Table 1. Trauma–Surgical Hospital Admissions Stratified According to Period.*

	2015–2019		2022	
	No. of Days	Mean Admissions per Day (95% CI)†	No. of Days	Mean Admissions per Day (95% CI)†
Overall	240	69.1 (64.3–73.9)	48	62.0 (52.9–71.1)
During Oktoberfest‡				
Friday and Saturday	30	137.2 (124.6–149.8)	6	117.8 (99.3–136.4)
Sunday–Thursday	50	75.8 (69.4–82.3)	10	62.9 (49.3–76.5)
Before and after Oktoberfest§				
Friday and Saturday	40	90.6 (85.8–95.3)	8	86.6 (77.2–96.0)
Sunday–Thursday	120	42.1 (39.3–44.9)	24	39.5 (33.3–45.7)

* Friday and Saturday were considered high-admission days.
† Confidence intervals have not been adjusted for multiplicity and should not be used for hypothesis testing.
‡ A period of 16 days during the festival was analyzed.
§ A reference period of 16 days before and after the festival was analyzed.

The mobile CT scanner introduced during peak hours at Munich Oktoberfest and the associated enhanced on-scene medical care that ruled out serious injury in a considerable proportion of cases might have reduced the necessity of transportation to the hospital and admission for persons with mild traumatic brain injury and relieved some of the the burden on EMS services and hospitals during this unique large-scale event.

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Disclosure forms provided by the authors are available with the full text of this letter at NEJM.org.

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Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

TO THE EDITOR: Kampmann et al. (Apr. 20 issue)[1] report the results of the Maternal Immunization Study for Safety and Efficacy (MATISSE). Breast-feeding is an important potential modifying factor for respiratory syncytial virus (RSV) infection,[2] and indeed the trial protocol says that these data will be collected. Can the authors provide outcomes stratified according to some, all, or no breast-feeding? In addition, a previous trial of a maternal RSV vaccine was halted after a safety signal regarding an increased rate of preterm birth was identified. Can the authors provide a complete distribution of gestational age and birth weight? Finally, the authors found that the vac-

cine had efficacy against medically attended severe RSV-associated lower respiratory tract illness and RSV-associated hospitalization. Although this sounds promising, they acknowledge that the vaccine had no effect on medically attended lower respiratory tract illness of any cause. Yet, the authors do not provide data on total hospitalizations (for any cause) during the follow-up or even hospitalizations for lower respiratory tract illness of any cause. Can they do so?

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1. Kampmann B, Madhi SA, Munjal I, et al. Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. N Engl J Med 2023;388:1451-64.
2. Mineva G, Philip R. Impact of breastfeeding on the incidence and severity of respiratory syncytial virus bronchiolitis in infants: systematic review. Rural Remote Health 2023;23:8088.

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TO THE EDITOR: Karron (Apr. 20 issue)[1] discusses advances and future challenges in the prevention of RSV illness in children on the basis of the efficacy of the maternal RSV prefusion F protein–based vaccine (RSVpreF) and long-acting monoclonal antibodies. However, there are more questions that remain to be addressed, given the lessons learned from the Covid-19 pandemic. Nonpharmacologic interventions that were implemented during the beginning of the pandemic almost eliminated RSV transmission and related morbidity and mortality.[2] However, as restrictions lifted, out-of-season rebounds with substantial stress on health care systems have been noticed globally. The largest nationwide study (conducted in Denmark) comparing RSV resurgence with prepandemic seasons showed that RSV-related admissions and intubations were unusually high among children 24 to 59 months of age, possibly owing to a postponed first RSV infection or immunity debt.[3] Because maternal vaccination and monoclonal antibodies provide only passive immunity, we cannot rule out that they — while substantially reducing the RSV burden in infants — may pose a higher risk of severe RSV illness among older children. Active monitoring of RSV remains important, as well as continued efforts to produce effective vaccines and antiviral agents.

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No potential conflict of interest relevant to this letter was reported.

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THE AUTHORS REPLY: The authors agree that breast-feeding is an important potential modifying factor for RSV infection. In our trial, most infants in both the vaccine group (96.1%) and the placebo group (95.6%) were breast-fed, with more than 50% of the infants in each group breast-feeding for at least 6 months. Substantial differences in vaccine efficacy against medically attended severe RSV-associated lower respiratory tract illness were not observed between those who were exclusively breast-fed (vaccine efficacy, 61.7%) and those who were not (vaccine efficacy, 71.2%) or between those who were breast-fed for a longer duration and those who were breast-fed for shorter periods.

In our trial, there was not a substantial difference between the trial groups in the overall incidence of preterm birth (birth at <37 weeks' gestation): 5.7% (95% confidence interval [CI], 4.9 to 6.5) in the vaccine group and 4.7% (95% CI, 4.1 to 5.5) in the placebo group. In each group, the median gestational age was 39 weeks (Fig. 1A) and the median birth weight was 3.3 kg (Fig. 1B). More preterm births were observed in upper-middle-income countries in the vaccine group than in the placebo group: 72 (7.5%; 95% CI, 5.9 to 9.3) as compared with 39 (4.1%; 95% CI, 2.9 to 5.5).

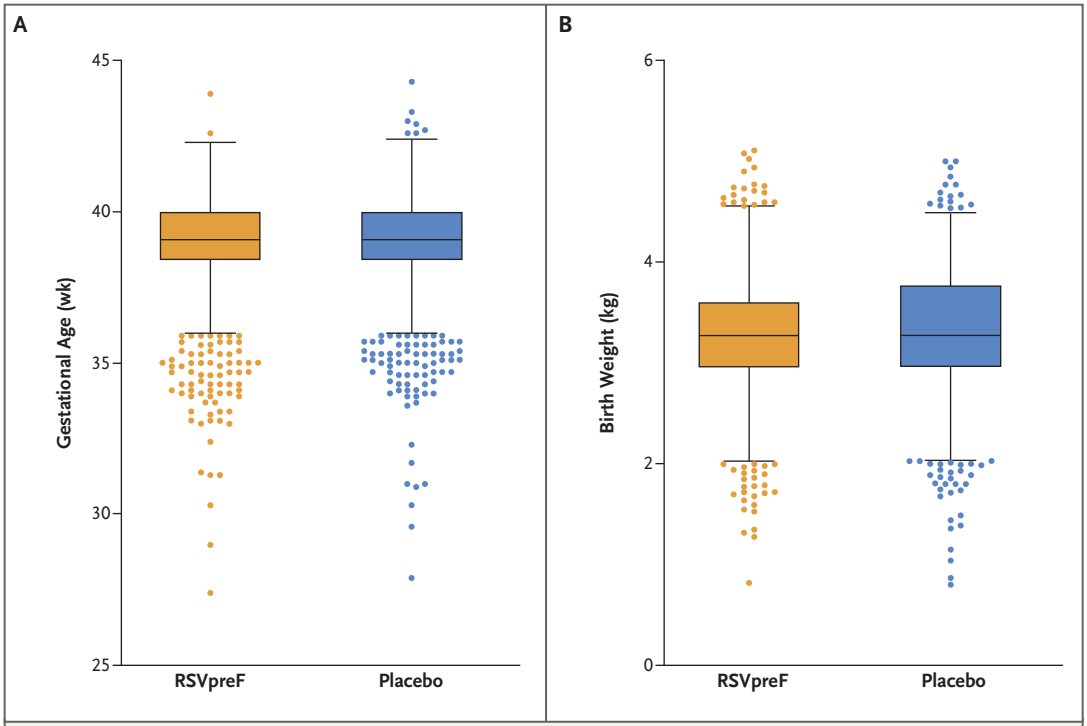

Figure 1. Gestational Age and Birth Weight of Infants Born to Mothers Who Received RSVpreF or Placebo.

In the box-and-whisker plots, the horizontal line indicates the median, the top and bottom of the box indicate the interquartile range, and the whiskers indicate 1.5 times the interquartile range. The outliers are represented as dots. The median gestational age (Panel A) was 39 weeks (interquartile range, 38 to 44) in each group, as a continuous variable. The median birth weight (Panel B) was 3.3 kg (interquartile range, 3.0 to 3.6) in each group, as a continuous variable. RSVpreF denotes respiratory syncytial virus prefusion F protein–based vaccine.

However, no difference was observed in high-income countries, including the United States (5.1% in both groups), and there was not a substantial difference in lower-middle-income or low-income countries (2.7% in the vaccine group and 3.5% in the placebo group). The clinical significance of the observed numerical imbalance is unknown, particularly given that it was not seen in all regions. Safety conclusions are supported by no observed adverse effects in preterm births, including no increase in infant mortality. Most preterm infants were late preterm (>34 weeks) and born more than 30 days after vaccination. In addition, the external data monitoring committee overseeing the trial has not identified any concerns.

Modest efficacy was observed against hospitalization for lower respiratory tract illness of any cause (vaccine efficacy, 29%; 95% CI, –2 to 51). However, this finding could have been influenced by the unusual epidemiologic circumstances during the Covid-19 pandemic, in which RSV-associated lower respiratory tract illnesses constituted 22% of bronchiolitis cases among infants younger than 1 year of age as compared with 50 to 80% of cases in prepandemic studies.[1]

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Since publication of their article, the authors report no further potential conflict of interest.

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THE EDITORIALIST REPLIES: Buonsenso provides a compelling description of the surge in RSV cases in the fall and winter of 2022–2023 in Northern Hemisphere countries, with unusual severity in toddlers and preschoolers. This epidemiologic pattern is plausibly linked to an immunity debt,[1] in which a lack of exposure to RSV as a result of stringent nonpharmaceutical interventions during the Covid-19 pandemic created a large cohort of young children who were susceptible to severe disease when encountering RSV for the first time. The author suggests that RSVpreF and monoclonal antibodies may create a similar immunity debt. Fortunately, that scenario is extremely unlikely. Although RSVpreF and nirsevimab are highly efficacious against severe RSV disease,[2] neither is likely to protect against RSV infection. A recent study confirmed that children who received nirsevimab could become infected with RSV and develop active immunity to the virus during the period of nirsevimab protection.[3] This is also probably true for RSVpreF, which offers a similar mechanism of passive antibody protection. Thus, infants who are protected against severe RSV disease through the passive immunity provided by nirsevimab or RSVpreF could also develop active immunity through RSV infection — conceivably, the best of both worlds.

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Since publication of her editorial, the author reports no further potential conflict of interest.

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A Dual-Chamber Leadless Pacemaker

TO THE EDITOR: We ask the investigators of the Aveir DR i2i study (June 22 issue)[1] to provide additional data to help clinicians assess the safety of the dual-chamber leadless pacemaker (Aveir, Abbott Medical). Cardiac implantable electronic devices, including pacemakers, are susceptible to intermediate-frequency electromagnetic interference that can lead to inappropriate device operation. Recently, the Food and Drug Administration (FDA) and others have warned that cell phones, smartwatches, and smartscales can generate electromagnetic interference that affect cardiac implantable electronic devices.[2,3] In fact, the Apple iPhone 12 Pro Max with wireless charging technology has been found to generate electromagnetic interference that causes cardiac implantable electronic devices to operate abnormally.[4] Beat-to-beat bidirectional wireless communication is key to atrioventricular synchrony of the dual-chamber leadless pacemaker.[1] The positioning of a leadless pacemaker will change from beat-to-beat and from breath-to-breath and may affect the sensing of the subcutaneous implantable cardioverter–defibrillator.[5] We would like to know about the standard electromagnetic shielding used in the Aveir DR system to block signals from cell phones and smartwatches, since the study of electromagnetic interference should be commonplace before market release.

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No potential conflict of interest relevant to this letter was reported.

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