Supplemental Online Content

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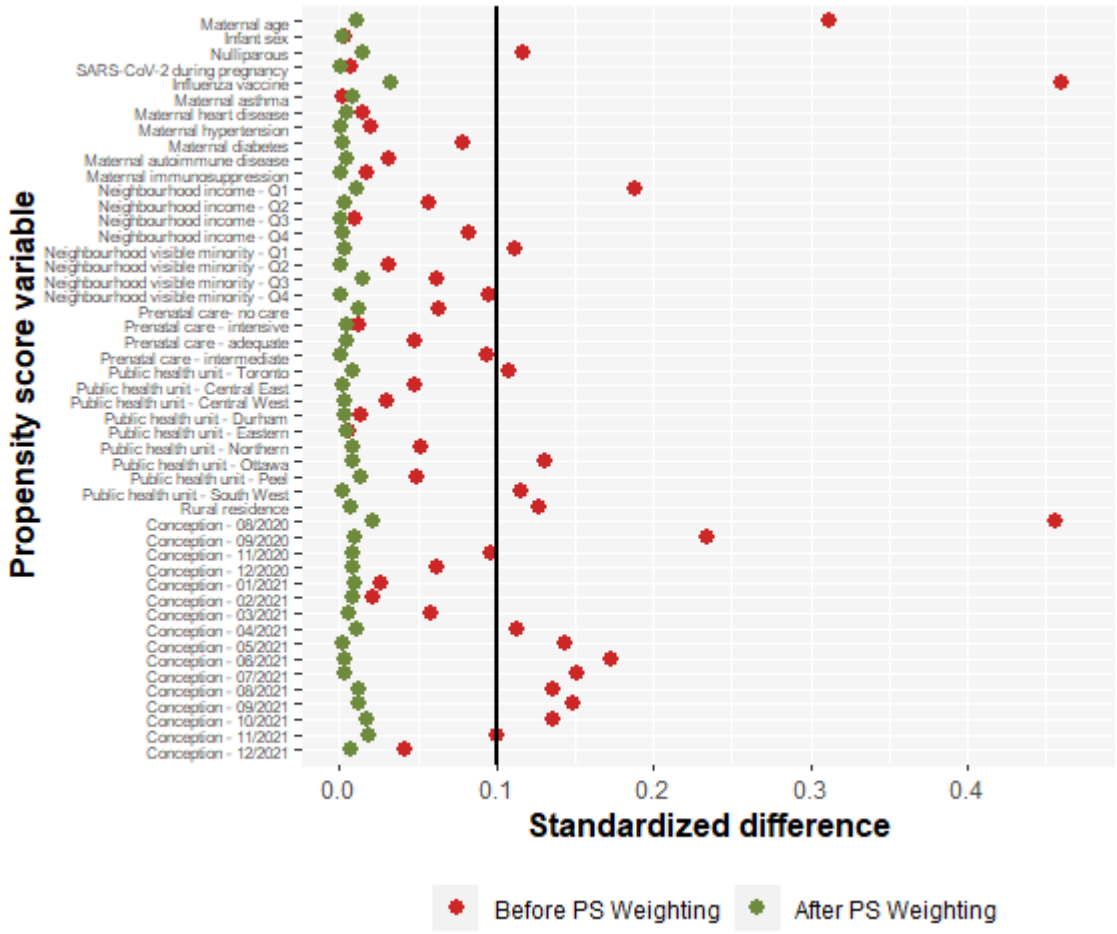
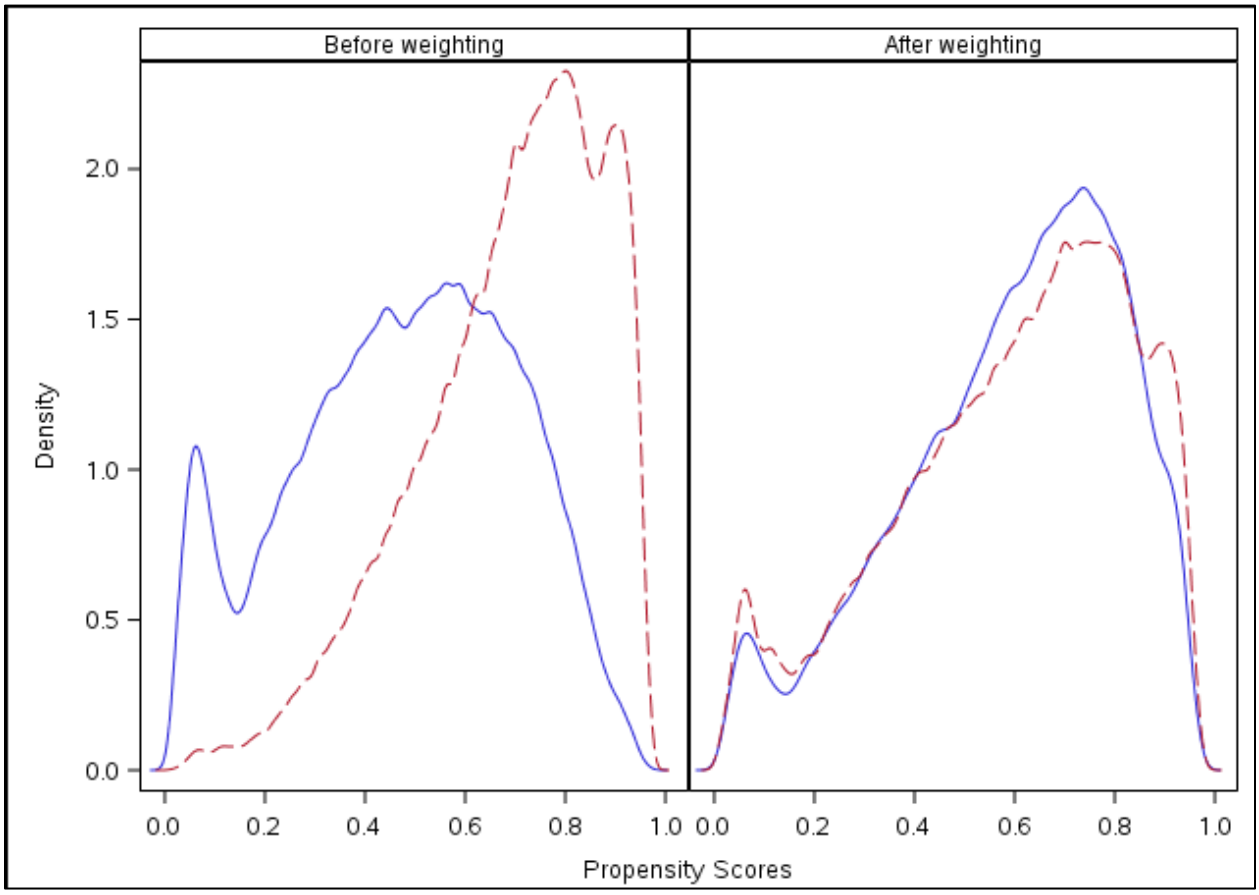
This supplemental material has been provided by the authors to give readers additional information about their work.

eFigure 1: Standardized differences for baseline characteristics in propensity score before and after weighting using stabilized inverse probability of treatment weights



Abbreviations: PS: propensity score; Q: quintile.
Absolute standardized difference <0.10 indicates covariate balance across exposure groups.

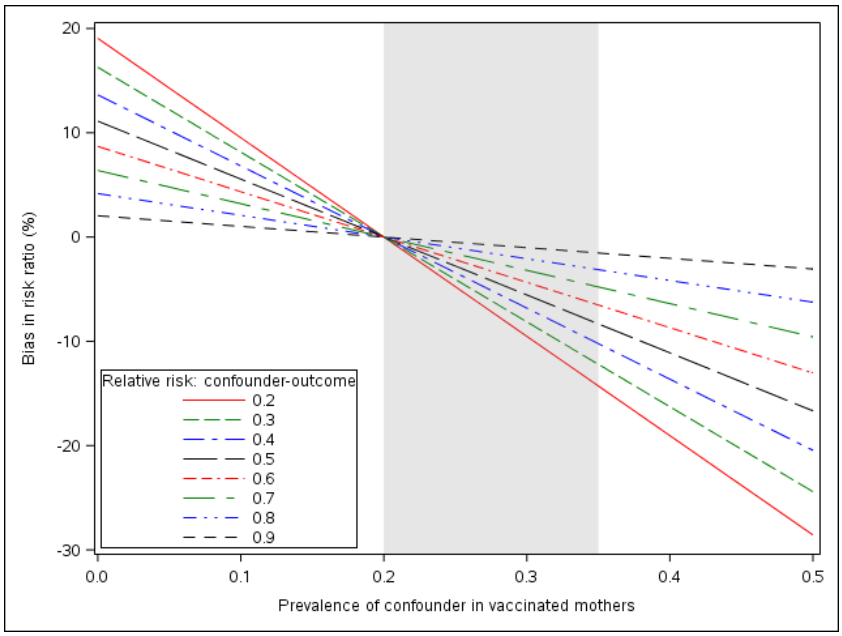
eFigure 2: Overlap in propensity score distributions by exposure group before and after weighting using stabilized inverse probability of treatment weights



Blue solid line: maternal COVID-19 vaccine unexposed before infant birth; red dashed line: maternal COVID-19 vaccine exposed during pregnancy.

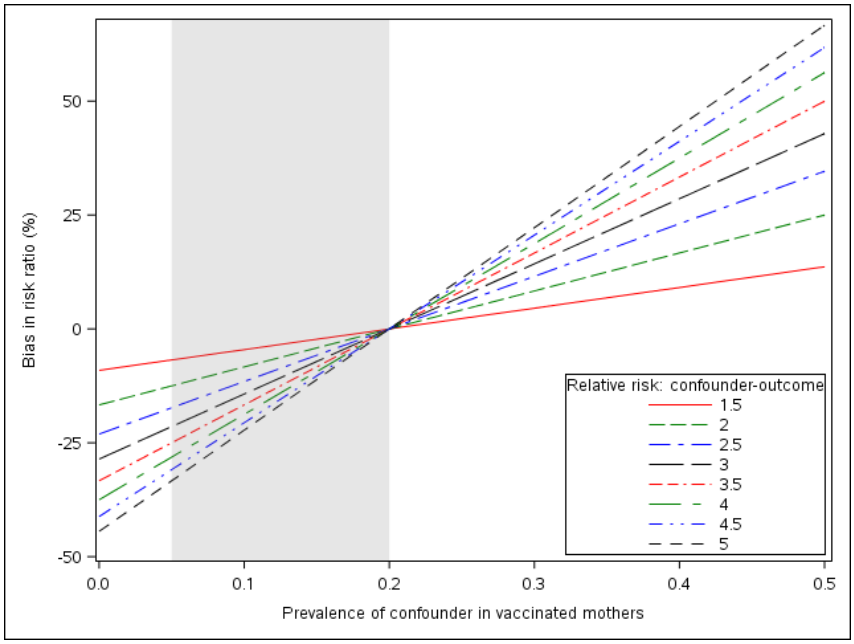
eFigure 3: Bias analyses for severe neonatal morbidity: percent bias as a function of the prevalence of the hypothetical confounder in the vaccine exposed group

A. Higher prevalence of a protective confounder in the vaccine exposed group



Prevalence of confounder held a 20% in the vaccine unexposed group and varied from 20% to 35% in the vaccine exposed group represented by the grey band

B. Lower prevalence of a harmful confounder in the vaccine exposed group



Prevalence of confounder held a 20% in the vaccine unexposed group and varied from 5% to 20% in the vaccine exposed group represented by the grey band

eTable 1: Linked health administrative databases

Database	Description
Linked Delivering Mother and Newborns (MOMBABY)	Deterministically linked maternal-newborn hospital delivery records and information on maternal and newborn characteristics (e.g., gestational age, birthweight), diagnoses for pre-existing health conditions (mothers) and complications that arise around the time of the delivery (mothers and newborns)
Registered Persons Database (RPDB)	Date of birth, sex, postal code, and death date (if applicable) for Ontario residents
Canadian Institute for Health Information Discharge Abstract Database (CIHI-DAD)	Information related to acute-care hospitalizations in Ontario (e.g., sociodemographic, diagnoses, procedures, treatments, transfers, deaths)
Ontario Health Insurance Plan (OHIP)	Diagnostic and procedure information from inpatient and outpatient claims submitted by Ontario physicians for Ontario residents
Ontario Drug Benefit (ODB)	Claims for prescription drugs and vaccines (influenza) received under the ODB program
National Ambulatory Care Reporting System (NACRS)	Information related to emergency department visits in Ontario
Same Day Surgery Database (SDS)	Information related to day surgeries in Ontario
Ontario Asthma Dataset (ASTHMA)	Information related to asthma diagnoses
Ontario Hypertension Dataset (HYPER)	Information related to hypertension diagnoses
Ontario Diabetes Dataset (ODD)	Information related to diabetes diagnoses
Canadian Organ Replacement Registry (CORR)	Canadian information system with information on patients who received dialysis or transplantation
Ontario Cancer Registry (OCR)	Information on Ontario residents with newly diagnosed cancer or who have died of cancer
Ontario HIV database (HIV)	Information on Ontario residents with HIV infection
Ontario Rheumatoid Arthritis Database (ORAD)	Information on Ontario residents with rheumatoid arthritis
Ontario Crohn's and Colitis Cohort Dataset (OCCC)	Information on Ontario residents with Crohn's disease or colitis
COVID-19 Integrated Testing Data (C19INTGR)	Comprehensive dataset of all COVID-19 laboratory diagnostic testing results in Ontario
Ontario COVID-19 Vaccine Data (COVaxON)	A centralized COVID-19 vaccine information system which contains comprehensive documentation (e.g., administration date, brand, dose) of all COVID-19 vaccination events in Ontario
Ontario Census Area Profiles (CENSUS)	Data from the 2016 Canadian Census
Postal Code Conversion File (PCCF)	Links six-character postal codes to standard geographic areas such as dissemination area and census tracts

eTable 2: Severe neonatal morbidity

Component[a]	Variable or diagnostic / procedural code
Gestational age < 32 weeks	B_GESTWKS_DEL (or M_GESTW KS_DEL)
Birth weight < 1500 grams	B_WEIGHT
Respiratory distress syndrome	P22.0
Seizures	P90, R56
Grade 2 to 4 intraventricular hemorrhage	P52.1, P52.2
Cerebral infarction	I63
Periventricular leukomalacia	P91.2
Birth trauma (intracranial hemorrhage paralysis due to brachial plexus injury, skull, or long bone fracture)	P10.0 to P10.3, P13.0, P13.2, P13.3, P14.0, P14.1
Hypoxic ischemic encephalopathy	P91.5, P91.81, P91.6
Necrotizing enterocolitis	P77
Bronchopulmonary dysplasia	P27.1
Sepsis/septicemia	P36, A40, A41.5, A41.9, B95.1, B96.2
Pneumonia	P23, J12 to J18
Primary atelectasis	P28.0
Respiratory failure	P28.5
Resuscitation	1.GZ.30
Ventilatory support	1.GZ.31
Central venous or arterial catheter	1.IS.53, 1.KV.53
Transfusion of blood or blood products	BTANY, BTOTHER
Pneumothorax requiring an intercostal catheter	1.GT.33
Death	

a. Between 0 and 27 days after birth or before discharge from the birth admission.

eTable 3: Additional analyses of the association between COVID-19 vaccination during pregnancy and neonatal and infant outcomes

	n/N (%)		Risk ratio or hazard ratio (95% confidence interval)	
Outcome	**Vaccine exposed**	**Unexposed**	**Crude**	**Adjusted[a]**
Number of vaccine doses during pregnancy				
One vaccine dose during pregnancy				
Severe neonatal morbidity	3,177/41,621 (7.6%)	4,697/56,336 (8.3%)	0.92 (0.88-0.96)	0.91 (0.86-0.96)
Neonatal death	40/41,621 (0.10%)	91/56,336 (0.16%)	0.60 (0.41-0.86)	0.59 (0.37-0.92)
Neonatal intensive care unit admission	4,958/41,621 (11.9%)	7,391/56,336 (13.1%)	0.91 (0.88-0.94)	0.95 (0.91-0.99)
Neonatal readmission	2,303/41,082 (5.6%)	2,820/55,417 (5.1%)	1.10 (1.05-1.17)	1.07 (1.00-1.15)
6-month readmission	1,876/21,940 (8.6%)	3,941/48,625 (8.1%)	1.06 (1.00-1.12)	1.05 (0.99-1.13)
Two vaccine doses during pregnancy				
Severe neonatal morbidity	2,974/42,523 (7.0%)	4,697/56,336 (8.3%)	0.84 (0.80-0.88)	0.84 (0.80-0.88)
Neonatal death	33/42,523 (0.08%)	91/56,336 (0.16%)	0.48 (0.32-0.72)	0.42 (0.28-0.65)
Neonatal intensive care unit admission	4,631/42,523 (10.9%)	7,391/56,336 (13.1%)	0.83 (0.80-0.86)	0.82 (0.79-0.86)
Neonatal readmission	2,292/42,190 (5.4%)	2,820/55,417 (5.1%)	1.07 (1.01-1.13)	1.02 (0.96-1.09)
6-month readmission	3,392/40,465 (8.4%)	3,941/48,625 (8.1%)	1.04 (0.99-1.08)	0.99 (0.94-1.04)
Three vaccine doses during pregnancy[b]				
Severe neonatal morbidity	78/1,483 (5.3%)	886/10,783 (8.2%)	0.64 (0.51-0.80)	0.69 (0.51-0.92)
Neonatal death	≤5/1,483 (≤0.3%)[c]	21/10,783 0.19%)	-[c]	0.70 (0.90-5.20)
Neonatal intensive care unit admission	131/1,483 (8.8%)	1,455/10,783 (13.5%)	0.65 (0.55-0.77)	0.75 (0.60-0.92)
Neonatal readmission	66/1,483 (4.5%)	518/10,603 (4.9%)	0.91 (0.70-1.17)	1.09 (0.79-1.50)
6-month readmission	91/1,409 (6.5%)	685/8,165 (8.4%)	0.76 (0.61-0.95)	0.85 (0.65-1.11)
Trimester of vaccination				
At least one vaccine dose in the first trimester[b]				
Severe neonatal morbidity	2,136/27,945 (7.6%)	3,064/37,324 (8.2%)	0.93 (0.88-0.98)	0.91 (0.85-0.97)
Neonatal death	33/27,945 (0.12%)	59/37,324 (0.16%)	0.75 (0.49-1.14)	0.71 (0.42-1.19)
Neonatal intensive care unit admission	3,275/27,945 (11.7%)	4,846/37,324 (13.0%)	0.90 (0.87-0.94)	0.87 (0.83-0.92)
Neonatal readmission	1,522/27,587 (5.5%)	1,898/36,721 (5.2%)	1.07 (1.00-1.14)	1.11 (1.02-1.20)
6-month readmission	1,652/19,096 (8.7%)	2,594/29,647 (8.8%)	0.99 (0.93-1.05)	1.08 (1.00-1.17)
At least one vaccine dose in the second trimester				
Severe neonatal morbidity	3,467/45,901 (7.6%)	4,697/56,336 (8.3%)	0.91 (0.87-0.94)	0.92 (0.87-0.96)
Neonatal death	39/45,901 (0.08%)	91/56,336 (0.16%)	0.53 (0.36-0.77)	0.55 (0.35-0.86)
Neonatal intensive care unit admission	5,392/45,901 (11.8%)	7,391/56,336 (13.1%)	0.90 (0.87-0.93)	0.90 (0.86-0.93)
Neonatal readmission	2,547/45,371 (5.6%)	2,820/55,417 (5.1%)	1.10 (1.05-1.16)	1.06 (1.00-1.13)
6-month readmission	2,955/33,615 (8.8%)	3,941/48,625 (8.1%)	1.09 (1.04-1.14)	1.05 (1.00-1.11)
At least one vaccine dose in third trimester				

	n/N (%)		Risk ratio or hazard ratio (95% confidence interval)	
Outcome	**Vaccine exposed**	**Unexposed**	**Crude**	**Adjusted[a]**
Severe neonatal morbidity	2,426/38,410 (6.3%)	4,697/56,336 (8.3%)	0.76 (0.72-0.79)	0.78 (0.74-0.82)
Neonatal death	17/38,410 (0.04%)	91/56,336 (0.16%)	0.27 (0.16-0.46)	0.24 (0.14-0.41)
Neonatal intensive care unit admission	3,904/38,410 (10.2%)	7,391/56,336 (13.1%)	0.77 (0.75-0.80)	0.79 (0.76-0.83)
Neonatal readmission	2,011/38,265 (5.3%)	2,820/55,417 (5.1%)	1.03 (0.97-1.09)	1.00 (0.94-1.07)
6-month readmission	2,839/36,636 (7.8%)	3,941/48,625 (8.1%)	0.96 (0.91-1.00)	0.96 (0.91-1.02)
Vaccine product				
BNT162b2				
Severe neonatal morbidity	4,189/58,533 (7.2%)	4,697/56,336 (8.3%)	0.86 (0.82-0.89)	0.84 (0.81-0.88)
Neonatal death	53/58,533 (0.09%)	91/56,336 (0.16%)	0.56 (0.40-0.79)	0.50 (0.34-0.71)
Neonatal intensive care unit admission	6,660/58,533 (11.4%)	7,391/56,336 (13.1%)	0.87 (0.84-0.89)	0.86 (0.83-0.89)
Neonatal readmission	3,192/57,927 (5.5%)	2,820/55,417 (5.1%)	1.08 (1.03-1.14)	1.03 (0.98-1.09)
6-month readmission	3,715/44,556 (8.3%)	3,941/48,625 (8.1%)	1.03 (0.99-1.08)	1.00 (0.95-1.05)
mRNA-1273				
Severe neonatal morbidity	1,545/20,215 (7.6%)	4,697/56,336 (8.3%)	0.92 (0.87-0.97)	0.91 (0.84-0.97)
Neonatal death	17/20,215 (0.08%)	91/56,336 (0.16%)	0.52 (0.31-0.87)	0.38 (0.20-0.72)
Neonatal intensive care unit admission	2,332/20,215 (11.5%)	7,391/56,336 (13.1%)	0.88 (0.84-0.92)	0.87 (0.82-0.92)
Neonatal readmission	1,118/20,009 (5.6%)	2,820/55,417 (5.1%)	1.10 (1.03-1.18)	1.07 (0.98-1.16)
6-month readmission	1,099/12,546 (8.8%)	3,941/48,625 (8.1%)	1.09 (1.02-1.16)	1.05 (0.97-1.13)
Heterologous mRNA vaccine doses[b]				
Severe neonatal morbidity	494/6,891 (7.2%)	3,230/39,525 (8.2%)	0.88 (0.80-0.96)	0.91 (0.81-1.02)
Neonatal death	≤5/6,891 (≤0.07%)[c]	62/39,525 (0.16%)	-[c]	0.27 (0.09-0.81)
Neonatal intensive care unit admission	726/6,891 (10.5%)	5,158/39,525 (13.1%)	0.81 (0.75-0.87)	0.79 (0.72-0.87)
Neonatal readmission	353/6,832 (5.2%)	1,982/38,879 (5.1%)	1.01 (0.90-1.13)	1.00 (0.87-1.16)
6-month readmission	547/6,732 (8.1%)	2,995/35,276 (8.5%)	0.96 (0.87-1.05)	1.00 (0.89-1.12)
Infants of mothers vaccinated postpartum as unexposed group				
Severe neonatal morbidity	6,229/85,670 (7.3%)	2,333/27,115 (8.6%)	0.85 (0.81-0.88)	0.81 (0.76-0.86)
Neonatal death	74/85,670 (0.09%)	49/27,115 (0.18%)	0.48 (0.33-0.69)	0.36 (0.22-0.57)
Neonatal intensive care unit admission	9,721/85,670 (11.4%)	3,654/27,115 (13.5%)	0.84 (0.81-0.87)	0.83 (0.80-0.87)
Neonatal readmission	4,664/84,798 (5.5%)	1,384/26,606 (5.2%)	1.06 (0.99-1.12)	0.98 (0.91-1.06)
6-month readmission	5,361/63,834 (8.4%)	2,187/26,849 (8.2%)	1.03 (0.98-1.09)	0.96 (0.90-1.02)
Infants of mothers with a positive SARS-CoV-2 PCR test during pregnancy excluded				
Severe neonatal morbidity	5,813/79,421 (7.3%)	4,325/52,113 (8.3%)	0.88 (0.85-0.92)	0.87 (0.83-0.91)
Neonatal death	67/79,421 (0.08%)	84/52,113 (0.16%)	0.52 (0.38-0.72)	0.47 (0.33-0.66)
Neonatal intensive care unit admission	9,046/79,421 (11.4%)	6,806/52,113 (13.1%)	0.87 (0.85-0.90)	0.86 (0.84-0.89)
Neonatal readmission	4,355/78,602 (5.5%)	2,593/51,272(5.1%)	1.10 (1.04-1.15)	1.04 (0.99-1.10)
6-month readmission	5,077/60,454 (8.4%)	3,661/45,279 (8.1%)	1.04 (1.00-1.09)	1.01 (0.96-1.06)

	n/N (%)		Risk ratio or hazard ratio (95% confidence interval)	
Outcome	**Vaccine exposed**	**Unexposed**	**Crude**	**Adjusted[a]**
Female infants				
Severe neonatal morbidity	2,581/41,931 (6.2%)	2,030/27,480 (7.4%)	0.83 (0.79-0.88)	0.83 (0.78-0.88)
Neonatal death	25/41,931 (0.06%)	40/27,480 (0.15%)	0.41 (0.25-0.68)	0.44 (0.26-0.75)
Neonatal intensive care unit admission	4,124/41,931 (9.8%)	3,191/27,480 (11.6%)	0.85 (0.81-0.88)	0.85 (0.80-0.89)
Neonatal readmission	2,087/41,578 (5.0%)	1,270/27,048 (4.7%)	1.07 (1.00-1.15)	1.02 (0.95-1.11)
6-month readmission	2,336/31,214 (7.5%)	1,754/23,719 (7.4%)	1.01 (0.95-1.08)	0.99 (0.92-1.06)
Male infants				
Severe neonatal morbidity	3,648/43,739 (8.3%)	2,667/28,856 (9.2%)	0.90 (0.86-0.95)	0.89 (0.84-0.94)
Neonatal death	49/43,739 (0.11%)	51/28,856 (0.18%)	0.63 (0.43-0.94)	0.49 (0.32-0.75)
Neonatal intensive care unit admission	5,597/43,739 (12.8%)	4,200/28,856 (14.6%)	0.88 (0.85-0.91)	0.87 (0.83-0.91)
Neonatal readmission	2,577/43,220 (6.0%)	1,550/28,369 (5.5%)	1.09(1.03-1.16)	1.04 (0.97-1.12)
6-month readmission	3,025/32,620 (9.3%)	2,187/24,906 (8.8%)	1.06 (1.00-1.12)	1.02 (0.96-1.08)
Excluding preterm infants (<37 weeks' gestation)				
Severe neonatal morbidity	4,571/80,844 (5.7%)	3,086/52,304 (5.9%)	0.96 (0.92-1.00)	0.96 (0.91-1.01)
Neonatal death	35/80,844 (0.04%)	34/52,304 (0.07%)	0.67 (0.42-1.07)	0.61 (0.36-1.04)
Neonatal intensive care unit admission	6,777/80,844 (8.4%)	4,711/52,304 (9.0%)	0.93 (0.90-0.96)	0.94 (0.90-0.98)
Neonatal readmission	4,160/80,709 (5.2%)	2,486/52,164 (4.8%)	1.08 (1.03-1.14)	1.04 (0.98-1.10)
6-month readmission	4,686/60,058 (7.8%)	3,383/45,074 (7.5%)	1.04 (1.00-1.09)	1.01 (0.96-1.06)
Untrimmed inverse probability of treatment weighting				
Severe neonatal morbidity	6,229/85,670 (7.3%)	4,697/56,336 (8.3%)	0.87 (0.84-0.90)	0.87 (0.83-0.91)
Neonatal death	74/85,670 (0.09%)	91/56,336 (0.16%)	0.53 (0.39-0.73)	0.45 (0.32-0.64)
Neonatal intensive care unit admission	9,721/85,670/ (11.4%)	7,391/56,336 (13.1%)	0.86 (0.84-0.89)	0.86 (0.83-0.89)
Neonatal readmission	4,664/84,798 (5.5%)	2,820/55,417 (5.1%)	1.08 (1.03-1.13)	1.03 (0.97-1.09)
6-month readmission	5,361/63,834 (8.4%)	3,941/48,625 (8.1%)	1.04 (1.00-1.08)	1.00 (0.95-1.05)
Birth trauma excluded from the Neonatal Adverse Outcome Indicator				
Severe neonatal morbidity	6,229/85,670 (7.3%)	4,697/56,336 (8.3%)	0.87 (0.84-0.90)	0.86 (0.83-0.90)

Abbreviation: PCR: polymerase chain reaction.

a. Risk ratios and hazard ratios were adjusted using stabilized inverse probability of treatment weighting, trimmed at the 99th percentile. Propensity scores were respecified for each analysis. Covariates used to construct the propensity scores included infant sex; calendar month and year of conception; maternal age at infant birth; parity; pre-existing maternal medical conditions (hypertension, heart disease, diabetes mellitus, asthma, autoimmune disease, immunosuppression); maternal influenza vaccination during either the 2019-2020 or 2020-2021 influenza seasons; adequacy of prenatal care using the Revised Graduated Prenatal Care Index; maternal positive SARS-CoV-2 PCR test result during pregnancy; neighbourhood-level income quintile; neighbourhood-level proportion of the population who self-identify as a visible minority quintiles; rural residence; and Public Health Unit region. Covariates that remained unbalanced after propensity score weighting, as indicated by a standardized difference ≥0.10, were added to weighted models.

b. Infants with insufficient overlap in the month and year of conception by exposure group were excluded.
c. In accordance with Ontario's privacy legislation, ICES data privacy policy prohibits us from reporting cells with fewer than 6 observations. Ranges reported in adjacent cells are to prevent back calculation of small cells.

eTable 4: Array approach sensitivity analyses for unmeasured potential confounders

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
Severe neonatal morbidity: higher prevalence of a protective confounder in the vaccine exposed group					
0.86	0.20	0.20	0.20	0.86	0.00
0.86	0.30	0.20	0.20	0.86	0.00
0.86	0.40	0.20	0.20	0.86	0.00
0.86	0.50	0.20	0.20	0.86	0.00
0.86	0.60	0.20	0.20	0.86	0.00
0.86	0.70	0.20	0.20	0.86	0.00
0.86	0.80	0.20	0.20	0.86	0.00
0.86	0.90	0.20	0.20	0.86	0.00
0.86	0.20	0.25	0.20	0.90	-4.76
0.86	0.30	0.25	0.20	0.90	-4.07
0.86	0.40	0.25	0.20	0.89	-3.41
0.86	0.50	0.25	0.20	0.88	-2.78
0.86	0.60	0.25	0.20	0.88	-2.17
0.86	0.70	0.25	0.20	0.87	-1.60
0.86	0.80	0.25	0.20	0.87	-1.04
0.86	0.90	0.25	0.20	0.86	-0.51
0.86	0.20	0.3	0.20	0.95	-9.52
0.86	0.30	0.3	0.20	0.94	-8.14
0.86	0.40	0.3	0.20	0.92	-6.82
0.86	0.50	0.3	0.20	0.91	-5.56
0.86	0.60	0.3	0.20	0.90	-4.35
0.86	0.70	0.3	0.20	0.89	-3.19
0.86	0.80	0.3	0.20	0.88	-2.08
0.86	0.90	0.3	0.20	0.87	-1.02
0.86	0.20	0.35	0.20	1.00	-14.29
0.86	0.30	0.35	0.20	0.98	-12.21
0.86	0.40	0.35	0.20	0.96	-10.23
0.86	0.50	0.35	0.20	0.94	-8.33
0.86	0.60	0.35	0.20	0.92	-6.52
0.86	0.70	0.35	0.20	0.90	-4.79
0.86	0.80	0.35	0.20	0.89	-3.12

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
0.86	0.90	0.35	0.20	0.87	-1.53
Severe neonatal morbidity: lower prevalence of a harmful confounder in the vaccine exposed group					
0.86	1.50	0.05	0.20	0.92	-6.82
0.86	2.00	0.05	0.20	0.98	-12.50
0.86	2.50	0.05	0.20	1.04	-17.31
0.86	3.00	0.05	0.20	1.09	-21.43
0.86	3.50	0.05	0.20	1.15	-25.00
0.86	4.00	0.05	0.20	1.20	-28.13
0.86	4.50	0.05	0.20	1.24	-30.88
0.86	5.00	0.05	0.20	1.29	-33.33
0.86	1.50	0.10	0.20	0.90	-4.55
0.86	2.00	0.10	0.20	0.94	-8.33
0.86	2.50	0.10	0.20	0.97	-11.54
0.86	3.00	0.10	0.20	1.00	-14.29
0.86	3.50	0.10	0.20	1.03	-16.67
0.86	4.00	0.10	0.20	1.06	-18.75
0.86	4.50	0.10	0.20	1.08	-20.59
0.86	5.00	0.10	0.20	1.11	-22.22
0.86	1.50	0.15	0.20	0.88	-2.27
0.86	2.00	0.15	0.20	0.90	-4.17
0.86	2.50	0.15	0.20	0.91	-5.77
0.86	3.00	0.15	0.20	0.93	-7.14
0.86	3.50	0.15	0.20	0.94	-8.33
0.86	4.00	0.15	0.20	0.95	-9.38
0.86	4.50	0.15	0.20	0.96	-10.29
0.86	5.00	0.15	0.20	0.97	-11.11
0.86	1.50	0.20	0.20	0.86	0.00
0.86	2.00	0.20	0.20	0.86	0.00
0.86	2.50	0.20	0.20	0.86	0.00
0.86	3.00	0.20	0.20	0.86	0.00
0.86	3.50	0.20	0.20	0.86	0.00
0.86	4.00	0.20	0.20	0.86	0.00
0.86	4.50	0.20	0.20	0.86	0.00
0.86	5.00	0.20	0.20	0.86	0.00

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
Neonatal death: higher prevalence of a protective confounder in the vaccine exposed group					
0.47	0.20	0.20	0.20	0.47	0.0
0.47	0.30	0.20	0.20	0.47	0.00
0.47	0.40	0.20	0.20	0.47	0.00
0.47	0.50	0.20	0.20	0.47	0.00
0.47	0.60	0.20	0.20	0.47	0.00
0.47	0.70	0.20	0.20	0.47	0.00
0.47	0.80	0.20	0.20	0.47	0.00
0.47	0.90	0.20	0.20	0.47	0.00
0.47	0.20	0.25	0.20	0.49	-4.76
0.47	0.30	0.25	0.20	0.49	-4.07
0.47	0.40	0.25	0.20	0.49	-3.41
0.47	0.50	0.25	0.20	0.48	-2.78
0.47	0.60	0.25	0.20	0.48	-2.17
0.47	0.70	0.25	0.20	0.48	-1.60
0.47	0.80	0.25	0.20	0.47	-1.04
0.47	0.90	0.25	0.20	0.47	-0.51
0.47	0.20	0.30	0.20	0.52	-9.52
0.47	0.30	0.30	0.20	0.51	-8.14
0.47	0.40	0.30	0.20	0.50	-6.82
0.47	0.50	0.30	0.20	0.50	-5.56
0.47	0.60	0.30	0.20	0.49	-4.35
0.47	0.70	0.30	0.20	0.49	-3.19
0.47	0.80	0.30	0.20	0.48	-2.08
0.47	0.90	0.30	0.20	0.47	-1.02
0.47	0.20	0.35	0.20	0.55	-14.29
0.47	0.30	0.35	0.20	0.54	-12.21
0.47	0.40	0.35	0.20	0.52	-10.23
0.47	0.50	0.35	0.20	0.51	-8.33
0.47	0.60	0.35	0.20	0.50	-6.52
0.47	0.70	0.35	0.20	0.49	-4.79
0.47	0.80	0.35	0.20	0.49	-3.12
0.47	0.90	0.35	0.20	0.48	-1.53
Neonatal death: lower prevalence of a harmful confounder in the vaccine exposed group					

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
0.47	1.50	0.05	0.20	0.50	-6.82
0.47	2.00	0.05	0.20	0.54	-12.50
0.47	2.50	0.05	0.20	0.57	-17.31
0.47	3.00	0.05	0.20	0.60	-21.43
0.47	3.50	0.05	0.20	0.63	-25.00
0.47	4.00	0.05	0.20	0.65	-28.13
0.47	4.50	0.05	0.20	0.68	-30.88
0.47	5.00	0.05	0.20	0.71	-33.33
0.47	1.50	0.10	0.20	0.49	-4.55
0.47	2.00	0.10	0.20	0.51	-8.33
0.47	2.50	0.10	0.20	0.53	-11.54
0.47	3.00	0.10	0.20	0.55	-14.29
0.47	3.50	0.10	0.20	0.56	-16.67
0.47	4.00	0.10	0.20	0.58	-18.75
0.47	4.50	0.10	0.20	0.59	-20.59
0.47	5.00	0.10	0.20	0.60	-22.22
0.47	1.50	0.15	0.20	0.48	-2.27
0.47	2.00	0.15	0.20	0.49	-4.17
0.47	2.50	0.15	0.20	0.50	-5.77
0.47	3.00	0.15	0.20	0.51	-7.14
0.47	3.50	0.15	0.20	0.51	-8.33
0.47	4.00	0.15	0.20	0.52	-9.38
0.47	4.50	0.15	0.20	0.52	-10.29
0.47	5.00	0.15	0.20	0.53	-11.11
0.47	1.50	0.20	0.20	0.47	0.0
0.47	2.00	0.20	0.20	0.47	0.0
0.47	2.50	0.20	0.20	0.47	0.0
0.47	3.00	0.20	0.20	0.47	0.0
0.47	3.50	0.20	0.20	0.47	0.0
0.47	4.00	0.20	0.20	0.47	0.0
0.47	4.50	0.20	0.20	0.47	0.0
0.47	5.00	0.20	0.20	0.47	0.0
Neonatal intensive care unit admission: higher prevalence of a protective confounder in the vaccine exposed group					
0.86	0.20	0.20	0.20	0.86	0.0

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
0.86	0.30	0.20	0.20	0.86	0.0
0.86	0.40	0.20	0.20	0.86	0.0
0.86	0.50	0.20	0.20	0.86	0.0
0.86	0.60	0.20	0.20	0.86	0.0
0.86	0.70	0.20	0.20	0.86	0.00
0.86	0.80	0.20	0.20	0.86	0.00
0.86	0.90	0.20	0.20	0.86	0.00
0.86	0.20	0.25	0.20	0.90	-4.76
0.86	0.30	0.25	0.20	0.90	-4.07
0.86	0.40	0.25	0.20	0.89	-3.41
0.86	0.50	0.25	0.20	0.88	-2.78
0.86	0.60	0.25	0.20	0.88	-2.17
0.86	0.70	0.25	0.20	0.87	-1.60
0.86	0.80	0.25	0.20	0.87	-1.04
0.86	0.90	0.25	0.20	0.86	-0.51
0.86	0.20	0.3	0.20	0.95	-9.52
0.86	0.30	0.3	0.20	0.94	-8.14
0.86	0.40	0.3	0.20	0.92	-6.82
0.86	0.50	0.3	0.20	0.91	-5.56
0.86	0.60	0.3	0.20	0.90	-4.35
0.86	0.70	0.3	0.20	0.89	-3.19
0.86	0.80	0.3	0.20	0.88	-2.08
0.86	0.90	0.3	0.20	0.87	-1.02
0.86	0.20	0.35	0.20	1.00	-14.29
0.86	0.30	0.35	0.20	0.98	-12.21
0.86	0.40	0.35	0.20	0.96	-10.23
0.86	0.50	0.35	0.20	0.94	-8.33
0.86	0.60	0.35	0.20	0.92	-6.52
0.86	0.70	0.35	0.20	0.90	-4.79
0.86	0.80	0.35	0.20	0.89	-3.12
0.86	0.90	0.35	0.20	0.87	-1.53
Neonatal intensive care unit admission: lower prevalence of a harmful confounder in the vaccine exposed group					
0.86	1.50	0.05	0.20	0.92	-6.82
0.86	2.00	0.05	0.20	0.98	-12.50

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
0.86	2.50	0.05	0.20	1.04	-17.31
0.86	3.00	0.05	0.20	1.09	-21.43
0.86	3.50	0.05	0.20	1.15	-25.00
0.86	4.00	0.05	0.20	1.20	-28.13
0.86	4.50	0.05	0.20	1.24	-30.88
0.86	5.00	0.05	0.20	1.29	-33.33
0.86	1.50	0.10	0.20	0.90	-4.55
0.86	2.00	0.10	0.20	0.94	-8.33
0.86	2.50	0.10	0.20	0.97	-11.54
0.86	3.00	0.10	0.20	1.00	-14.29
0.86	3.50	0.10	0.20	1.03	-16.67
0.86	4.00	0.10	0.20	1.06	-18.75
0.86	4.50	0.10	0.20	1.08	-20.59
0.86	5.00	0.10	0.20	1.11	-22.22
0.86	1.50	0.15	0.20	0.88	-2.27
0.86	2.00	0.15	0.20	0.90	-4.17
0.86	2.50	0.15	0.20	0.91	-5.77
0.86	3.00	0.15	0.20	0.93	-7.14
0.86	3.50	0.15	0.20	0.94	-8.33
0.86	4.00	0.15	0.20	0.95	-9.38
0.86	4.50	0.15	0.20	0.96	-10.29
0.86	5.00	0.15	0.20	0.97	-11.11
0.86	1.50	0.20	0.20	0.86	0.00
0.86	2.00	0.20	0.20	0.86	0.00
0.86	2.50	0.20	0.20	0.86	0.00
0.86	3.00	0.20	0.20	0.86	0.00
0.86	3.50	0.20	0.20	0.86	0.00
0.86	4.00	0.20	0.20	0.86	0.00
0.86	4.50	0.20	0.20	0.86	0.00
0.86	5.00	0.20	0.20	0.86	0.00
Neonatal readmission: higher prevalence of a protective confounder in the vaccine exposed group					
1.03	0.20	0.20	0.20	1.03	0.00
1.03	0.30	0.20	0.20	1.03	0.00
1.03	0.40	0.20	0.20	1.03	0.00

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
1.03	0.50	0.20	0.20	1.03	0.00
1.03	0.60	0.20	0.20	1.03	0.00
1.03	0.70	0.20	0.20	1.03	0.00
1.03	0.80	0.20	0.20	1.03	0.00
1.03	0.90	0.20	0.20	1.03	0.00
1.03	0.20	0.25	0.20	1.08	-4.76
1.03	0.30	0.25	0.20	1.07	-4.07
1.03	0.40	0.25	0.20	1.07	-3.41
1.03	0.50	0.25	0.20	1.06	-2.78
1.03	0.60	0.25	0.20	1.05	-2.17
1.03	0.70	0.25	0.20	1.05	-1.60
1.03	0.80	0.25	0.20	1.04	-1.04
1.03	0.90	0.25	0.20	1.04	-0.51
1.03	0.20	0.30	0.20	1.14	-9.52
1.03	0.30	0.30	0.20	1.12	-8.14
1.03	0.40	0.30	0.20	1.11	-6.82
1.03	0.50	0.30	0.20	1.09	-5.56
1.03	0.60	0.30	0.20	1.08	-4.35
1.03	0.70	0.30	0.20	1.06	-3.19
1.03	0.80	0.30	0.20	1.05	-2.08
1.03	0.90	0.30	0.20	1.04	-1.02
1.03	0.20	0.35	0.20	1.20	-14.29
1.03	0.30	0.35	0.20	1.17	-12.21
1.03	0.40	0.35	0.20	1.15	-10.23
1.03	0.50	0.35	0.20	1.12	-8.33
1.03	0.60	0.35	0.20	1.10	-6.52
1.03	0.70	0.35	0.20	1.08	-4.79
1.03	0.80	0.35	0.20	1.06	-3.12
1.03	0.90	0.35	0.20	1.05	-1.53
Neonatal readmission: lower prevalence of a harmful confounder in the vaccine exposed group					
1.03	1.50	0.05	0.20	1.11	-6.82
1.03	2.00	0.05	0.20	1.18	-12.50
1.03	2.50	0.05	0.20	1.25	-17.31
1.03	3.00	0.05	0.20	1.31	-21.43

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
1.03	3.50	0.05	0.20	1.37	-25.00
1.03	4.00	0.05	0.20	1.43	-28.13
1.03	4.50	0.05	0.20	1.49	-30.88
1.03	5.00	0.05	0.20	1.55	-33.33
1.03	1.50	0.10	0.20	1.08	-4.55
1.03	2.00	0.10	0.20	1.12	-8.33
1.03	2.50	0.10	0.20	1.16	-11.54
1.03	3.00	0.10	0.20	1.20	-14.29
1.03	3.50	0.10	0.20	1.24	-16.67
1.03	4.00	0.10	0.20	1.27	-18.75
1.03	4.50	0.10	0.20	1.30	-20.59
1.03	5.00	0.10	0.20	1.32	-22.22
1.03	1.50	0.15	0.20	1.05	-2.27
1.03	2.00	0.15	0.20	1.07	-4.17
1.03	2.50	0.15	0.20	1.09	-5.77
1.03	3.00	0.15	0.20	1.11	-7.14
1.03	3.50	0.15	0.20	1.12	-8.33
1.03	4.00	0.15	0.20	1.14	-9.38
1.03	4.50	0.15	0.20	1.15	-10.29
1.03	5.00	0.15	0.20	1.16	-11.11
1.03	1.50	0.20	0.20	1.03	0.00
1.03	2.00	0.20	0.20	1.03	0.00
1.03	2.50	0.20	0.20	1.03	0.00
1.03	3.00	0.20	0.20	1.03	0.00
1.03	3.50	0.20	0.20	1.03	0.00
1.03	4.00	0.20	0.20	1.03	0.00
1.03	4.50	0.20	0.20	1.03	0.00
1.03	5.00	0.20	0.20	1.03	0.00
6-month readmission: higher prevalence of a protective confounder in the vaccine exposed group					
1.01	0.20	0.20	0.20	1.01	0.00
1.01	0.30	0.20	0.20	1.01	0.00
1.01	0.40	0.20	0.20	1.01	0.00
1.01	0.50	0.20	0.20	1.01	0.00
1.01	0.60	0.20	0.20	1.01	0.00

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
1.01	0.70	0.20	0.20	1.01	0.00
1.01	0.80	0.20	0.20	1.01	0.00
1.01	0.90	0.20	0.20	1.01	0.00
1.01	0.20	0.25	0.20	1.06	-4.76
1.01	0.30	0.25	0.20	1.05	-4.07
1.01	0.40	0.25	0.20	1.05	-3.41
1.01	0.50	0.25	0.20	1.04	-2.78
1.01	0.60	0.25	0.20	1.03	-2.17
1.01	0.70	0.25	0.20	1.03	-1.60
1.01	0.80	0.25	0.20	1.02	-1.04
1.01	0.90	0.25	0.20	1.02	-0.51
1.01	0.20	0.30	0.20	1.12	-9.52
1.01	0.30	0.30	0.20	1.10	-8.14
1.01	0.40	0.30	0.20	1.08	-6.82
1.01	0.50	0.30	0.20	1.07	-5.56
1.01	0.60	0.30	0.20	1.06	-4.35
1.01	0.70	0.30	0.20	1.04	-3.19
1.01	0.80	0.30	0.20	1.03	-2.08
1.01	0.90	0.30	0.20	1.02	-1.02
1.01	0.20	0.35	0.20	1.18	-14.29
1.01	0.30	0.35	0.20	1.15	-12.21
1.01	0.40	0.35	0.20	1.13	-10.23
1.01	0.50	0.35	0.20	1.10	-8.33
1.01	0.60	0.35	0.20	1.08	-6.52
1.01	0.70	0.35	0.20	1.06	-4.79
1.01	0.80	0.35	0.20	1.04	-3.12
1.01	0.90	0.35	0.20	1.03	-1.53
6-month readmission: lower prevalence of a harmful confounder in the vaccine exposed group					
1.01	1.50	0.05	0.20	1.08	-6.82
1.01	2.00	0.05	0.20	1.15	-12.50
1.01	2.50	0.05	0.20	1.22	-17.31
1.01	3.00	0.05	0.20	1.29	-21.43
1.01	3.50	0.05	0.20	1.35	-25.00
1.01	4.00	0.05	0.20	1.41	-28.13

Observed adjusted risk ratio or hazard ratio in primary analysis	Risk ratio or hazard ratio between confounder and outcome	Prevalence of hypothetical unmeasured confounder in vaccine exposed group	Prevalence of hypothetical unmeasured confounder in vaccine unexposed group	Risk ratio or hazard ratio adjusted for hypothetical unmeasured confounder	Percent bias[a]
1.01	4.50	0.05	0.20	1.46	-30.88
1.01	5.00	0.05	0.20	1.52	-33.33
1.01	1.50	0.10	0.20	1.06	-4.55
1.01	2.00	0.10	0.20	1.10	-8.33
1.01	2.50	0.10	0.20	1.14	-11.54
1.01	3.00	0.10	0.20	1.18	-14.29
1.01	3.50	0.10	0.20	1.21	-16.67
1.01	4.00	0.10	0.20	1.24	-18.75
1.01	4.50	0.10	0.20	1.27	-20.59
1.01	5.00	0.10	0.20	1.30	-22.22
1.01	1.50	0.15	0.20	1.03	-2.27
1.01	2.00	0.15	0.20	1.05	-4.17
1.01	2.50	0.15	0.20	1.07	-5.77
1.01	3.00	0.15	0.20	1.09	-7.14
1.01	3.50	0.15	0.20	1.10	-8.33
1.01	4.00	0.15	0.20	1.11	-9.38
1.01	4.50	0.15	0.20	1.13	-10.29
1.01	5.00	0.15	0.20	1.14	-11.11
1.01	1.50	0.20	0.20	1.01	0.00
1.01	2.00	0.20	0.20	1.01	0.00
1.01	2.50	0.20	0.20	1.01	0.00
1.01	3.00	0.20	0.20	1.01	0.00
1.01	3.50	0.20	0.20	1.01	0.00
1.01	4.00	0.20	0.20	1.01	0.00
1.01	4.50	0.20	0.20	1.01	0.00
1.01	5.00	0.20	0.20	1.01	0.00

a. Percent bias = [(observed RR–bias-corrected RR)/(bias-corrected RR–1)] x 100.