JAMA | Original Investigation

Neonatal Outcomes After COVID-19 Vaccination in Pregnancy

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IMPORTANCE Better knowledge about neonatal adverse events after COVID-19 vaccination during pregnancy could help address concerns about vaccine safety.

OBJECTIVE To evaluate the risks of neonatal adverse events after exposure to COVID-19 vaccination during pregnancy.

DESIGN, SETTING, AND PARTICIPANTS Population-based cohort study including all infants in Sweden and Norway born from June 2021 to January 2023. Unique personal identity numbers were used to link individual information from different national registers.

EXPOSURE Administration of any mRNA vaccine against COVID-19 during pregnancy, irrespective of previous vaccination, number of doses during pregnancy, or vaccine manufacturer.

MAIN OUTCOMES AND MEASURES Outcomes were neonatal conditions with bleeding/thrombosis or inflammation/infection; disorders of the central nervous system; circulatory, respiratory, or gastrointestinal problems; and neonatal mortality. Statistical methods included logistic regression adjusted for characteristics of the pregnant individuals, with additional restricted and stratified analyses.

RESULTS Of 196 470 newborn infants included (51.3% male, 93.8% born at term, 62.5% born in Sweden), 94 303 (48.0%) were exposed to COVID-19 vaccination during pregnancy. Exposed infants exhibited no increased odds of adverse neonatal outcomes, and they exhibited lower odds for neonatal nontraumatic intracranial hemorrhage (event rate, 1.7 vs 3.2/1000; adjusted odds ratio [aOR], 0.78 [95% CI, 0.61-0.99]), hypoxic-ischemic encephalopathy (1.8 vs 2.7/1000; aOR, 0.73 [95% CI, 0.55-0.96]), and neonatal mortality (0.9 vs 1.8/1000; aOR, 0.68 [95% CI, 0.50-0.91]). Subgroup analyses found a similar association between vaccination during pregnancy and lower neonatal mortality; subgroups were restricted to infants delivered by individuals unvaccinated before pregnancy, individuals vaccinated before pregnancy, individuals vaccinated after a general recommendation of vaccination during pregnancy was issued, and individuals without COVID-19 infection during pregnancy. Analyses restricted to term infants, singleton births, or infants without birth defects yielded similar results. Stratifying the analysis by vaccine manufacturer did not attenuate the association between vaccination and low neonatal mortality.

CONCLUSIONS AND RELEVANCE In this large population-based study, vaccination of pregnant individuals with mRNA COVID-19 vaccines was not associated with increased risks of neonatal adverse events in their infants.

Related article page 408

Supplemental content

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JAMA. 2024;331(5):396-407. doi:10.1001/jama.2023.26945

Vaccination during pregnancy has been associated with reduced rates of COVID-19 in pregnant individuals and their newborn infants.[1,2] Based on these findings and careful monitoring of potentially adverse outcomes, vaccination during pregnancy has been recommended by different authorities.[3,4]

The balance between benefits and risks of COVID-19 vaccination during pregnancy may be more nuanced among newborn infants than in the childbearing individual. Vertical transmission of COVID-19 has been found to be low (1%-3%).[5] In addition, the infection in newborn infants may be milder than in older children and adults,[5,6] and hospitalizations for COVID-19 in infancy are very rare (0.2-1/1000 person-years).[7]

Concerns about potential adverse fetal and neonatal effects have resulted in lower vaccination rates among pregnant individuals than in the general population of the same age.[8,9] Vaccination has not been associated with adverse pregnancy outcomes or higher admission rates to neonatal care,[1,10] but information on neonatal outcomes is limited. Previous studies have reported unchanged[11] or lower neonatal mortality[12,13] in exposed infants, and lower composite neonatal morbidity after vaccination during pregnancy.[12] A meta-analysis of 2 smaller studies reported lower rates of neonatal brain injury after vaccination during pregnancy.[14]

The aim of this large population-based cohort study was to perform a comprehensive assessment of neonatal safety for mRNA COVID-19 vaccines. Because clinicians and authorities have expressed unease about potential neonatal brain lesions associated with COVID-19 vaccination, a particular priority was to explore neonatal cerebrovascular outcomes.

Key Points

Question Does exposure to mRNA COVID-19 vaccination during pregnancy increase the risk of adverse events in newborn infants?

Findings In this population-based cohort study from Sweden and Norway that included 94 303 infants exposed to COVID-19 vaccination during pregnancy and 102 167 control infants born between June 2021 and January 2023, vaccination during pregnancy was associated with lower odds of neonatal intracranial hemorrhage, cerebral ischemia and hypoxic-ischemic encephalopathy, and neonatal mortality.

Meaning In this large population-based study, vaccination of pregnant individuals with mRNA COVID-19 vaccines was not associated with increased risks of neonatal adverse events in their infants.

Methods

The Swedish Ethical Review Authority (approvals: 2020-01499, 2020-02468, 2021-00274) and the Regional Committee for Medical and Health Research Ethics of South/East Norway (No. 141135) approved this research. The same authorities provided a waiver of consent for registered individuals.

Study Participants and Setting

This was a population-based cohort study of all livebirths at 22 weeks or more of gestational age in Sweden and Norway, including newborn infants with birth defects as defined by the European network of population-based registries for the epidemiologic surveillance of birth defects.[15] Exclusion criteria were no valid personal identity number in the registers of the pregnant individual or the infant and non-mRNA vaccine used during pregnancy (**Figure 1**). After exclusions, 97.4% of all live births in Sweden and 98.6% of all live births in Norway were included.

The study period's start date was selected to include infants delivered by individuals eligible for SARS-CoV-2 vaccination in pregnancy, ie, infants of individuals with estimated conception dates after January 1, 2021. To avoid oversampling preterm infants, the study period's end date was selected to include only pregnancies that could result in a term infant and with sufficient time given for neonatal follow-up (at least 4 weeks after estimated date of birth) before data extraction, ie, infants of individuals with estimated conception dates before April 12, 2022. Conception dates were estimated based on early fetal ultrasonography or last menstrual period, except in cases of assisted reproduction where the date was exact. The first infant was born in June 2021 and the last in January 2023, and register data were extracted on March 9, 2023, in Sweden and April 11, 2023, in Norway.

Data Sources

The unique personal identity numbers for pregnant individuals and infants were used to link relevant individual information from different national registers. Swedish data were retrieved from the Swedish Pregnancy Register,[16] the Swedish Neonatal Quality Register,[17] the National Vaccination Register in Sweden, and the Swedish Register for Communicable Diseases. Norwegian data were retrieved from the Medical Birth Registry of Norway, the Norwegian Immunization Register, the Norwegian Surveillance System for Communicable Diseases, and Statistics Norway. Data from the Norwegian registries were made available through the Emergency Preparedness Register for COVID-19.[18] Comprehensive information on the data sources in the 2 countries has previously been reported.[10]

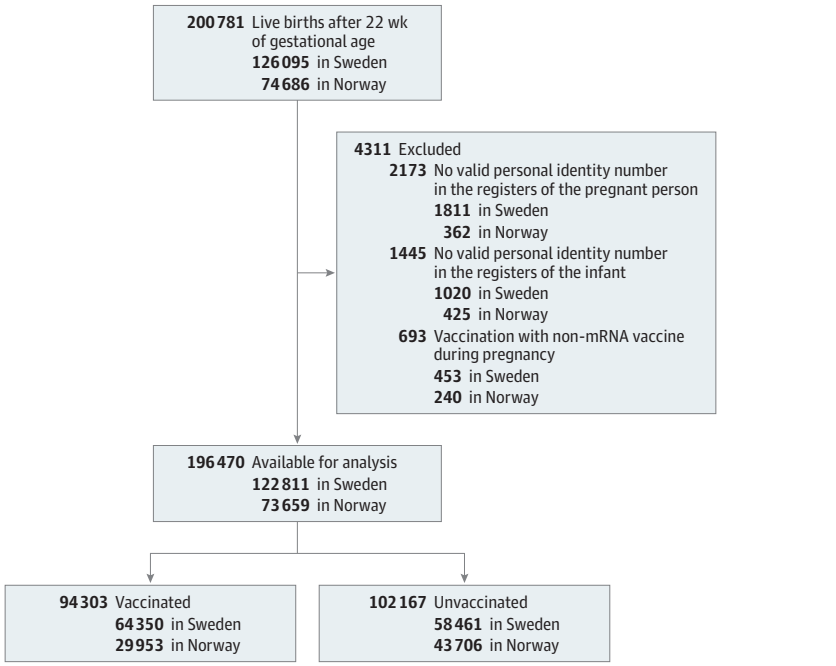
Exposures

The exposure was vaccination with mRNA vaccine against COVID-19 during pregnancy, irrespective of previous mRNA vaccination, number of doses during pregnancy, or vaccine manufacturer. Vaccination during pregnancy was defined as vaccination any time between dates of conception and delivery. The vaccines recommended for pregnant individuals were the 2 mRNA vaccines manufactured by Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273).

The number of doses with mRNA vaccine before pregnancy (0, 1, 2, 3, or 4), number of doses with mRNA vaccine during pregnancy (0, 1, 2, or 3), vaccine manufacturer, time from conception to last vaccination (days), and time from last vaccination to birth (days) were also recorded.

In both countries, nationwide vaccination of pregnant individuals was initiated beginning with those at highest risk of COVID-19 or severe disease. Universal vaccination in pregnancy was recommended starting in May 2021 in Sweden and

Figure 1. Cohort Development in a Study of COVID-19 Vaccination During Pregnancy



August 2021 in Norway. Vaccination of previously unvaccinated pregnant individuals was recommended to start after gestational week 12.

Covariates

The following covariates were examined: the pregnant individual's country of birth (Nordic [Denmark, Finland, Iceland, Norway, or Sweden], non-Nordic Europe, Middle East/Africa, or other), educational level (≤9 years, 10-12 years, and >12 years), living with partner (yes/no), age, parity (0, 1, or ≥2), prepregnancy smoking status (yes/no), and body mass index (BMI, calculated as weight in kilograms divided by height in meters squared; <18.5, 18.5-<25, 25-<30, 30-<35, ≥35), prepregnancy comorbidity (any antenatal record of hypertension, chronic kidney disease, asthma, cardiovascular disease, thrombosis, or diabetes; yes/no), season of conception (January-April 2021, May-August 2021, September-December 2021, or January-April 2022), gestational diabetes (yes/no), multiple or singleton pregnancy, SARS-CoV-2 infection (test positive) before or during pregnancy, onset (induction of labor, cesarean delivery, or spontaneous), and mode of delivery (vaginal or cesarean delivery) (**Table 1**). In addition, pregnancy outcomes such as gestational age (GA) at birth (weeks), infant sex, Apgar score less than 4 and less than 7 at 5 minutes after birth, birth weight (grams), small for gestational age (SGA) or large for gestational age (LGA) (yes/no), and admissions to neonatal care (yes/no) were recorded.

Outcomes

This study aimed to investigate a broad range of neonatal outcomes, and no single primary outcome was predefined. Outcomes were prospectively collected in the registers and refer to in-hospital events. Outcomes selected for this study were chosen based on content in national registers, previous literature on suspected adverse events in children and adults,[3,4,19] investigator input, and expressed clinical and authority concerns. The outcomes included neonatal conditions with bleeding/thrombosis (traumatic and nontraumatic intracranial hemorrhages, neonatal stroke/intracranial thrombosis, other bleedings, hematemesis/melena, thrombocytopenia or anemia, thrombosis); neonatal inflammation/infection (myocarditis, septicemia); disorders of central nervous system (convulsions, cerebral ischemia including hypoxic-ischemic encephalopathy); circulatory problems (heart failure, persistent ductus arteriosus, persistent pulmonary hypertension of the neonate, cardiac ischemia); problems with respiration (any respiratory distress); gastrointestinal problems (feeding problems, vomiting, necrotizing enterocolitis in very preterm infants); and neonatal mortality (death <28 days after birth) as defined by *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* codes provided in eTable 1 in Supplement 1. All outcomes were assessed for at least the first 4 weeks of life; follow-up for some neonatal morbidity outcomes exceeded 4 weeks depending on the length of hospitalization.

Statistical Analyses

The main analysis explored neonatal outcomes after vaccination at any time during pregnancy, while secondary analyses examined differences by pregnancy trimester of vaccination as previously defined.[10] Infants could only be at risk of neonatal outcomes after they were born (time zero). Because the exposure (vaccination) was defined during pregnancy but before delivery/birth, the exposure status was defined prior to

Table 1. Exposure Data and Pregnancy and Infant Covariates by COVID-19 Vaccination Status in Individuals With Estimated Conception From January 1, 2021, to April 12, 2022

Characteristic	No. (%) of liveborn infants			
	Sweden		Norway	
	Vaccination during pregnancy (n = 64 350)	No vaccination during pregnancy (n = 58 461)	Vaccination during pregnancy (n = 29 952)	No vaccination during pregnancy (n = 43 706)
Exposure data				
No. of doses with mRNA vaccine before pregnancy				
0	31 913 (49.6)	34 755 (59.4)	16 022 (53.5)	15 500 (35.5)
1	9965 (15.5)	2277 (3.9)	5391 (18.0)	2410 (5.5)
2	20 230 (31.4)	17 813 (30.5)	7960 (26.6)	21 376 (48.9)
3-4	2242 (3.5)	3616 (6.2)	579 (1.9)	4420 (10.1)
No. of doses with mRNA vaccine during pregnancy				
1	31 527 (49.0)		16 015 (53.5)	
2	29 469 (45.8)		13 770 (46.0)	
3	3354 (5.2)		167 (0.6)	
Vaccine used in pregnancy[a]				
BNT162b2	52 181 (81.1)		21 956 (73.3)	
mRNA-1273	12 169 (18.9)		7996 (26.7)	
Data on pregnant individual				
Age, y				
<25	3242 (5.0)	6463 (11.1)	1687 (5.6)	3739 (8.6)
25-29	16 231 (25.2)	17 723 (30.3)	8362 (27.9)	13 368 (30.6)
30-34	27 597 (42.9)	21 062 (36.0)	12 684 (42.3)	16 590 (38.0)
35-39	13 818 (21.5)	10 419 (17.8)	5954 (19.9)	8136 (18.6)
≥40	3462 (5.4)	2794 (4.8)	1265 (4.2)	1873 (4.3)
BMI	n = 61 786	n = 55 918	n = 28 419	n = 41 437
<18.5	1197 (1.9)	1361 (2.4)	786 (2.8)	1460 (3.5)
18.5-<25	33 200 (53.7)	27 761 (49.6)	16 371 (57.6)	23 252 (56.1)
25-<30	17 062 (27.6)	16 475 (29.5)	6846 (24.1)	10 178 (24.6)
30-<35	6916 (11.1)	6979 (12.5)	2863 (10.1)	4398 (10.6)
≥35	3411 (5.5)	3342 (6.0)	1553 (5.5)	2149 (5.2)
Educational level, y	n = 57 379	n = 49 081	n = 28 073	n = 36 908
≤9	1961 (3.4)	5019 (10.2)	2907 (10.4)	7193 (19.5)
10-12	15 545 (27.1)	20 854 (42.5)	5285 (18.8)	9022 (24.4)
>12	39 873 (69.5)	23 208 (47.3)	19 881 (70.8)	20 693 (56.1)
Smoking status	n = 61 951	n = 56 185	n = 26 346	n = 37 118
Smoked during pregnancy	1097 (1.8)	2576 (4.6)	331 (1.3)	762 (2.1)
Place of birth				
Nordic country[b]	50 318 (78.2)	32 738 (56.0)	25 177 (84.1)	29 400 (67.3)
Europe (non-Nordic)	2465 (3.8)	5165 (8.8)	1830 (6.1)	6286 (14.4)
Middle East/Africa	4782 (7.4)	13 173 (22.5)	956 (3.2)	4402 (10.1)
Other birth place than above[c]	6785 (10.5)	7385 (12.6)	1989 (6.6)	3618 (8.3)
Living with partner	n = 62 908	n = 57 111	n = 29 574	n = 43 008
Yes	59 225 (94.1)	51 641 (90.4)	28 588 (96.7)	40 785 (94.8)
Prepregnancy comorbidity[d]	7392 (11.5)	5730 (9.8)	3151 (10.5)	3716 (8.5)
COVID-19 before pregnancy	10 128 (15.7)	11 273 (19.3)	1075 (3.6)	6121 (14.0)
Pregnancy data				
Parity				
Nulliparous	29 308 (45.5)	24 227 (41.4)	16 421 (54.8)	25 225 (57.7)
Multiparous	35 042 (54.5)	34 234 (58.6)	13 531 (45.2)	18 481 (42.3)

(continued)

Table 1. Exposure Data and Pregnancy and Infant Covariates by COVID-19 Vaccination Status in Individuals With Estimated Conception From January 1, 2021, to April 12, 2022 (continued)

Characteristic	No. (%) of liveborn infants			
	Sweden		Norway	
	Vaccination during pregnancy (n = 64 350)	No vaccination during pregnancy (n = 58 461)	Vaccination during pregnancy (n = 29 952)	No vaccination during pregnancy (n = 43 706)
Season of conception				
January-April 2021	16 924 (26.3)	14 177 (24.3)	8885 (29.7)	7414 (17.0)
May-August 2021	23 585 (36.7)	10 891 (18.6)	12 942 (43.2)	4765 (10.9)
September-December 2021	16 602 (25.8)	17 235 (29.5)	5658 (18.9)	12 655 (29.0)
January-April 2022	7239 (11.2)	16 158 (27.6)	1695 (5.7)	13 384 (30.6)
Singletons	62 754 (97.5)	56 838 (97.2)	29 091 (97.1)	42 357 (96.9)
Multiple pregnancy	1596 (2.5)	1623 (2.8)	861 (2.9)	1349 (3.1)
Gestational diabetes[e]	3680 (5.7)	4467 (7.6)	1763 (5.9)	3198 (7.3)
COVID-19 in pregnancy	10 846 (16.9)	9771 (16.7)	5029 (16.8)	9954 (22.8)
Onset of delivery				
Induction of labor	17 016 (26.4)	15 454 (26.4)	8786 (29.3)	12 886 (29.5)
Cesarean	6552 (10.2)	6376 (10.9)	1955 (6.5)	3192 (7.3)
Spontaneous	40 782 (63.4)	36 631 (62.7)	19 211 (64.1)	27 628 (63.2)
Mode of delivery				
Vaginal	51 927 (80.7)	46 688 (79.9)	25 172 (84.0)	36 227 (82.9)
Cesarean	12 423 (19.3)	11 773 (20.1)	4780 (16.0)	7479 (17.1)
Infant data				
Infant sex				
Male	33 029 (51.3)	30 061 (51.4)	15 452 (51.6)	22 333 (51.1)
Female	31 321 (48.7)	28 400 (48.6)	14 500 (48.4)	21 373 (48.9)
Gestational age				
Mean (SD), d	276.8 (12.2)	276.2 (13.2)	277.4 (12.9)	276.4 (14.2)
22-<32 wk	418 (0.6)	599 (1.0)	210 (0.7)	532 (1.2)
32-<37 wk	3193 (5.0)	2988 (5.1)	1637 (5.5)	2566 (5.9)
37-<41 wk	48 229 (74.9)	44 209 (75.6)	21 421 (71.5)	31 489 (72.0)
≥41 wk	12 510 (19.4)	10 665 (18.2)	6684 (22.3)	9119 (20.9)
Apgar score at 5 min	n = 64 039	n = 58 127	n = 29 935	n = 43 669
<7	990 (1.5)	1020 (1.8)	447 (1.5)	726 (1.7)
<4	176 (0.3)	225 (0.4)	67 (0.2)	123 (0.3)
Birth weight	n = 63 924	n = 57 767	n = 29 950	n = 43 696
Mean (SD), g	3514 (555)	3458 (572)	3508 (566)	3461 (594)
Large for gestational age (birth weight *z* score >+2 SD)	6957 (10.9)	5620 (9.7)	2982 (10.0)	4021 (9.2)
Small for gestational age (birth weight *z* score <−2 SD)	5507 (8.6)	6010 (10.4)	2757 (9.2)	4546 (10.4)
Admission to neonatal intensive care	6176 (9.6)	5853 (10.0)	3092 (10.3)	4758 (10.9)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

[a] Vaccination of pregnant individuals started in those at highest risk of COVID-19 or of severe disease. From May 2021 in Sweden and August 2021 in Norway, vaccination of pregnant individuals was generally recommended.

[b] Nordic countries: Denmark, Finland, Iceland, Norway, and Sweden.

[c] Other birth place: Antarctic, rest of Asia, North and South America, and Oceania.

[d] Prepregnancy comorbidity: any antenatal record of hypertension, chronic kidney disease, asthma, cardiovascular disease, thrombosis, or diabetes.

[e] Gestational diabetes defined according to *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* code O24.4.

when the newborn infants became at risk for the neonatal outcome of interest.

The multivariable analyses adjusted for characteristics of the pregnant individuals (age, BMI, education, smoking status, country of birth), season of conception, parity, multiple pregnancy, and gestational age. These covariates were selected because they may influence the likelihood of being vaccinated and of neonatal outcomes. For example, gestational age influences the time available for vaccination and the risk of outcomes and, therefore, could confound results. In contrast, neither Apgar score nor SGA status were plausible confounders and, therefore, were not included in the adjusted analyses.

Because several of the outcomes were rare, logistic regression was used to estimate adjusted odds ratios (aORs) with

95% CIs for neonatal outcomes in infants born to vaccinated vs unvaccinated individuals (reference). Groups with fewer than 4 events were neither presented nor used in calculations to avoid potential breaches of confidentiality and sparse data bias.

The analyses were initially conducted separately for Sweden and Norway according to a common protocol, and subsequently meta-analyzed with a fixed-effect model using the method of Mantel and Haenszel. The I^2 statistic was calculated to estimate the heterogeneity between the 2 countries.

Sensitivity and stratified subanalyses were performed to evaluate the robustness of the primary analysis results. Restriction analyses included only infants delivered by individuals (1) unvaccinated before pregnancy, (2) vaccinated before pregnancy, (3) vaccinated after a general recommendation of vaccination in pregnancy was issued, or (4) without COVID-19 infection in pregnancy. Additional sensitivity analyses were restricted to infants born at term, singleton births, and infants without birth defects. A stratified analysis by vaccine manufacturer was also performed.

All analyses used the individual infant as the unit of analysis and tests conducted were 2-sided, with *P* values less than .05 or 95% CIs not including 1 considered statistically significant. Because of the potential for type I error due to multiple comparisons, findings for the analyses should be interpreted with caution. Analyses were conducted in Stata version 17 (StataCorp) and SAS version 9.4 (SAS Institute).

Results

Exposure Data

In total, 196 470 newborn infants (193 753 pregnancies) were included and of these, 94 303 (48.0%) were exposed to vaccination against COVID-19 during pregnancy with 1 (50.4%), 2 (45.9%), or 3 (3.7%) doses of mRNA vaccine. The percentage of infants whose child-bearing parent had not been vaccinated prior to pregnancy was 50.8% in the exposed group and 49.2% in the unexposed group.

Most infants were exposed to the BNT162b2 vaccine (n = 74 137 [78.6%]) and the remainder to mRNA-1273 (n = 20 165 [21.4%]) (Table 1). The median time from conception to last vaccination was 153 days (IQR, 112-199) in Sweden and 157 days (IQR, 106-210) in Norway, and the median time from last vaccination to birth was 124 days (IQR, 77-166) in Sweden and 120 days (IQR, 66-171) in Norway. In total, 41 311 infants (32.4%) were exposed during the first trimester, 55 221 (43.3%) during the second trimester, and 30 905 (24.3%) during the third trimester (eTable 2 in Supplement 1).

Characteristics of Pregnant Individuals and Infants, and Pregnancy Outcomes

In both Sweden and Norway, individuals vaccinated during pregnancy were older and more often nulliparous and of Nordic origin, had longer education, conceived earlier in the study period, and had more prepregnancy comorbidity but less gestational diabetes than individuals unvaccinated in pregnancy (*P* < .001 for all comparisons) (Table 1).

The distribution of infant sex did not differ between the 2 exposure groups. Infants exposed to vaccine during pregnancy compared with those who were not were less likely to be preterm (5.8% vs 6.5%), SGA (8.8% vs 10.3%), or have an Apgar score less than 7 (1.6% vs 1.8%) or less than 4 (0.26% vs 0.34%) at 5 minutes (data from both countries combined, *P* ≤ .001 for all comparisons) (Table 1).

Neonatal Outcomes

In the meta-analysis of both countries, vaccination during pregnancy was associated with lower odds of neonatal nontraumatic intracranial hemorrhage (event rate, 1.7 vs 3.2/1000 live births; aOR, 0.78 [95% CI, 0.61-0.99]) and neonatal mortality (0.9 vs 1.8/1000; aOR, 0.68 [95% CI, 0.50-0.91]) (**Table 2**). In addition, vaccination in the second trimester was associated with reduced odds of cerebral ischemia and hypoxic-ischemic encephalopathy (1.8 vs 2.7/1000; aOR, 0.73 [95% CI, 0.55-0.96]) (**Table 3**). Other neonatal outcomes did not differ significantly between the 2 groups.

Differences in neonatal mortality between vaccine-exposed and vaccine-unexposed infants appeared shortly after birth in Sweden but evolved more gradually in Norway (**Figure 2**). The point estimates for neonatal mortality were robust in the restricted subanalyses (restricting to infants of pregnant individuals unvaccinated before pregnancy; to infants of individuals vaccinated before pregnancy; to infants of individuals with an estimated start of pregnancy after the general recommendations of COVID-19 vaccination came in place in Sweden and Norway; or to infants of individuals without COVID-19 during pregnancy). Similar findings were seen after restricting the analyses to full-term infants, singleton births, or infants without birth defects (eTables 3-5 in Supplement 1). In the analysis stratified by vaccine manufacturer, the association between vaccination during pregnancy and lower neonatal mortality was no longer statistically significant for the mRNA-1273 vaccine (eTables 3-5 in Supplement 1).

Discussion

This large population-based safety study found no evidence of increases in adverse neonatal events in infants born to individuals vaccinated against COVID-19 during pregnancy. In contrast, exposure to COVID-19 vaccination during pregnancy was associated with reduced rates of nontraumatic intracranial hemorrhage, hypoxic-ischemic encephalopathy, and neonatal mortality. The observed reduction in risk may reflect residual confounding rather than an actual protective effect of vaccination. However, these findings may provide reassurance to public health authorities, clinicians, pregnant individuals, and their families that infants are not at higher risk of adverse events due to COVID-19 vaccination during pregnancy.

This study had findings concordant with smaller studies and had the advantage of evaluating specific neonatal diagnoses that were selected a priori as having biologically plausible links to COVID-19 vaccination. It also included information on BMI in pregnant individuals, a potentially important

Table 2. Associations Between COVID-19 Vaccination in Pregnancy and Neonatal Outcomes

Neonatal outcome	Sweden				Norway				Meta-analysis of both countries				
	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95%CI)[a]	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95% CI)[a]	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95% CI)[a]	I^2, %
	Vaccinated (n = 64 350)	Unvaccinated (n = 58 461)			Vaccinated (n = 29 953)	Unvaccinated (n = 43 706)			Vaccinated (n = 94 303)	Unvaccinated (n = 102 167)			
Bleeding/thrombosis													
Thrombocytopenia or anemia	316 (4.9)	371 (6.3)	−1.4 (−2.3 to −0.6)	1.09 (0.90 to 1.32)	195 (6.5)	398 (9.1)	−2.6 (−3.9 to −1.3)	0.90 (0.71 to 1.14)	511 (5.4)	769 (7.5)	−2.1 (−2.8 to −1.4)	1.01 (0.87 to 1.18)	34.2
Intracranial nontraumatic hemorrhage, intraventricular hemorrhage	94 (1.5)	139 (2.4)	−0.9 (−1.4 to −0.4)	0.86 (0.62 to 1.18)	64 (2.1)	183 (4.2)	−2.0 (−2.9 to −1.2)	0.67 (0.46 to 0.99)	158 (1.7)	322 (3.2)	−1.5 (−1.9 to −1.0)	0.78 (0.61 to 0.99)	0.0
Other bleedings, hematemesis/ melena	16 (0.2)	38 (0.7)	−0.4 (−0.6 to −0.2)	0.47 (0.25 to 0.91)	51 (1.7)	82 (1.9)	−0.2 (−0.8 to 0.4)	0.97 (0.64 to 1.46)	67 (0.7)	120 (1.2)	−0.5 (−0.7 to −0.2)	0.79 (0.56 to 1.12)	69.9
Neonatal stroke/ intracranial thrombosis	17 (0.3)	15 (0.3)	0.0 (−0.2 to 0.2)	1.15 (0.53 to 2.50)	9 (0.3)	20 (0.5)	−0.2 (−0.4 to 0.1)	0.80 (0.30 to 2.13)	26 (0.3)	35 (0.3)	−0.1 (−0.2 to 0.1)	1.00 (0.54 to 1.83)	0.0
Intracranial hemorrhage, traumatic	4 (0.1)	5 (0.1)	−0.0 (−0.1 to 0.1)	0.45 (0.11 to 1.89)	15 (0.5)	24 (0.5)	−0.1 (−0.4 to 0.3)	1.11 (0.51 to 2.42)	19 (0.2)	29 (0.3)	−0.1 (−0.2 to 0.1)	0.90 (0.45 to 1.79)	14.6
Thrombosis[b]	9 (0.1)	5 (0.1)	0.1 (−0.1 to 0.2)	1.71 (0.50 to 5.90)	<4 events[c]	6 (0.1)	−0.1 (−0.2 to 0.0)	0.62 (0.14 to 2.77)	<4 events in Norway[c]	11 (0.1)	0.0 (−0.1 to 0.1)	1.13 (0.44 to 2.94)	4.0
Inflammation/infection[d]													
Neonatal septicemia[e]	485 (7.5)	522 (8.9)	−1.4 (−2.4 to −0.4)	0.96 (0.83 to 1.10)	194 (6.5)	319 (7.3)	−0.8 (−2.1 to 0.4)	1.15 (0.92 to 1.43)	679 (7.2)	841 (8.2)	−1.0 (−1.8 to −0.3)	1.01 (0.90 to 1.14)	43.3
Central nervous system													
Neonatal convulsions	121 (1.9)	124 (2.1)	−0.2 (−0.7 to 0.3)	1.01 (0.76 to 1.33)	66 (2.2)	106 (2.4)	−0.2 (−0.9 to 0.5)	0.99 (0.70 to 1.39)	187 (2.0)	230 (2.3)	−0.3 (−0.7 to 0.1)	1.00 (0.81 to 1.24)	0.0
Cerebral ischemia, hypoxic-ischemic encephalopathy	124 (1.9)	152 (2.6)	−0.7 (−1.2 to −0.1)	0.78 (0.60 to 1.02)	66 (2.2)	123 (2.8)	−0.6 (−1.3 to 0.1)	0.89 (0.63 to 1.27)	190 (2.0)	275 (2.7)	−0.7 (−1.1 to −0.2)	0.82 (0.67 to 1.02)	0.0
Cardiac and circulatory problems													
Heart failure, persistent ductus arteriosus, persistent pulmonary hypertension of the neonate, cardiac ischemia	399 (6.2)	424 (7.3)	−1.1 (−2.0 to −0.1)	1.05 (0.89 to 1.23)	308 (10.3)	475 (10.9)	−0.6 (−2.1 to 0.9)	0.94 (0.79 to 1.11)	707 (7.5)	899 (8.8)	−1.3 (−2.1 to −0.5)	0.99 (0.88 to 1.12)	0.0
Respiration													
Respiratory distress, any	3191 (49.6)	2811 (48.1)	1.5 (−0.9 to 3.9)	1.07 (1.00 to 1.14)	1321 (44.1)	2139 (48.9)	−4.8 (−8.0 to −1.6)	1.01 (0.92 to 1.11)	4512 (47.8)	4950 (48.5)	−0.6 (−2.5 to 1.3)	1.05 (1.00 to 1.11)	0.0

(continued)

Table 2. Associations Between COVID-19 Vaccination in Pregnancy and Neonatal Outcomes (continued)

Neonatal outcome	Sweden				Norway				Meta-analysis of both countries				
	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95%CI)[a]	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95% CI)[a]	Events, rate/1000 liveborn infants (%)		Absolute difference in rates (95% CI)	aOR (95% CI)[a]	I^2, %
	Vaccinated (n = 64 350)	Unvaccinated (n = 58 461)			Vaccinated (n = 29 953)	Unvaccinated (n = 43 706)			Vaccinated (n = 94 303)	Unvaccinated (n = 102 167)			
Gastrointestinal problems													
Feeding problems, vomiting	1297 (20.2)	1262 (21.6)	−1.4 (−3.0 to 0.2)	0.95 (0.87 to 1.04)	2672 (89.2)	3905 (89.3)	−0.1 (−4.4 to 4.2)	1.03 (0.96 to 1.10)	3969 (42.1)	5167 (50.6)	−8.5 (−10.3 to −6.6)	1.00 (0.95 to 1.06)	52.1
Necrotizing enterocolitis	17 (0.3)	40 (0.7)	−0.4 (−0.7 to −0.2)	0.65 (0.33 to 1.27)	5 (0.2)	31 (0.7)	−0.5 (−0.8 to −0.2)	0.46 (0.17 to 1.22)	22 (0.2)	71 (0.7)	−0.5 (−0.7 to −0.3)	0.58 (0.34 to 1.01)	0.0
Neonatal mortality[f]													
	55 (0.9)	117 (2.0)	−1.1 (−1.6 to −0.7)	0.60 (0.42 to 0.87)	33 (1.1)	71 (1.6)	−0.5 (−1.1 to 0.0)	0.86 (0.51 to 1.44)	88 (0.9)	188 (1.8)	−0.9 (−1.2 to −0.6)	0.68 (0.50 to 0.91)	16.2

Abbreviation: aOR, adjusted odds ratio.

[a] Odds ratios (95% CIs) adjusted for maternal characteristics (age, parity, body mass index, education, smoking status, and country of birth), calendar period of conception, multiple pregnancy, and gestational age.

[b] Thrombosis as diagnosed by an *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* (*ICD-10*) code of I81 or I82.

[c] To avoid potential breaches of confidentiality, event rates <4 (directly or indirectly presented) are not shown.

[d] There were no cases of myocarditis in the vaccinated group and <4 in the unvaccinated group. Data not disclosed in the table.

[e] Neonatal septicemia as diagnosed by an *ICD-10* code of P36.

[f] Neonatal mortality defined as death from day 0 to 27. Neonatal morbidities were diagnosed during hospital stay in neonatal care, irrespective of postnatal age in days.

Table 3. Associations Between COVID-19 Vaccination in Pregnancy and Neonatal Outcomes by Exposure Trimester in Sweden and Norway

Outcome	Vaccination during trimester 1			Vaccination during trimester 2			Vaccination during trimester 3		
	Events, rate/1000 liveborn infants (%)			Events, rate/1000 liveborn infants (%)			Events, rate/1000 liveborn infants (%)		
	Vaccinated (n = 41 311)	Unvaccinated (n = 102 167)	aOR (95% CI)[a]	Vaccinated (n = 55 221)	Unvaccinated (n = 102 167)	aOR (95%CI)[a]	Vaccinated (n = 30 905)	Unvaccinated (n = 102 167)	aOR (95% CI)[a]
Bleeding/thrombosis									
Neonatal thrombocytopenia or anemia	251 (6.1)	769 (7.5)	1.08 (0.90-1.31)	298 (5.4)	769 (7.5)	0.99 (0.82-1.18)	116 (3.8)	769 (7.5)	0.82 (0.64-1.05)
Intracranial nontraumatic hemorrhage, intraventricular hemorrhage	72 (1.7)	322 (3.2)	0.82 (0.60-1.11)	92 (1.7)	322 (3.2)	0.67 (0.48-0.93)	28 (0.9)	322 (3.2)	0.64 (0.39-1.03)
Other bleedings, hematemesis/melena	25 (0.6)	120 (1.2)	0.70 (0.44-1.12)	38 (0.7)	120 (1.2)	0.88 (0.57-1.36)	29 (0.9)	120 (1.2)	0.87 (0.53-1.43)
Neonatal stroke and intracranial thrombosis	15 (0.4)	35 (0.3)	1.48 (0.69-3.13)	15 (0.3)	35 (0.3)	0.96 (0.44-2.12)	4 (0.1)	35 (0.3)	0.43 (0.14-1.32)
Intracranial traumatic hemorrhage	11 (0.3)	29 (0.3)	1.43 (0.64-3.17)	10 (0.2)	29 (0.3)	0.79 (0.30-2.09)	0	29 (0.3)	
Thrombosis[b]	6 (0.1)	11 (0.1)	1.98 (0.71-5.52)	9 (0.2)	11 (0.1)	1.17 (0.39-3.52)	0	11 (0.1)	
Inflammation/infection[c]									
Neonatal septicemia[d]	342 (8.3)	841 (8.2)	1.00 (0.86-1.15)	362 (6.6)	841 (8.2)	1.04 (0.90-1.21)	197 (6.4)	841 (8.2)	1.11 (0.92-1.33)
Central nervous system									
Neonatal convulsions	83 (2.0)	230 (2.3)	1.11 (0.85-1.45)	111 (2.0)	230 (2.3)	1.00 (0.76-1.31)	57 (1.8)	230 (2.3)	0.94 (0.68-1.30)
Cerebral ischemia including hypoxic-ischemic encephalopathy	93 (2.3)	275 (2.7)	0.90 (0.70-1.16)	102 (1.8)	275 (2.7)	0.73 (0.55-0.96)	50 (1.6)	275 (2.7)	0.75 (0.53-1.05)
Cardiac and circulatory problems									
Heart failure, PDA, persistent pulmonary hypertension of the neonate, cardiac ischemia	303 (7.3)	899 (8.8)	0.98 (0.84-1.13)	403 (7.3)	899 (8.8)	0.97 (0.84-1.12)	227 (7.3)	899 (8.8)	1.02 (0.85-1.21)
Respiration									
Respiratory distress	2008 (48.6)	4950 (48.5)	1.06 (0.99-1.13)	2701 (48.9)	4950 (48.5)	1.06 (0.99-1.13)	1242 (40.2)	4950 (48.5)	1.02 (0.94-1.10)
Gastrointestinal problems									
Feeding problems, vomiting	1570 (38.0)	5167 (50.6)	0.94 (0.88-1.01)	2246 (40.7)	5167 (50.6)	1.01 (0.95-1.08)	1559 (50.4)	5167 (50.6)	1.05 (0.98-1.13)
Necrotizing enterocolitis in very preterm infants	11 (0.3)	71 (0.7)	0.63 (0.30-1.32)	15 (0.3)	71 (0.7)	0.63 (0.33-1.18)	0	71 (0.7)	
Neonatal mortality[e]									
	47 (1.1)	188 (1.8)	0.75 (0.52-1.08)	53 (1.0)	188 (1.8)	0.72 (0.50-1.04)	18 (0.6)	188 (1.8)	0.63 (0.36-1.07)

Abbreviations: aOR, adjusted odds ratio; PDA, persistent ductus arteriosus.

[a] Odds ratios (95% CI) adjusted for maternal characteristics (age, parity, body mass index, education, smoking status, and country of birth), calendar period of conception, multiple pregnancy, and gestational age.

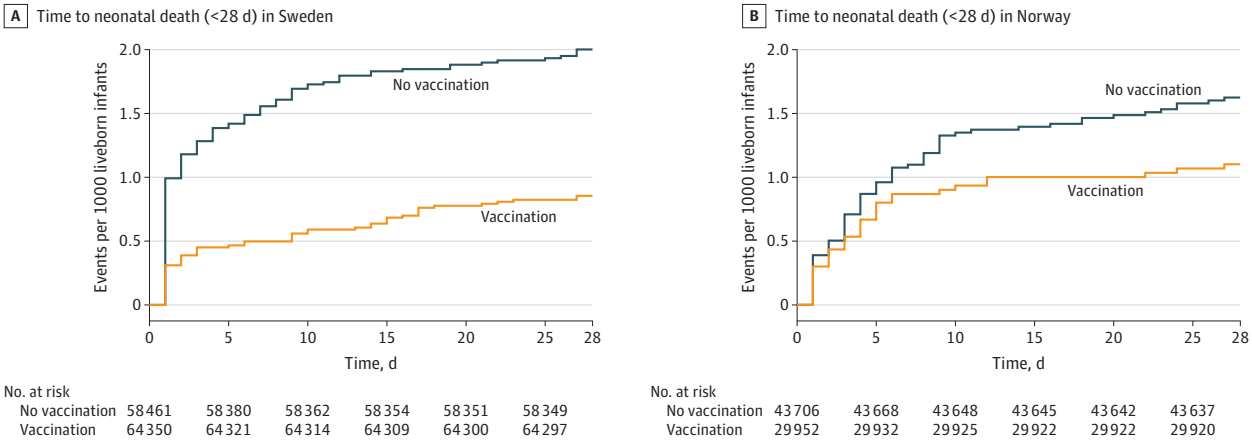
[b] Thrombosis as diagnosed by an *ICD-10* code of I81 or I82.

[c] There were no cases of myocarditis in the vaccinated group and <4 cases in the unvaccinated group.

[d] Neonatal septicemia as diagnosed by an *ICD-10* code of P36.

[e] Neonatal mortality defined as death from day 0 to 27. Neonatal morbidities were diagnosed during hospital stay in neonatal care, irrespective of postnatal age in days.

Figure 2. Time to Death in Liveborn Infants Exposed or Unexposed to mRNA COVID-19 Vaccine in Pregnancy in Sweden and Norway



confounder.[20,21] A parallel study of 142 006 singleton infants (85 670 exposed) born in Ontario, Canada, found that infants of individuals vaccinated against COVID-19 during pregnancy had significantly lower risk of neonatal death than those born to unvaccinated individuals.[12] The Canadian study also reported that infants of vaccinated individuals had lower risk of severe neonatal morbidity, defined as a composite consisting of 7 neonatal procedures and 15 different diagnoses, including gestational age and birth weight.[12] Accordingly, the selective contributions of pregnancy outcomes and specific neonatal outcomes to the association with vaccination in pregnancy were unresolved.

The current study explored a broad range of neonatal morbidity outcomes after exposure to COVID-19 vaccination in pregnancy. Several of the neonatal outcomes were selected because they touched areas of interest in previous reports of possible adverse events associated with mRNA COVID-19 vaccines administered to children or adults.[3,4,19] Suspected adverse events in adults and children—ie, events that have been observed following vaccination, but which were not necessarily related to or caused by the vaccine—that have drawn particular attention include coagulation disorders (thrombosis, bleedings), immune reactions (allergic reactions, Guillain-Barré syndrome), inflammation (myocarditis/pericarditis), and reports of deaths.[3,4,19]

Thrombosis with thrombocytopenia and brain bleeding have been reported as rare but potentially fatal complications to COVID-19 vaccination. However, these adverse events have only been seen in association with use of adenovirus vector vaccines, which were not recommended or used in pregnancy in Sweden and Norway.[3,4,19,22] The results of the current study were overall reassuring, with no indication of increased risks for cerebrovascular conditions in newborn infants after COVID-19 vaccination in pregnancy with mRNA vaccines. In addition, the present data do not suggest an increased risk of hypoxic-ischemic encephalopathy after vaccination during pregnancy, confirming previous findings from a smaller study.[14]

Pericarditis/myocarditis has been highlighted as a potential adverse effect of mRNA COVID-19 vaccines in young people, particularly in boys.[3,4,19,23] Reassuringly and irrespective of mRNA vaccine manufacturer or trimester of administration, there were no cases of neonatal myocarditis among infants after maternal vaccination during pregnancy. In addition, no indications of an increased risk for other inflammatory neonatal diseases, such as respiratory distress syndrome or necrotizing enterocolitis, were observed.

Exposure during the first part of the study period, before general recommendations to pregnant individuals were in place, was largely restricted to individuals at high risk of severe COVID-19 and individuals at high risk of infection due to their occupation, such as pregnant health care workers. Although this selection into vaccination might have influenced the risk of some of the outcomes, a sensitivity analysis restricted to the period after universal recommendations for vaccination of pregnant individuals was issued did not provide any evidence for bias related to neonatal mortality.

The prepandemic neonatal mortality in 2019 in Sweden and Norway was 1.3 and 1.2/1000, respectively.[24] The higher neonatal mortality (2.0 and 1.6/1000, respectively) found herein among pregnant individuals who were not vaccinated during pregnancy may reflect a higher likelihood of their having unfavorable risk factors for neonatal death related to lower socioeconomic status and poorer living conditions than the general pregnant population. To account for different distributions of risk factors, all analyses were adjusted for age, BMI, education, smoking status, and country of birth of the pregnant individuals.

It is unlikely that mRNA COVID-19 vaccination during pregnancy directly reduces neonatal mortality, although others have suggested that such a protective effect is biologically plausible.[12] The vaccine does not seem to pass the placenta or induce placental inflammation, and could not be traced in cord blood.[25,26] The current study's results could not elucidate the mechanisms that explain why infants of vaccinated individuals had lower risks of some outcomes including mortality. Unmeasured confounding due to vaccinated individuals being healthier may have contributed to the lower neonatal morbidity and mortality associated with COVID-19 vaccination during pregnancy.

This study's findings were robust across many different sensitivity analyses and are unlikely to be the result of a reduction in stillbirths or preterm births. Previous studies have not found that vaccination against COVID-19 during pregnancy influences the risk of miscarriage or stillbirth.[10,27] However, COVID-19 infection was recently shown to increase the risk of stillbirth in this study population.[28] Although vaccination may have reduced the rate of stillbirths and thereby increased the number of infants at risk for neonatal outcomes, the number of stillbirths was very low and unlikely to have substantially influenced vaccination estimates when restricting to live births.

This study's analyses treated gestational age as a potential confounder, although several studies—including a subsample of this study's population—have not found differences in preterm birth rates between vaccinated and unvaccinated pregnant individuals.[10,13,29,30] In contrast to exposure to COVID-19 during pregnancy in which preterm birth may have acted as a mediator of neonatal outcomes,[5] gestational age should be considered as potentially associated with both the exposure and outcome in vaccination studies.

The strengths of this study include its linkage of several national registers in 2 countries, neonatal follow-up on all live births during the study period, the population-based design, the high completeness, and the large numbers of both vaccinated and unvaccinated individuals, which enabled exploration of several rare but serious neonatal outcomes. A broad range of neonatal outcomes could be explored from the time when vaccinations became available in both countries until very recent dates. Adjusted, stratified, and restricted sensitivity analyses underpinned the interpretations. There were no recommendations in the Swedish or Norwegian guidelines for COVID-19 to manage vaccinated individuals and their infants differently from unvaccinated individuals during delivery or neonatal care, which mitigated management bias.

Limitations

These findings should be interpreted in light of several limitations. First, this study was observational in design and despite several measures taken to explore potential bias, residual or unknown confounding could not be excluded. Second, power to identify group differences in rare outcomes, particularly in analyses stratified by exposure trimester, may have been insufficient. Nevertheless, the power of this study exceeded that of previous investigations of neonatal outcomes.[11-13,31,32] Third, misclassification of some register data cannot be excluded, although the data sources have been found to be valid.[17] Fourth, no information was available on lifestyle factors, breastfeeding rates, or outcomes beyond the neonatal period.

Conclusions

In this large population-based study, vaccination of pregnant individuals with mRNA COVID-19 vaccines was not associated with increased risks of neonatal adverse events in their infants.

ARTICLE INFORMATION

Accepted for Publication: December 10, 2023.

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Statistical analysis: Magnus, Söderling.
Obtained funding: Norman, Magnus, Håberg, Stephansson.
Administrative, technical, or material support: Juliusson, Örtqvist, Håberg, Stephansson.
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Conflict of Interest Disclosures: Dr Magnus reported receiving grants from Research Council of Norway, NordForsk, and European Research Council during the conduct of the study. No other disclosures were reported.

Funding/Support: The study was supported by grants from a regional agreement on clinical research (ALF) between Region Stockholm and Karolinska Institutet (2020-0443), the Childhood Foundation of the Swedish Order of Freemasons (2021), NordForsk (grant No. 135876), and the Norwegian Research Council (grants No. 324312 and No. 262700). The Swedish Neonatal Quality Register and the Swedish Pregnancy Register are funded by the Swedish government (Ministry of Health and Social Affairs) and the body of regional health care providers (County Councils).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement 2.

Additional Contributions: We thank all obstetric and pediatric departments for contributing and sharing data to the population registers and the quality registers.

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