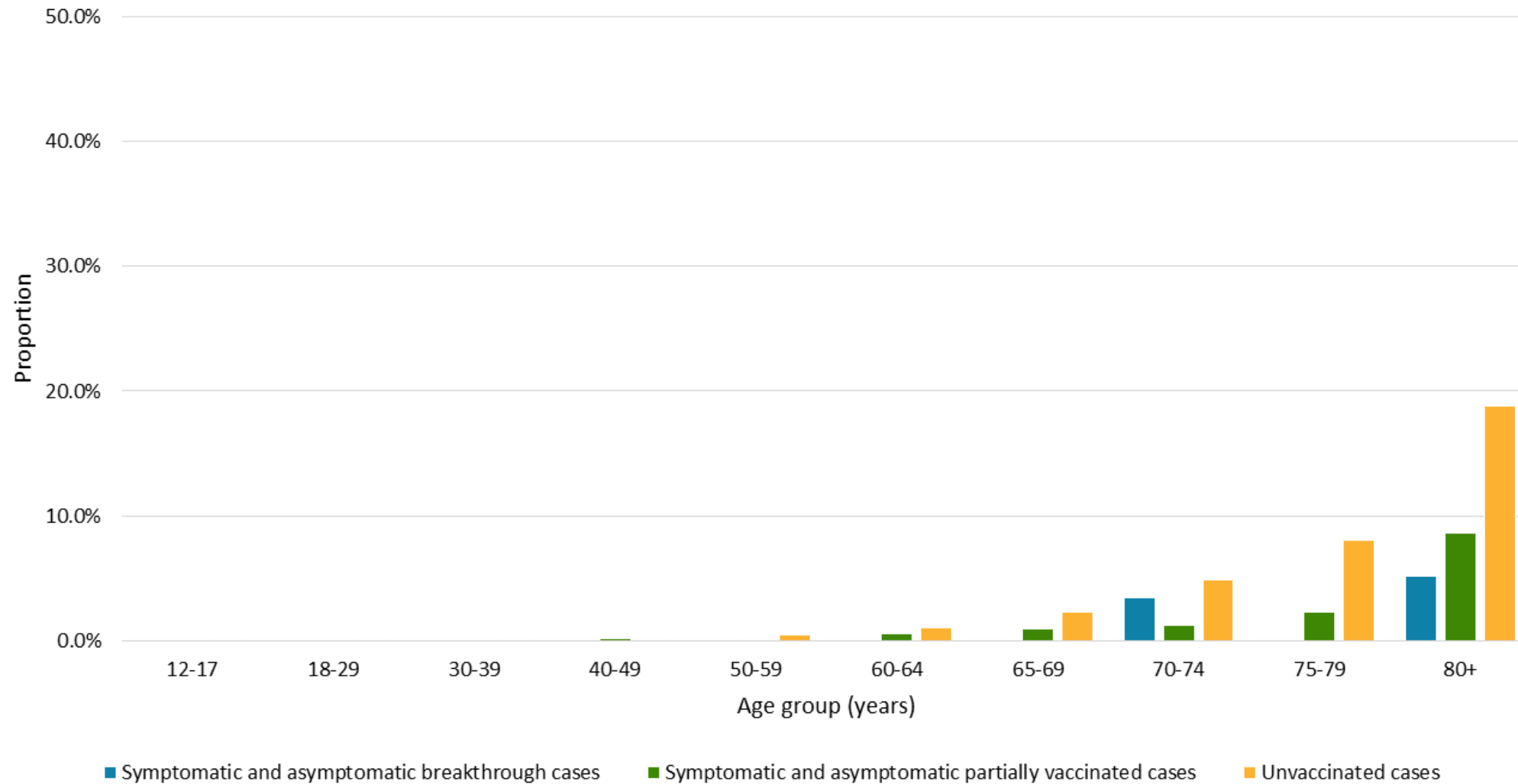
Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Figure 3a. Proportion of hospitalizations among symptomatic and asymptomatic partially vaccinated, breakthrough and unvaccinated cases of COVID-19



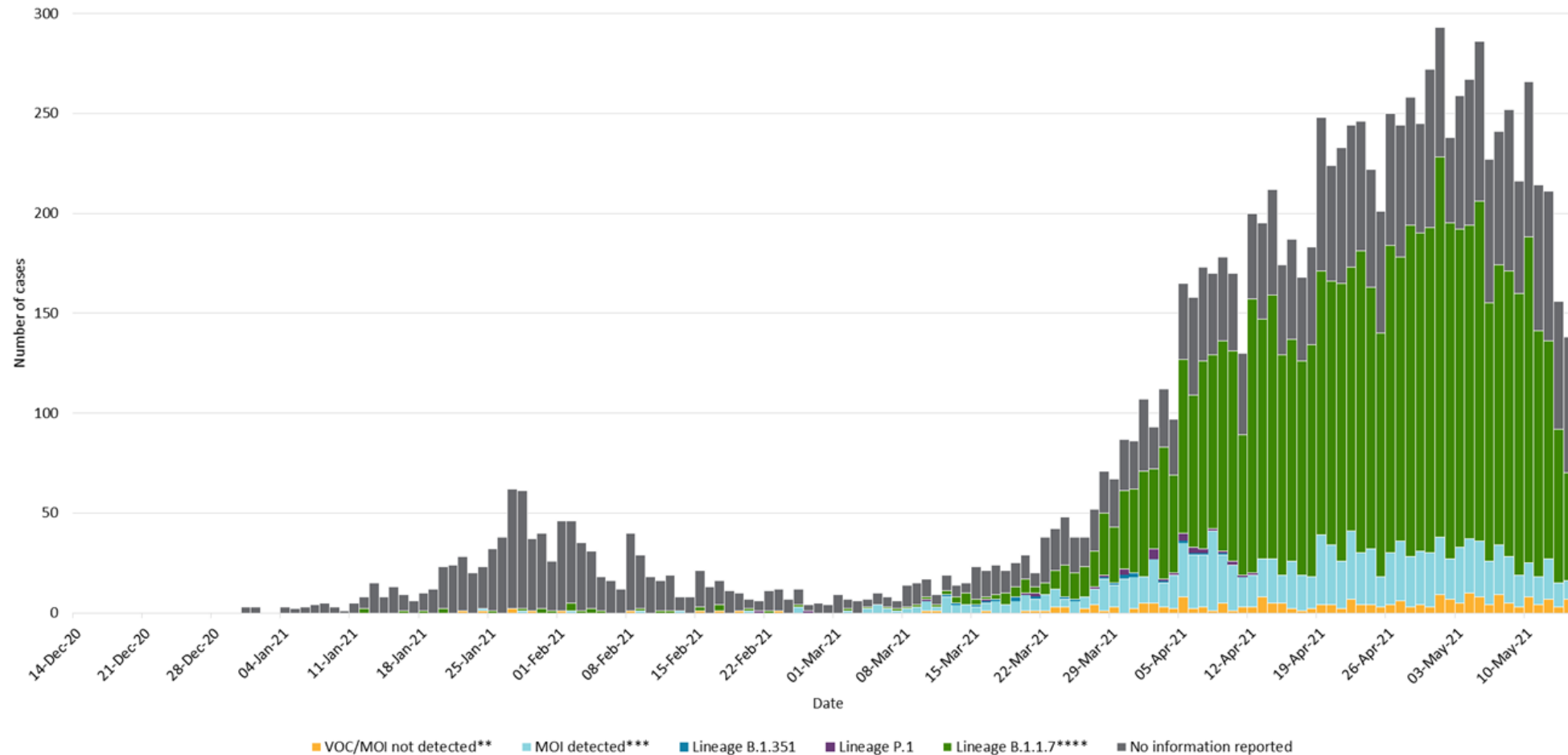
Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Figure 3b. Proportion of fatalities among symptomatic and asymptomatic partially vaccinated, breakthrough and unvaccinated cases of COVID-19



Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Figure 4. Partially vaccinated and breakthrough confirmed cases of COVID-19 by mutation of interest (MOI) or variant of concern (VOC) and symptom onset date*



*Symptomatic partially vaccinated and breakthrough cases are shown by symptom onset date. Asymptomatic partially vaccinated and breakthrough cases are shown by the first available of specimen collection or reported date, as an approximation of symptom onset date. Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Confirmed cases of COVID-19 following vaccination in Ontario: December 14, 2020 to May 15, 2021 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 May 31]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-confirmed-cases-post-vaccination.pdf?la=en>

Summary, Limitations and Next Steps

- Summary
 - The number of partially vaccinated and breakthrough cases is small
 - Vaccination reduces severity of illness
 - Trends in VOCs are similar to overall trends in VOCs in COVID-19 cases
- Limitations
 - Asymptomatic cases
 - VOC under-reporting
- Next steps
 - Regular updating of report and with new analyses

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COVID-19 VE for Ontario using the test-negative design

Jeff Kwong

PHO Rounds

June 3, 2021



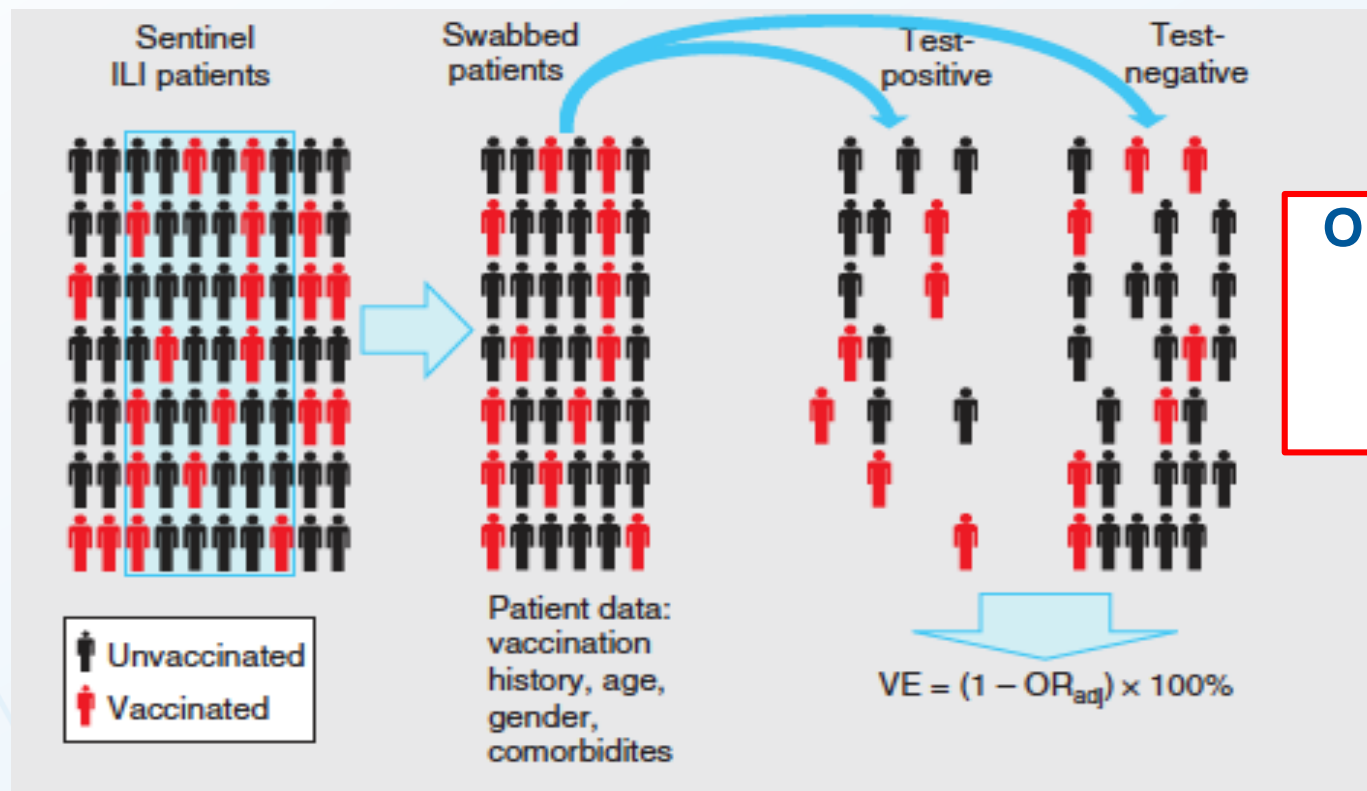
Data
Discovery
Better Health

Disclosure statement

I have no financial conflicts of interest to disclose.



Test-negative design




$$OR = \frac{\text{odds of vaccination in TP}}{\text{odds of vaccination in TN}}$$

$$VE = (1 - OR) \times 100\%$$



Study population

- Included:
 - Aged ≥ 16 years, community-dwelling
 - Tested for SARS-CoV-2 by PCR between 14 Dec 2020 and 19 April 2021 with COVID-19 symptoms recorded in the Ontario Laboratories Information System (OLIS)
- Excluded:
 - Individuals with positive SARS-CoV-2 test prior to 14 Dec 2020
-  AstraZeneca vaccine recipients

Outcomes

- Primary: Symptomatic infection
 - From OLIS
- Secondary: Severe outcomes (hospitalization or death)
 - From the Public Health Case and Contact Management system (CCM) (hospitalizations and deaths), CIHI Discharge Abstract Database (hospitalizations), Ontario Registered Persons Database (deaths)

Exposure

- Ascertained COVID-19 vaccination from COVaxON
 - Number of doses received by the index date (date of specimen collection)
 - Interval from most recent vaccination to index date

Statistical analysis

- Estimated VE against symptomatic infection for various intervals after 1 dose and after 2 doses
- Estimated VE against severe outcomes for various intervals after 1 dose and after 2 doses
- Stratified analyses (≥ 14 d after 1 dose, ≥ 7 d after 2 doses):
 - By vaccine (Pfizer vs. Moderna), sex, age group, presence of any comorbidity, epidemic wave (wave 2, inter-wave period, wave 3), lineage (earlier variant vs. B.1.1.7 [N501Y+, E484K-] vs. B.1.351/P.1 [E484K+])

Figure 1. Confirmed cases of COVID-19 by likely acquisition and public health unit reported date: Ontario, January 15, 2020 to April 22, 2021

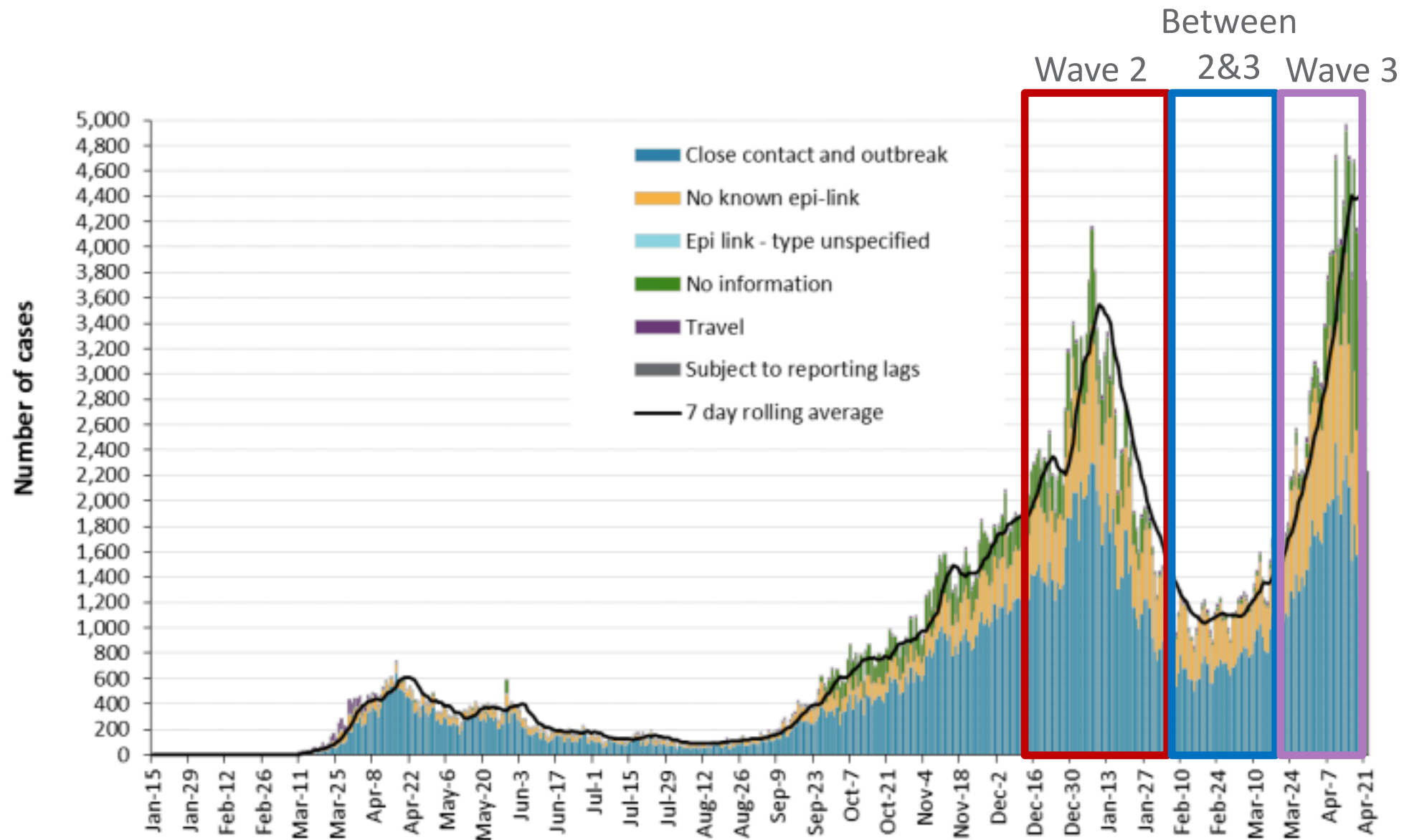


Figure 5. Number of confirmed COVID-19 cases and percent positive for mutations or VOCs: Ontario, February 7, 2021 to May 1, 2021

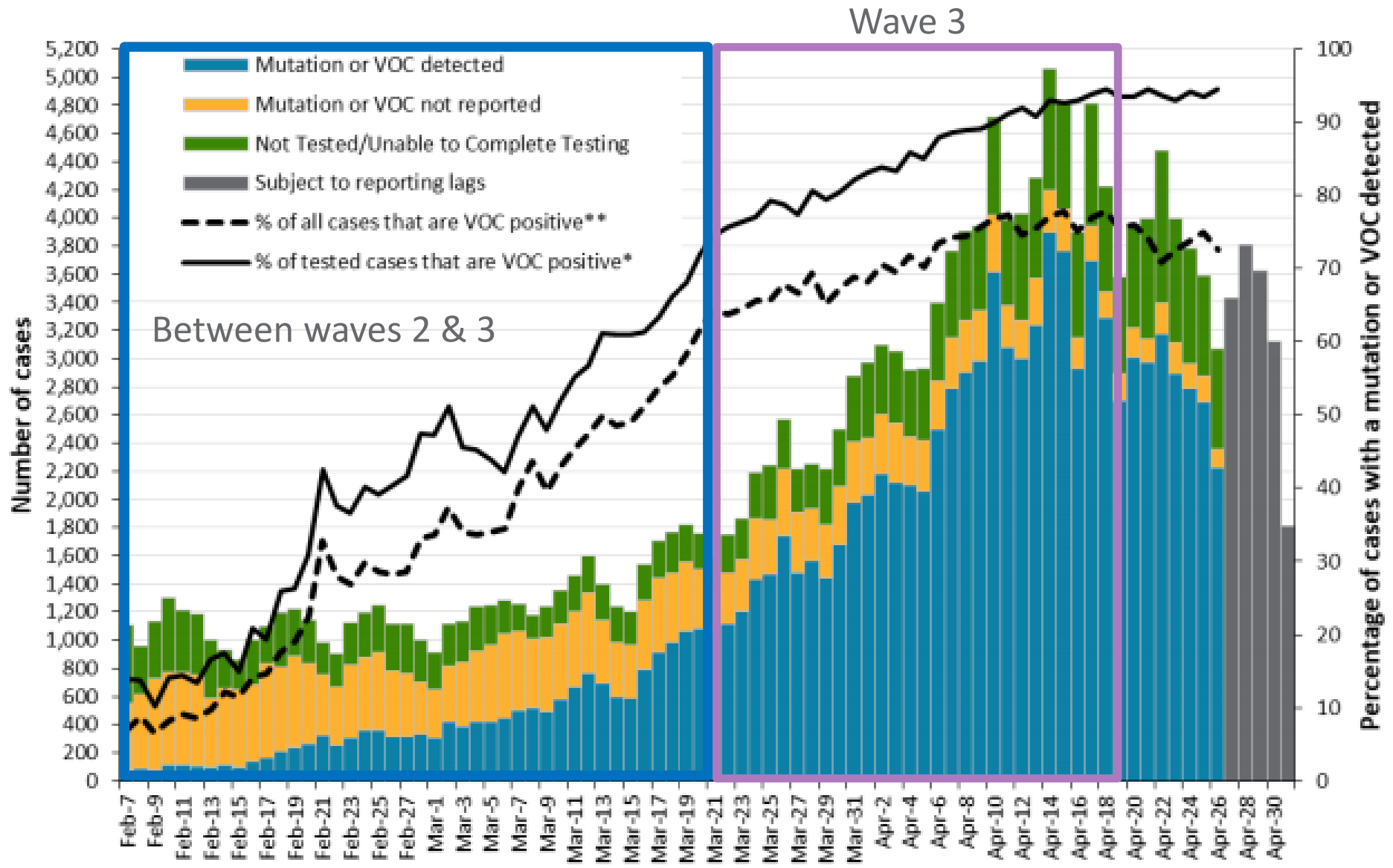
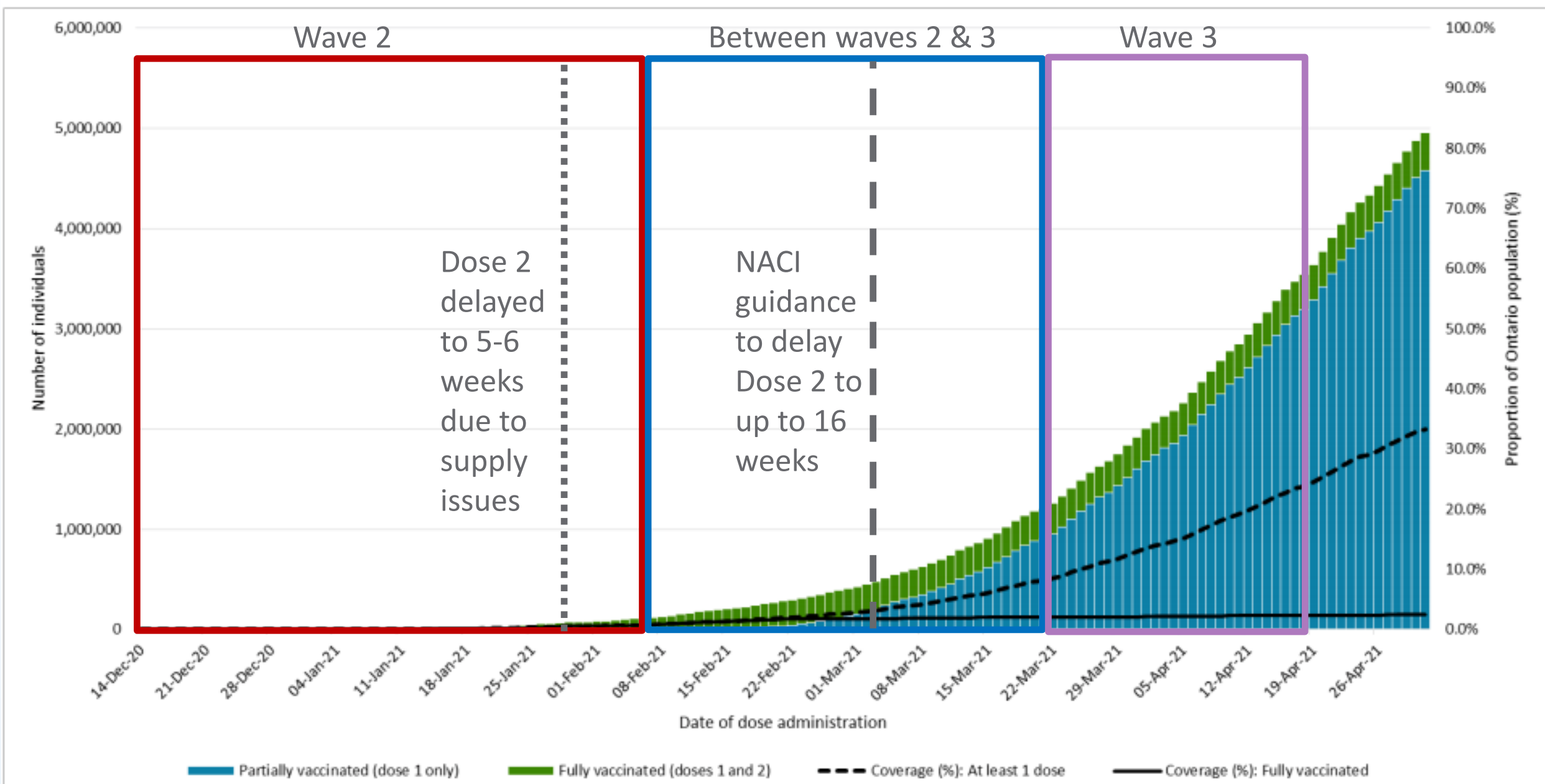


Figure 2. Cumulative number of individuals who received a COVID-19 vaccine and provincial coverage estimates by administration date*



Statistical analysis

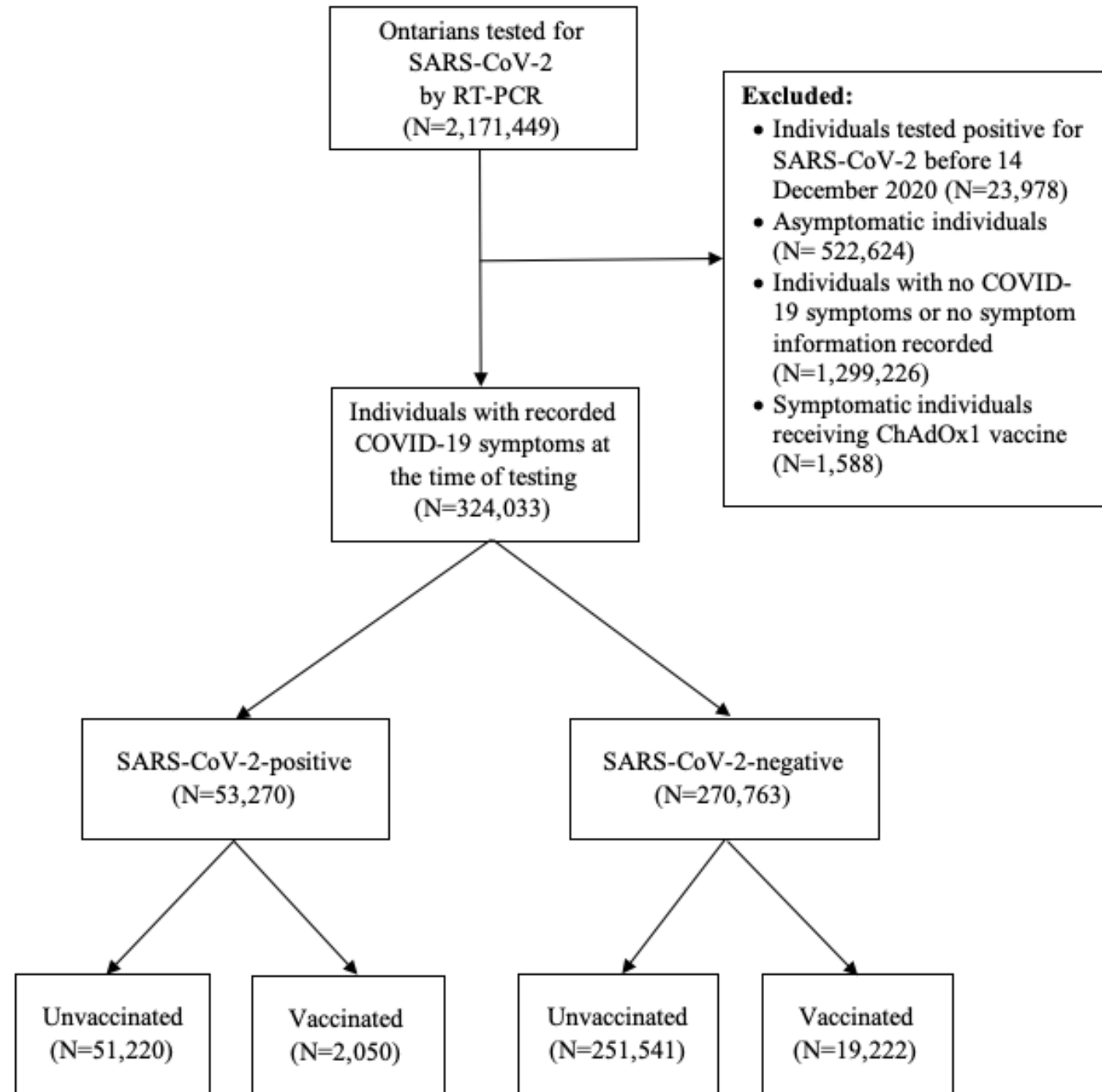
- Estimated VE against symptomatic infection for various intervals after 1 dose and after 2 doses, stratified by age group
- Estimated VE against severe outcomes for various intervals after 1 dose and after 2 doses, stratified by age group

Covariates adjusted for

- Age
- Sex
- PHU region
- Biweekly period of test
- # of tests during the 3 months prior to 14 Dec 2020
- Any comorbidity
- Influenza vaccination during 2019-20 and/or 2020-21
- Area-level measures: income, essential workers, household size, visible minorities

Results

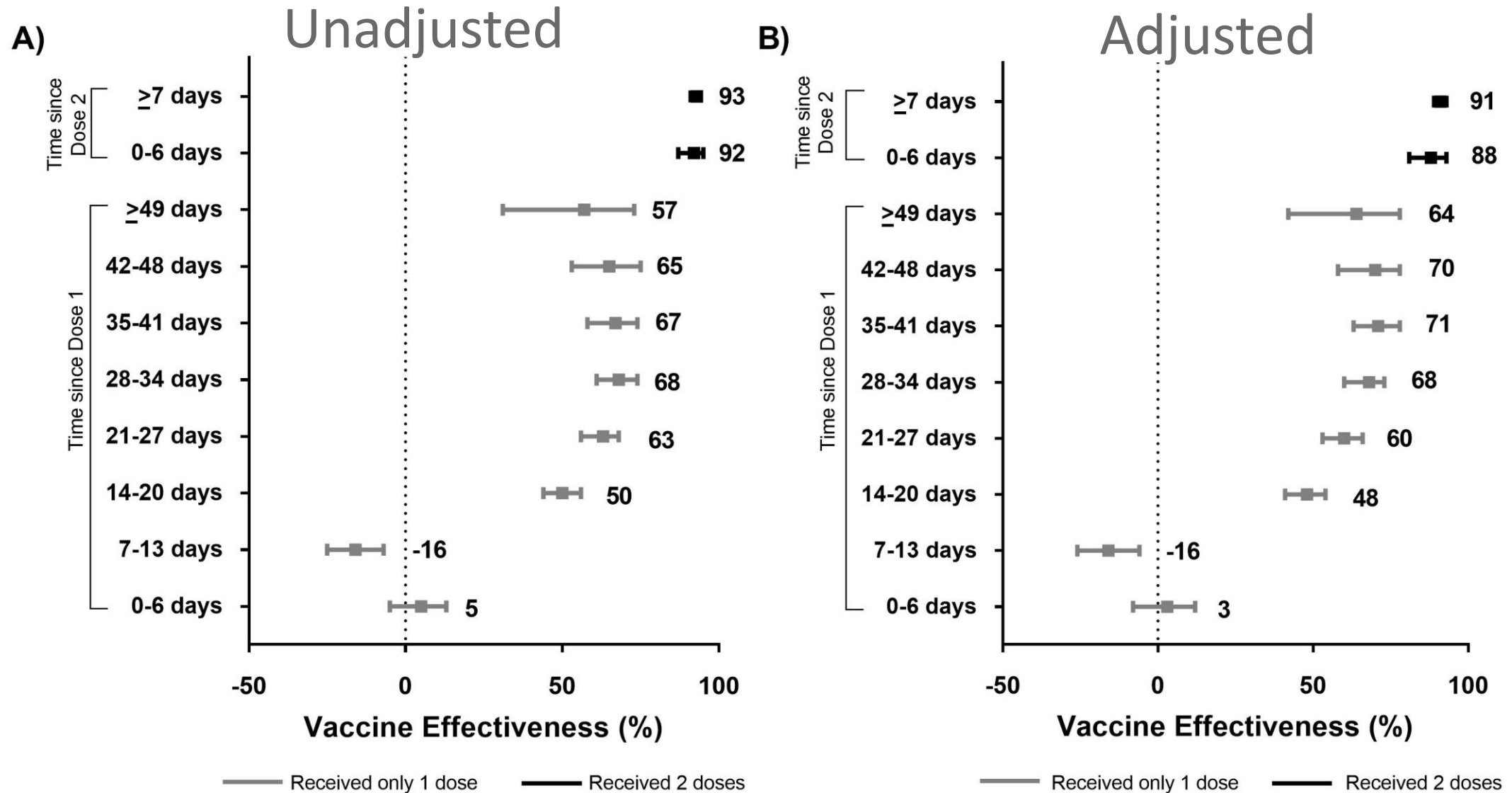
- 16.4% positive
- 6.6% received ≥ 1 dose of mRNA vaccine
- Pfizer: 86%
 - 1 dose: 77%
 - 2 doses: 23%
- Moderna: 14%
 - 1 dose: 76%
 - 2 doses: 24%



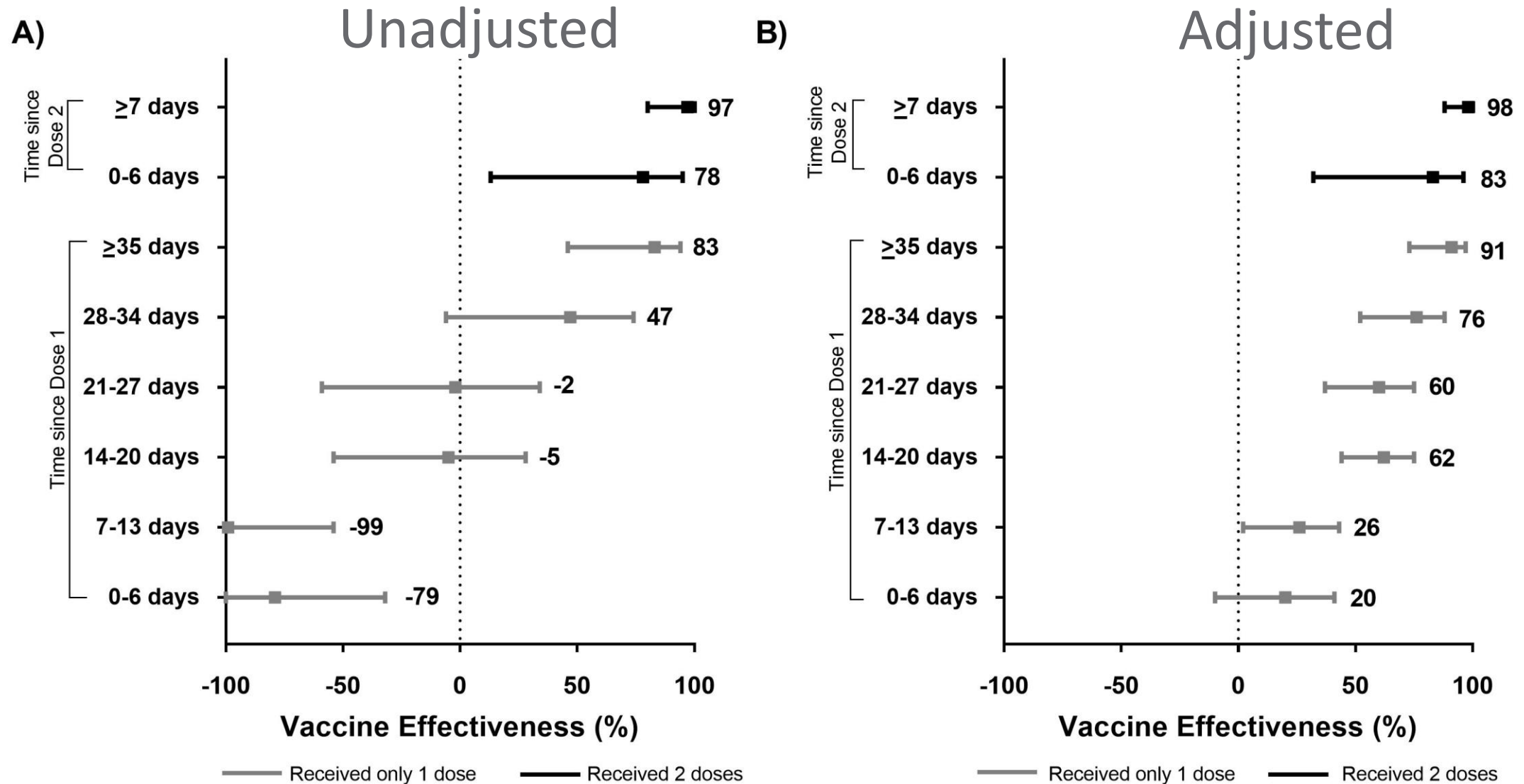
Characteristics of the study population

Characteristic	(%)	Characteristic	(%)
Female sex	57	Age group	
		16-29	27
Income quintile		30-39	21
1 (lowest)	19	40-49	17
2	19	50-59	16
3	20	60-69	10
4	21	70-79	5
5 (highest)	21	≥80	3

VE against symptomatic infection

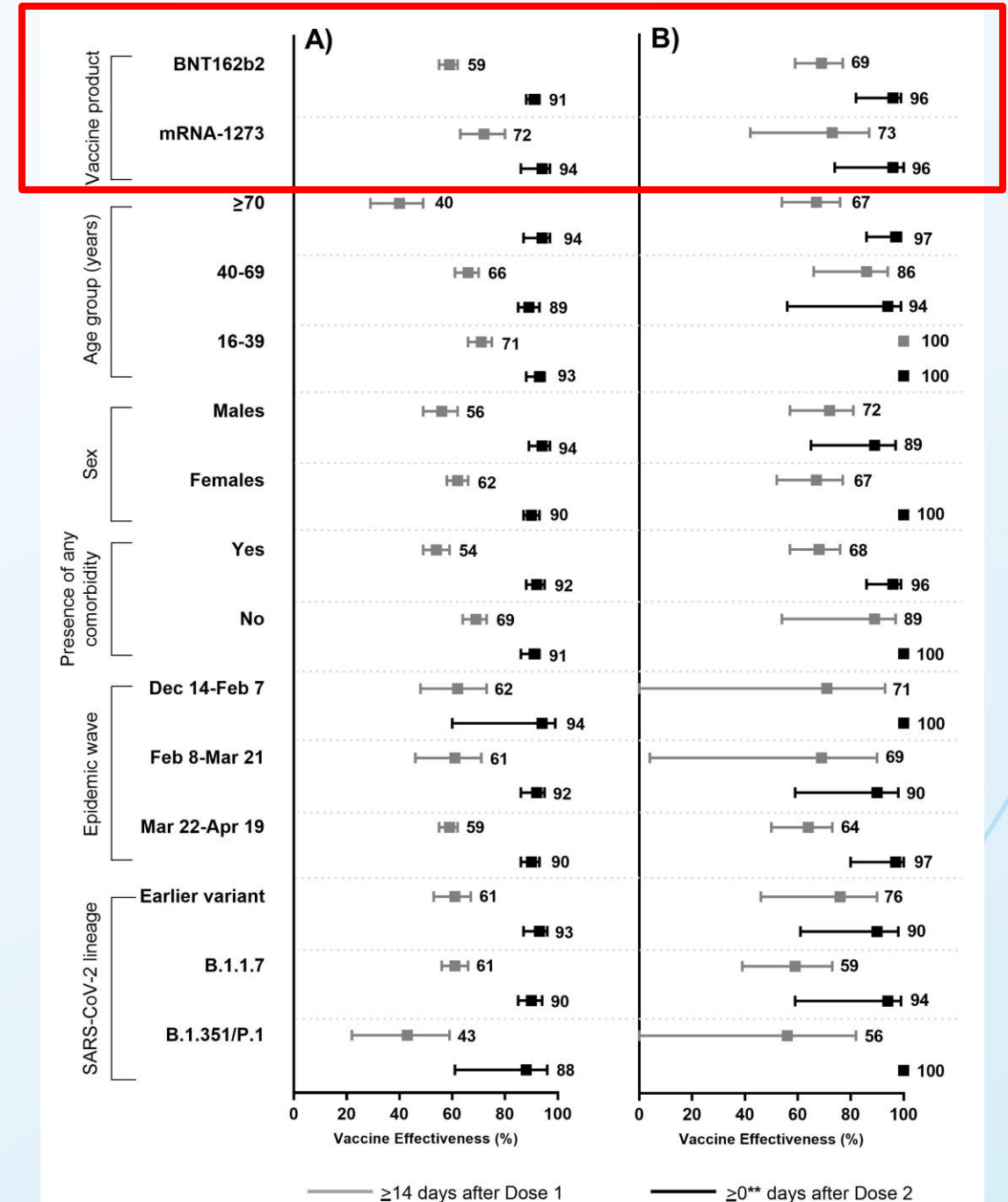


VE against severe outcomes



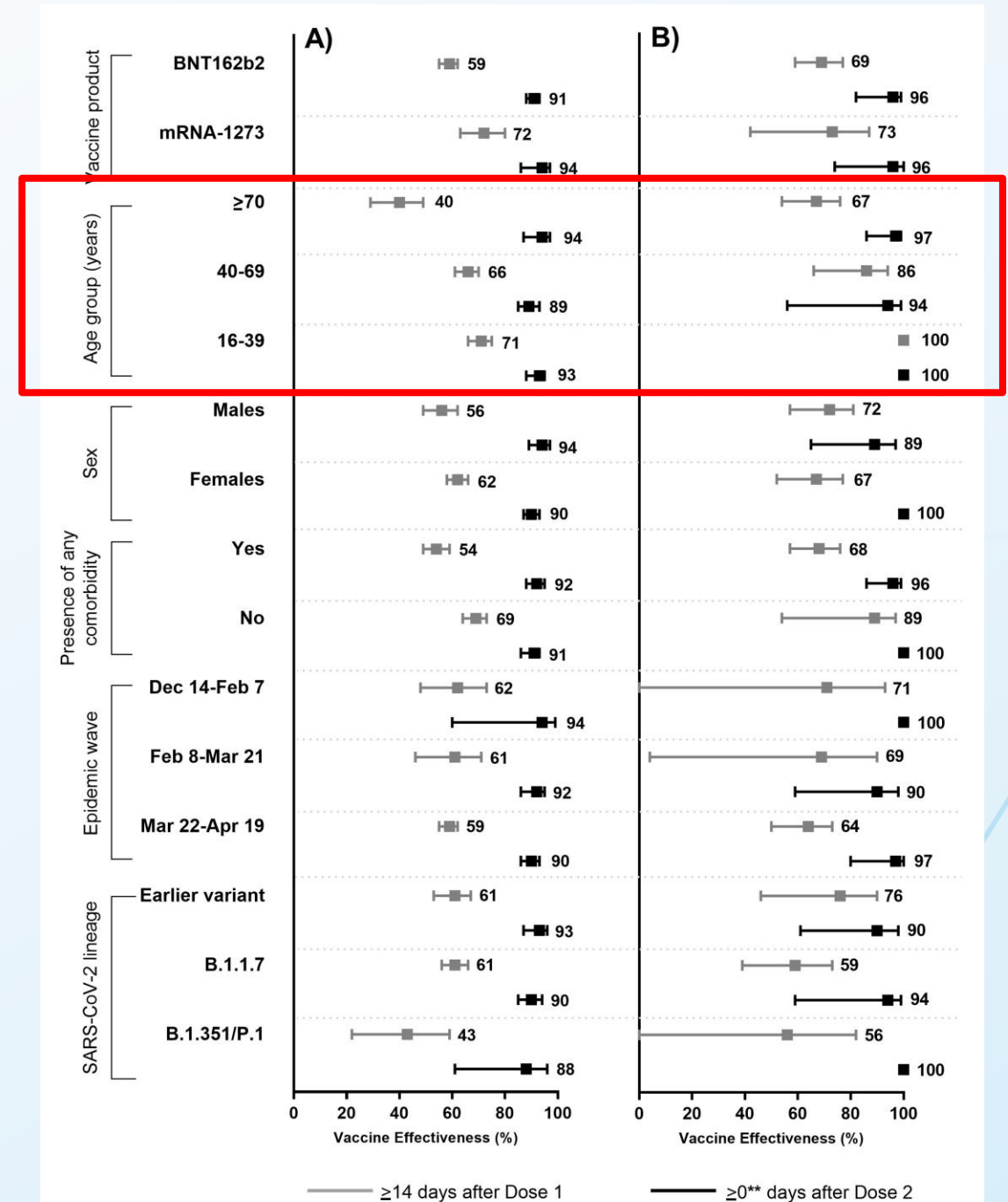
VE by vaccine

- A: symptomatic infection
- After 1 dose, lower VE for Pfizer vaccine
- B: severe outcomes
- After 1 dose, higher VE than infection (Pfizer)
- Both A & B:
 - After 2 doses, high VE for both vaccines



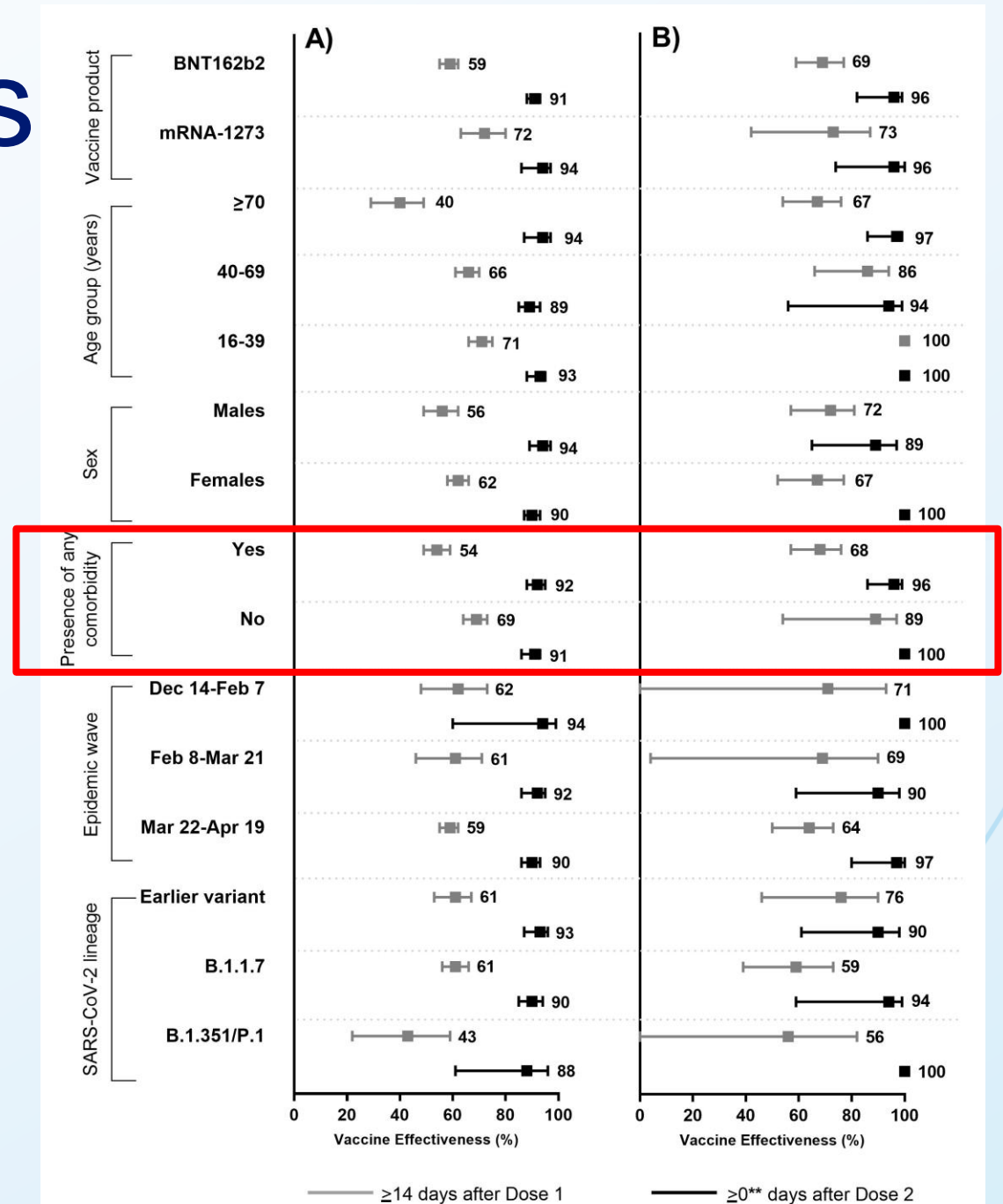
VE by age group

- A: symptomatic infection
- After 1 dose, lower VE for adults ≥ 70 years
- B: severe outcomes
- After 1 dose, higher VE than infection
- Both A & B:
 - After 2 doses, high VE for all age groups



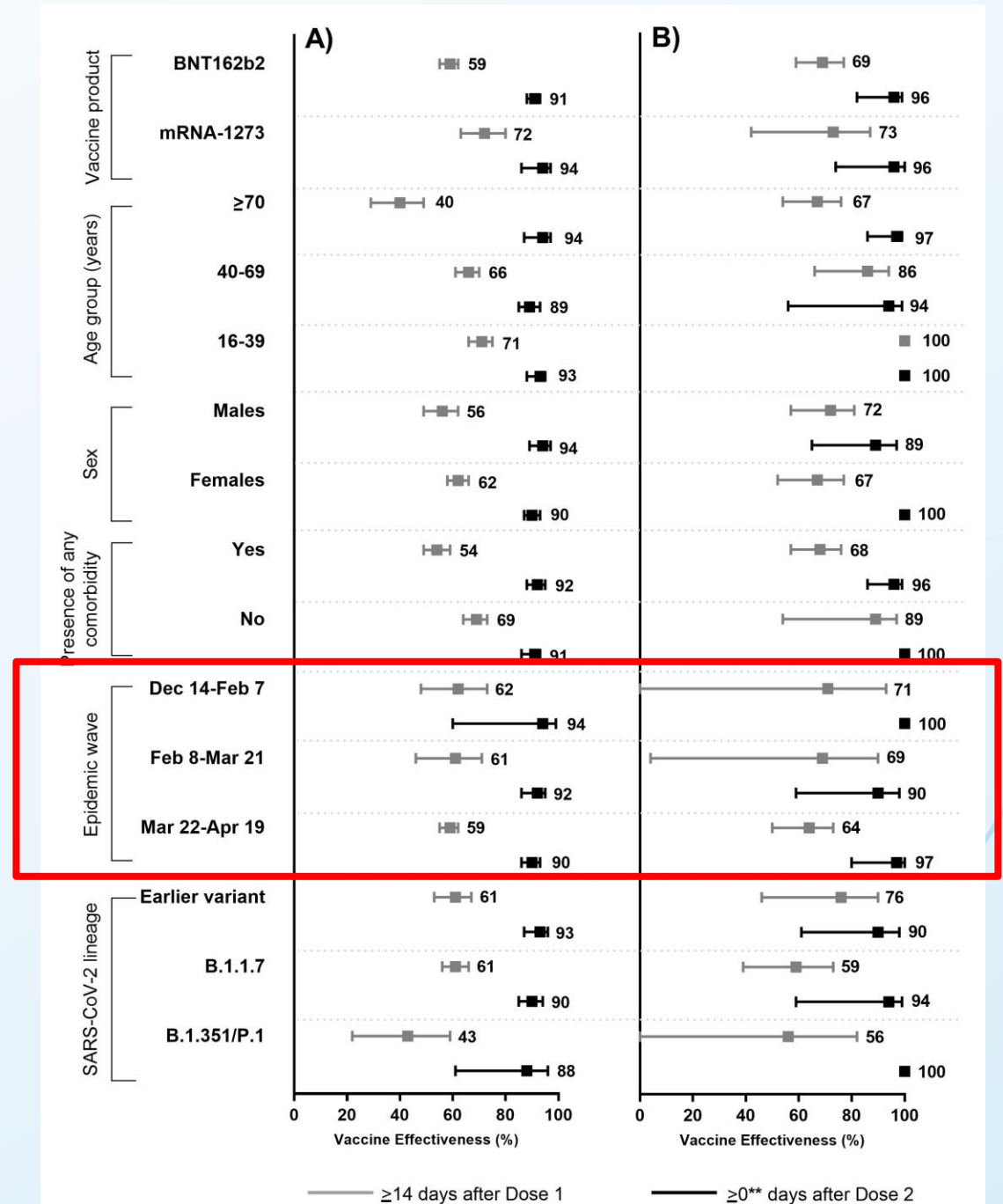
VE by comorbidities

- A: symptomatic infection
- After 1 dose, lower VE for those with comorbidities
- B: severe outcomes
- Higher VE than infection
- Both A & B:
 - After 2 doses, high VE +/- comorbidities



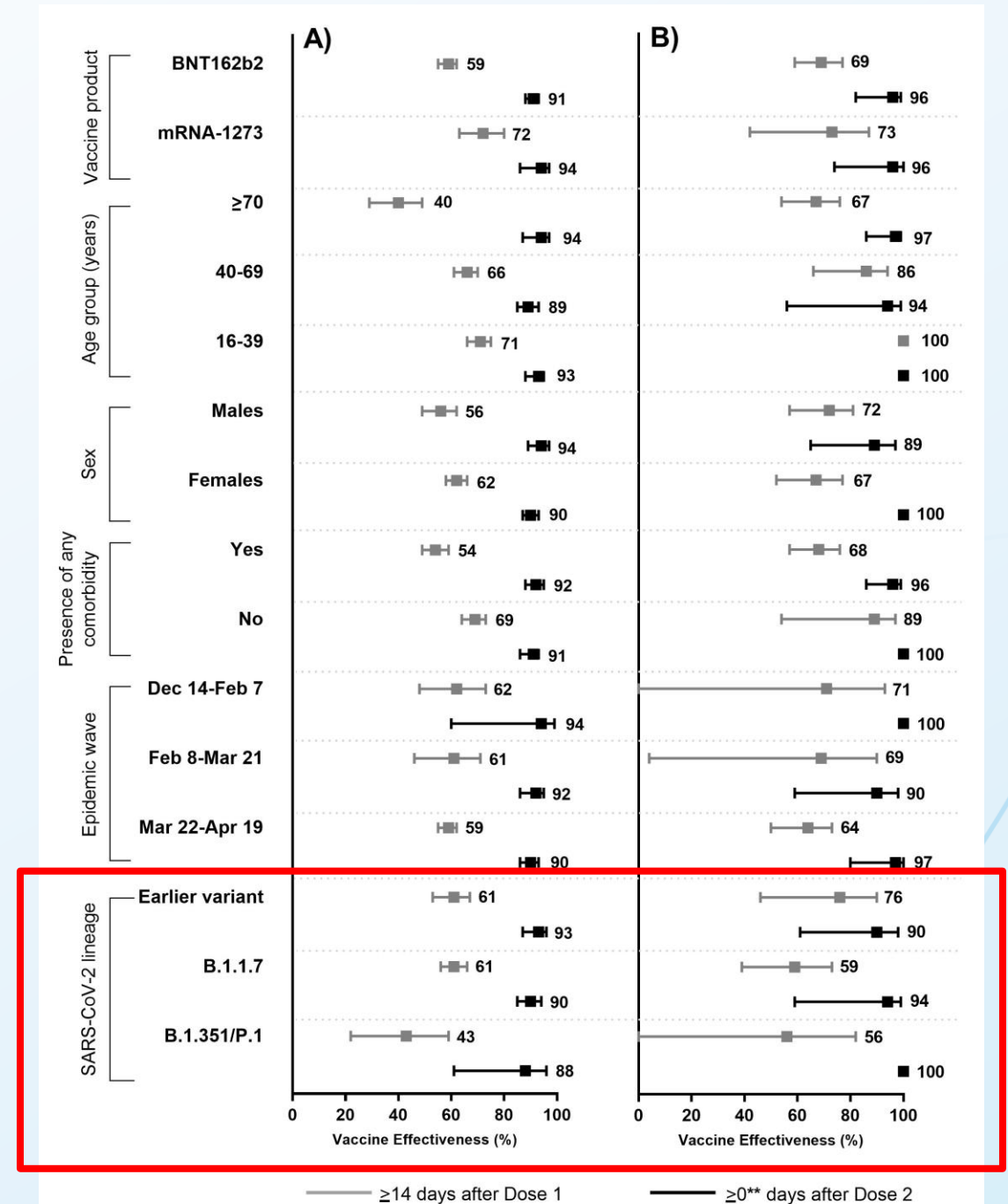
VE by wave

- A: symptomatic infection
- Similar VE across the 3 periods
- B: severe outcomes
- Wide confidence intervals
- Both A & B:
- After 2 doses, high VE across the 3 periods



VE by lineage

- A: symptomatic infection
- After 1 dose, lower VE for E484K+ mutants
- B: severe outcomes
- Wide confidence intervals
- Both A & B:
 - After 2 doses, high VE for all lineages

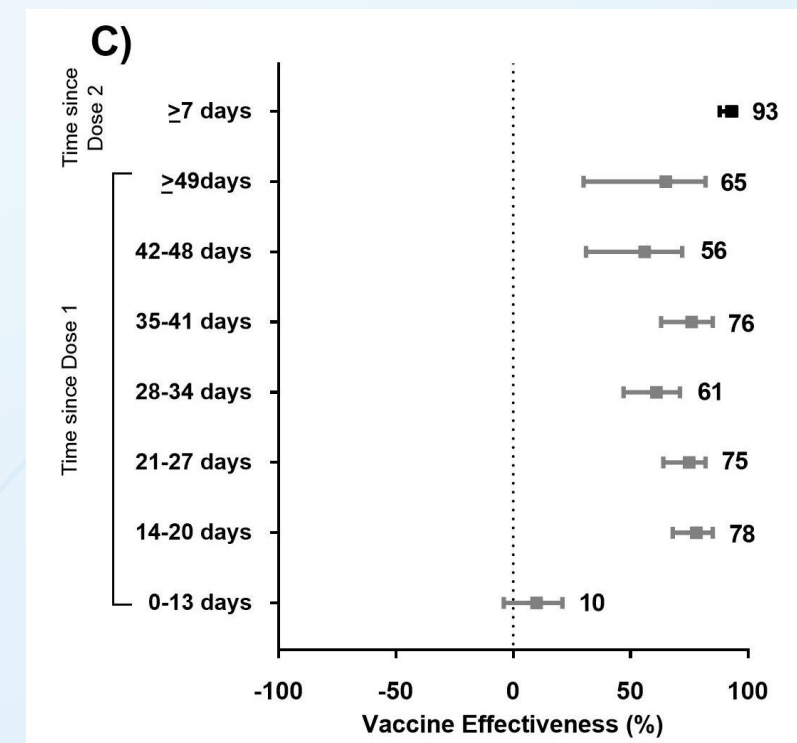
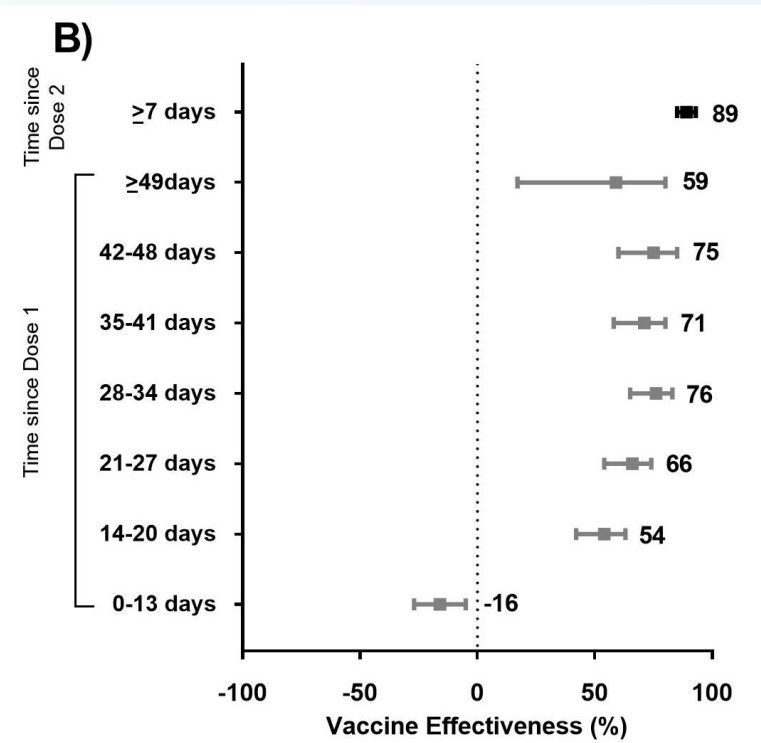
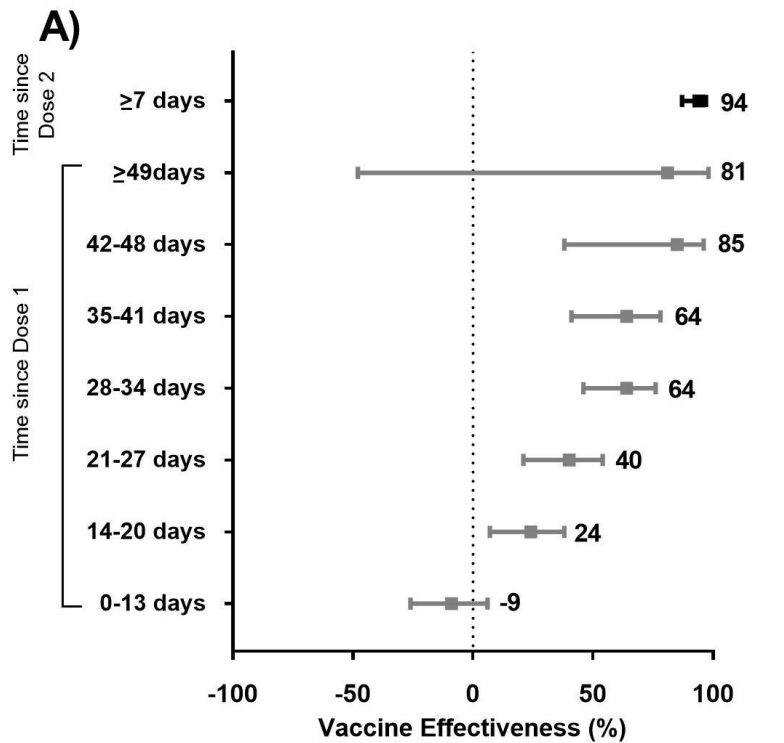


VE against symptomatic infection, stratified by age group

≥70 years

40-69 years

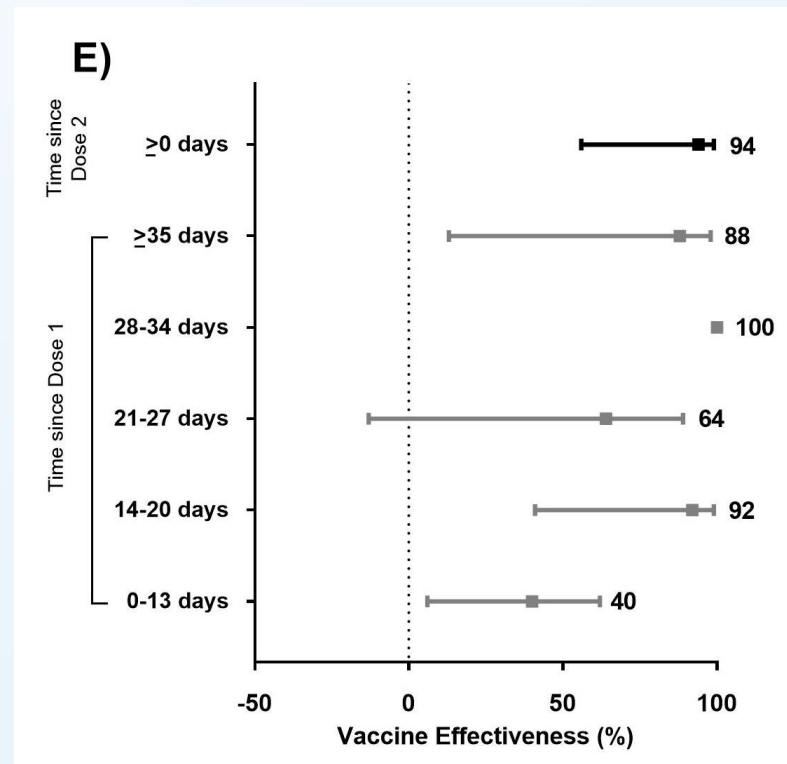
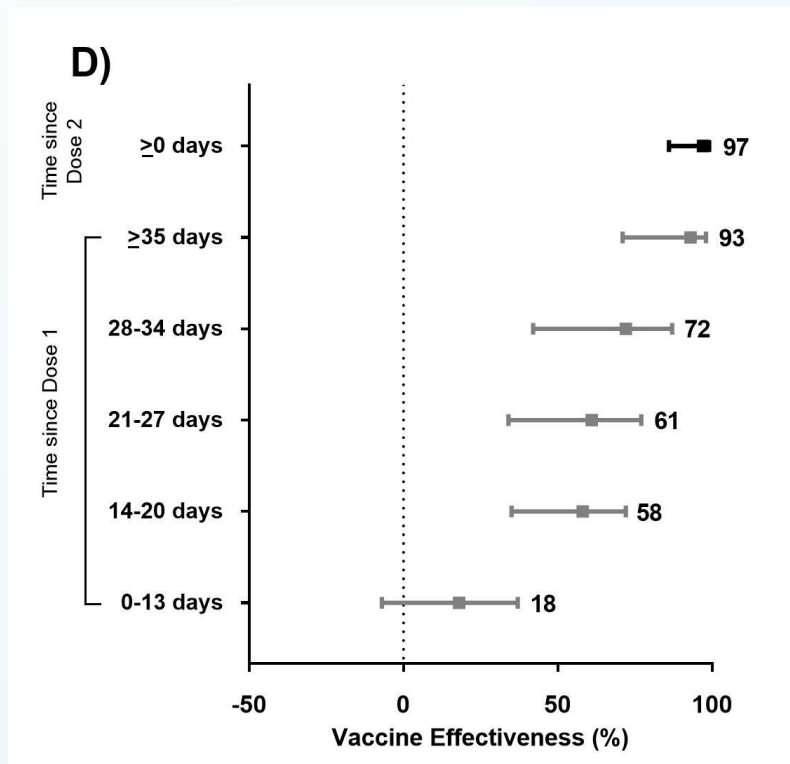
16-39 years



VE against severe outcomes, stratified by age group

≥70 years

40-69 years



Summary of findings

- Against symptomatic infection:
 - Moderate VE after 1 dose, very high VE after 2 doses
 - Slightly increased risk on days 7-13 after Dose 1
 - Lower VE after 1 dose for recipients of Pfizer vaccine, adults ≥ 70 years, those with comorbidities, B.1.351/P.1 lineages – differences eliminated after 2 doses
 - For older adults, VE after 1 dose lower initially, but increased to higher levels over time (before Dose 2)

Summary of findings

- Against severe outcomes:
 - Higher VE (than infection) after 1 dose, very high VE after 2 doses

Implications

- Increase messaging that vaccinated individuals must continue to adhere to public health measures, especially for older adults
- Minimize the delay to the second dose for high-risk individuals
- Continue monitoring VE, especially against new VOCs

Next steps

- Generate VE estimates:
 - Combining data from other provinces
 - For viral vector vaccines
 - By longer intervals after Dose 1
 - By varying intervals between doses
 - Against new VOCs (e.g., B.1.617)
 - Using other study designs (cohort design)



PCN study team

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Data
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