Reducing Susceptibility to Misconceptions About Vaccination During Pregnancy: RSV

A report of the Annenberg Public Policy Center in partnership with Critica

August 2023







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THE ANNENBERG PUBLIC POLICY CENTER

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^{*} This is the second in a series of white papers that will form a Vaccination Communication and Fact-Checking Toolkit.

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APPC Vaccination Communication and Fact-Checking Toolkit

- #1) Minimizing public susceptibility to misconceptions about the effects of vaccination: Vaccine Adverse Event Reporting System (VAERS) (May 2023)
- #2) Reducing Susceptibilities to Misconceptions About Vaccination During Pregnancy: RSV (August 2023)

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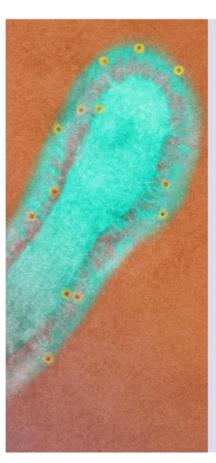
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Background explainer on RSV & the vaccine*

Vaccines against illnesses caused by respiratory syncytial virus (RSV) may be available soon. In February 2023, the Food and Drug Administration (FDA) granted priority review to a new Pfizer vaccine agent against RSV, to be given to pregnant people whose antibodies, activated by the RSV vaccine, could help protect infants in their first half-year from what can be a serious respiratory infection. Two vaccines, including Pfizer's, against RSV for those over 60 have recently been approved as well. Here we focus on the former.

Nearly <u>all children</u> are exposed to RSV by the age of 2 (Centers for Disease Control and Prevention, 2022d), and in 2022, there was <u>a notable surge</u> in RSV-associated hospitalizations (Centers for Disease Control and Prevention, 2023a). The FDA has approved a monoclonal antibody and is now considering a vaccine aimed at protecting infants from this common virus.



FACTS TO KNOW: About respiratory syncytial virus (RSV)



- Virtually all children get an RSV infection by the time they are 2 years old
- RSV usually causes mild, cold-like symptoms
- Most people recover in a week or two
- But RSV can be serious and poses particular risks for infants & older adults over 60 years of age
- RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) & pneumonia (infection of the lungs) in children younger than 1 year of age in the United States
- RSV is the leading cause of hospitalization in children
 4 year of age

Source: CDC (Centers for Disease Control and Prevention, 2022c) & FDA (U.S. Food & Drug Administration & Sen, 2023)

^{*} The RSV and vaccine information in this section was <u>published</u> by FactCheck.org/SciCheck on March 23, 2023, updated on July 19, 2023, written by Lori Robertson (Robertson, 2023a).

RSV circulates in colder weather during fall and winter and causes a mild cold in most people. But infants and older adults can experience serious and dangerous illness. Two vaccines for older adults have been approved (Robertson, 2023b), including one from <a href="https://prizer.pfizer.p



FACTS TO KNOW: About how RSV spreads

- RSV can spread when:
 - o An infected person coughs or sneezes
 - Virus droplets from a cough or sneeze get in your eyes, nose, or mouth
 - You have direct contact with the virus, as you do when kissing the face of a child with RSV
 - You touch a surface that has the virus on it, like a doorknob, and then touch your face before washing your hands
- People infected with RSV are usually contagious for 3 to 8 days
- A person may become contagious a day or two before they start showing signs of illness (asymptomatic transmission)

Source: CDC (Centers for Disease Control and Prevention, 2022c)



Although RSV is a health threat, the public knows little about it

The Annenberg Science and Public Health (ASAPH) Knowledge Monitor comprises survey reports that track national levels of health knowledge and misinformation over time. Building on the Annenberg Public Policy Center's <u>Annenberg Science Knowledge</u> (ASK) surveys (Annenberg Science Knowledge/ASAPH Surveys Archives, n.d.), which since 2016 have been focused on health knowledge and misinformation about topics such as the <u>Zika virus</u>, <u>measles</u>,

and COVID-19 and vaccination (Chan et al., 2020; Jamieson et al., 2021; Ophir & Jamieson, 2018; Romer & Jamieson, 2020; Stecuła et al., 2020), the ASAPH Knowledge Monitor generates indices of knowledge about such vital health topics as maternal and reproductive health, vaccination, COVID-19, Mpox, and indications and treatment of heat-related illness ("Annenberg Debuts Science and Public Health Knowledge Monitor," 2022). It also provides an ongoing measure of public confidence in the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA).

To determine the state of public knowledge about RSV, we draw on survey data from the 11th wave of a nationally representative panel of 1,601 U.S. adults, first empaneled in April 2021, conducted for the Annenberg Public Policy Center by SSRS, an independent market research company. This wave of the Annenberg Science and Public Health Knowledge (ASAPH) survey was fielded May 31-June 6, 2023, and has a margin of sampling error (MOE) of ± 3.3 percentage points at the 95% confidence level.

*Citations in box: (Centers for Disease Control and Prevention, 2021; U.S. Food & Drug Administration & Sen, 2023).



The effects of RSV on infants & children*

- The CDC estimates that 58,000 to 80,000 children under 5 years old are hospitalized each year because of RSV and that among every 100 babies under 6 months of age with RSV, 1 to 2 may need hospitalization.
- According to the <u>FDA</u> (U.S. Food & Drug Administration & Sen, 2023):
 - "Among infants <6 months of age, RSV is associated with around 1.4 million hospital admissions, and around 13,000 in-hospital deaths globally each year."
 - "In the US, RSV is the leading cause of infant hospitalization, with approximately 1% to 3% of all children in the first 12 months of life hospitalized due to RSV lower respiratory tract disease"
- Deaths are "uncommon," in the U.S. the CDC <u>says</u> (Centers for Disease Control and Prevention, 2021), at an estimated 100 to 500 each year for kids under 5.

Underestimating the prevalence of RSV – but awareness of potential severity

A quarter of the public (27%) expresses worry about contracting or having a family member contract RSV, less than the one-third (33%) who were worried in our January survey, which was conducted during the tripledemic. The decrease in concern is not surprising since RSV circulates during the fall and winter, and there was media coverage of the surge of cases last winter that, combined with flu and COVID-19 cases, filled some hospitals.

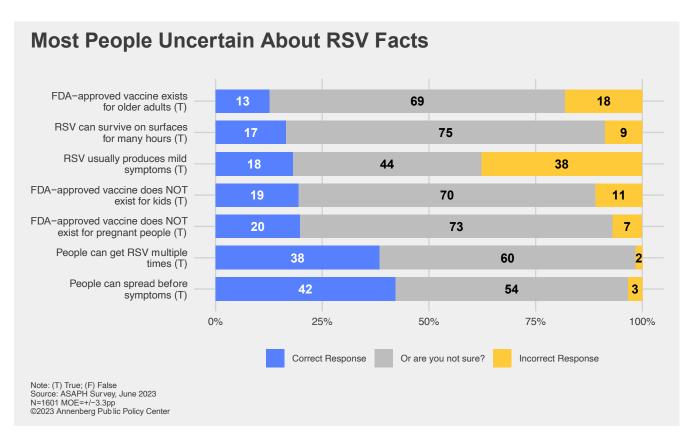
Familiarity with RSV is less common than one might expect given the prevalence of the illness. Only 22% in the current survey say they know children who have had RSV – and among these respondents, over half say they have known just one child or two children who have had it. Asked how many children contract RSV before the age of 2, 2% of respondents say, "virtually all." Yet, according to the CDC, "Almost all children will have had an RSV infection by their second birthday" (Centers for Disease Control and Prevention, 2022b).

But among the people who say they know children who have had RSV, its potential severity is clear. Among these respondents, over half (54%) say the illness was somewhat or very serious. Most children with cold-like symptoms are not tested for RSV, but when a child becomes severely ill, it's more likely that child will undergo diagnostic testing. While RSV can cause severe illnesses such as bronchiolitis and pneumonia (Centers for Disease Control and Prevention, 2022d), the CDC says it usually causes mild, cold-like symptoms – like runny nose, coughing, sneezing, fever, wheezing, and decreased appetite – and is often mistaken for cold or flu (Centers for Disease Control and Prevention, 2022b).

This does not mean, however, that some do not experience serious illness. Among 100 babies under the age of six months who get RSV, one to two may require hospitalization, the CDC says. Although RSV-associated deaths are "uncommon" in the United States, they nonetheless do occur at an estimated rate of 100 to 500 per year for children under 5, according to the CDC (Centers for Disease Control and Prevention, 2021). Worldwide deaths of children under 5 years old attributable to RSV exceed 100,000 annually (Wadman, 2023).

Far fewer people say they know older adults who have had RSV. Only 6% of those surveyed say they know someone age 65 or older who has had the illness. Among this group of respondents, most (71%) say they know one or two people who have had it and most (72%) say the infection was somewhat or very serious. The CDC reports that among adults 65 and older, there are 60,000 to 160,000 hospitalizations per year from RSV and 6,000 to 10,000 deaths.

Figure 1. Many survey respondents showed uncertainty when asked about the facts of RSV. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.



Great uncertainty about RSV

Only small segments of the American public correctly answer questions about RSV. Most people say they are not sure. The survey found that:

- **Symptoms**: Fewer than 1 in 5 people (18%) know it's more accurate to say that RSV usually produces mild, cold-like symptoms than serious difficulties in breathing (38%). And 44% say they are not sure.
- **Persistence**: Fewer than 1 in 5 people (17%) know it's more accurate to say that RSV is able to survive for many hours on hard surfaces such as a table or crib rails than to say RSV can't survive for many hours on these hard surfaces (9%). Most people (75%) say they are not sure.
- **Reoccurrence**: Fewer than 4 in 10 people (38%) know it's more accurate to say that once a person contracts RSV, they can get it again. Only 2% incorrectly believe it's more accurate to say that you can't get RSV again, but 60% say they are not sure.

- **Spreading the virus**: Just over 4 in 10 people (42%) know it's more accurate to say it is possible to have and spread RSV before showing symptoms than to say it is not possible (3%). But over half of those surveyed (54%) are not sure.
- Vaccine for older adults: Just 13% knew at the time the survey was fielded about the existence of an FDA-approved vaccine against RSV for older adults, while 18% said there was not an FDA-approved vaccine. Nearly 7 in 10 people (69%) said they were not sure. The FDA approved one RSV vaccine for adults 60 and older on May 3, 2023, and the second one on May 31, the beginning of the survey period. The CDC subsequently recommended that those over 60 consult with their healthcare provider about whether taking an RSV vaccine was advisable for them.
- Vaccine for pregnant people: Just 1 in 5 people (20%) knew when the survey was fielded that there was not an FDA-approved vaccine against RSV for those who are pregnant to benefit their newborns, while 7% thought there was one. Nearly three-quarters of those surveyed (73%) were not sure. Since an FDA advisory panel had recommended approval at that point, we would expect a high level of uncertainty about whether an FDA-approved vaccine existed (Jewett, 2023).
- **Vaccine for infants and children**: About 1 in 5 people (19%) know there is currently not an FDA-approved vaccine against RSV for infants and children in the United States, while 11% say incorrectly that there is one and 70% are not sure.

Fewer than half recognize the symptoms

Fewer than half of those surveyed recognized some of the most common symptoms of RSV (respondents were asked to select all that applied):

• Wheezing: 46% know this is a symptom

• Runny nose: 38% know this is a symptom

• **Pauses in breathing:** 33% know this is a symptom

• **Decreased activity**: 32% know this is a symptom

• **Decreased appetite**: 29% know this is a symptom

Very few people incorrectly selected non-respiratory symptoms as associated with RSV:

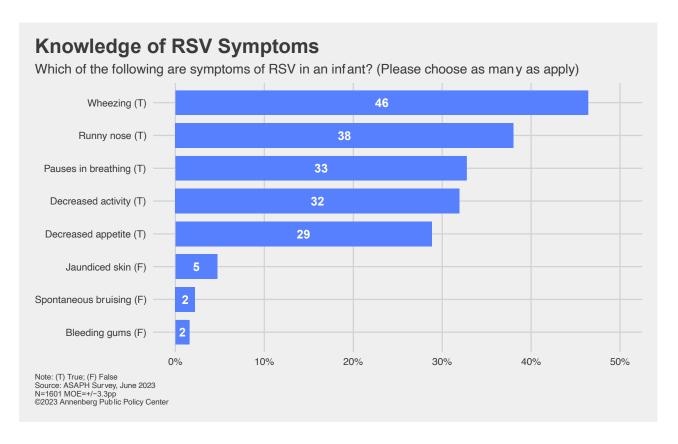
• Jaundiced skin: 5% incorrectly say this is a symptom

• **Spontaneous bruising**: 2% incorrectly say this is a symptom

• Bleeding gums: 2% incorrectly say this is a symptom

Many survey respondents showed uncertainty when asked about the facts of RSV.

Figure 2. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.



The status of potential RSV vaccines

In February 2023, the FDA <u>accepted</u> Pfizer's application for its vaccine candidate for pregnant people (Pfizer, 2023a). The vaccine is the same formulation as Pfizer's vaccine for older adults, but it would be given to pregnant people so they could pass antibodies on to babies to protect them from birth to at least 6 months of age. Pfizer expects a decision from the FDA in August.

"Starting immunization in the second trimester of pregnancy, protective antibodies are naturally passed from the mother's circulation across the placenta and to the developing fetus," Pfizer told FactCheck.org in an email. "Maternal immunization takes advantage of this natural process, resulting in infants having maternally derived protective antibodies at levels similar to or even higher than their mother."

What do we know about the efficacy & safety of Pfizer's vaccine for pregnant individuals?

Pfizer's Dr. Iona Munjal, senior director of vaccine research and development, presented data <u>from a phase 3 clinical trial</u> (Munjal, 2023) to the CDC's Advisory Committee on Immunization Practices (ACIP) on February 23. For more on the FDA approval process and clinical trial phases, see Figure 14.



Vaccination literacy: **Efficacy** is a measure of reduced risk for those receiving vaccination compared with those who aren't vaccinated.

The <u>phase 3 study</u> began in June 2020, enrolling nearly 7,400 pregnant participants in 18 countries, with half receiving the vaccine and half getting a placebo (Pfizer, 2022). Nearly all participants got the vaccine or placebo at 24 to 36 weeks gestation. The average age of the mothers was 29. Among the infants, 7,128 continued with the study. About half were enrolled in the first year and are being followed for 24 months. The rest are followed for one year.

Severe illness in the study was defined as at least one symptom including tachypnea, or rapid breathing; low blood oxygen; mechanical ventilation or supplemental oxygen therapy; or ICU admission for more than four hours or being unresponsive/unconscious.

The study showed a vaccine efficacy of 81.8% against severe RSV-confirmed lower respiratory tract illness requiring a medical visit in the first 90 days after birth. Efficacy was 69.4% through 180 days after birth.

There were 63 hospitalizations due to RSV up to 180 days after birth — 19 in the vaccine group and 44 in the placebo — for an efficacy in preventing hospitalization of 56.8%.

Mothers reported common, mild or moderate vaccine side effects. Nearly 41% in the vaccine group reported pain at the injection site within a week of vaccination; nearly 27% reported muscle pain; 31% reported headache, which was slightly higher than the incidence in the placebo group.

In preparation for the May 18 meeting (U.S. Food & Drug Administration, 2023c) of the FDA's Vaccines and Related Biological Products Advisory Committee, the FDA released its briefing document on the Pfizer vaccine (U.S. Food & Drug Administration, 2023a). The briefing document said the "safety data appear generally favorable for vaccine administration," but the FDA noted a "numerical imbalance of 1%" in premature births. FDA said the difference was not statistically significant but indicated the imbalance could be discussed by the advisory committee.

One premature birth was assessed to be "possibly related" to the vaccine. The infant had "a normal birth outcome and no complications," the FDA said. In the case of one infant death, due to complications of preterm birth, the FDA said it was "unable to exclude the possibility" that the prematurity and death were related to the vaccine.

In terms of preventing all medically attended cases of RSV, the trial data found an efficacy of 51.3% at 180 days after birth.

VRBPAC, the FDA advisory committee, voted unanimously, <u>14-0</u>, that the data <u>supported the effectiveness</u> of the Pfizer maternal vaccine in preventing RSV lower respiratory tract disease and severe disease in babies from birth to age 6 months (U.S. Food and Drug Administration, 2023). The vote was <u>10-4</u> in favor of the data <u>supporting the safety</u> of the vaccine.

Those who voted "no" expressed concern about the data not providing enough certainty on whether the imbalance in preterm births was a safety issue. Dr. Paul A. Offit, a vaccine expert and pediatrician at the Children's Hospital of Philadelphia, posed the question of whether the data was "adequate in terms of reassuring one that what was seen with GSK's vaccine is not going to be seen here" (U.S. Food and Drug Administration, 2023). Offit <u>said</u>, "If you're in any sense risking premature births with this vaccine, I think there'll be a big price to pay, and so I guess I just don't feel we have enough data to be reassuring."

Others who voted yes said the difference in preterm births wasn't statistically significant.

The FDA will now consider whether to approve the vaccine.

CDC vaccination recommendations

CDC recommends that pregnant people receive the inactivated flu vaccine and the tetanus, diphtheria, and pertussis (Tdap) vaccine, and recommends COVID-19 vaccination for "everyone ages 6 months and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or who might become pregnant in the future" (Centers for Disease Control and Prevention, 2023b).

The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant people receive the influenza and the Tdap vaccinations (American College of Obstetricians and Gynecologists, 2023b). ACOG also recommends the COVID-19 for everyone, "including anyone who is pregnant, breastfeeding, or thinking about getting pregnant" (American College of Obstetricians and Gynecologists, 2023a).

Evidence of public reluctance to vaccinate those who are pregnant

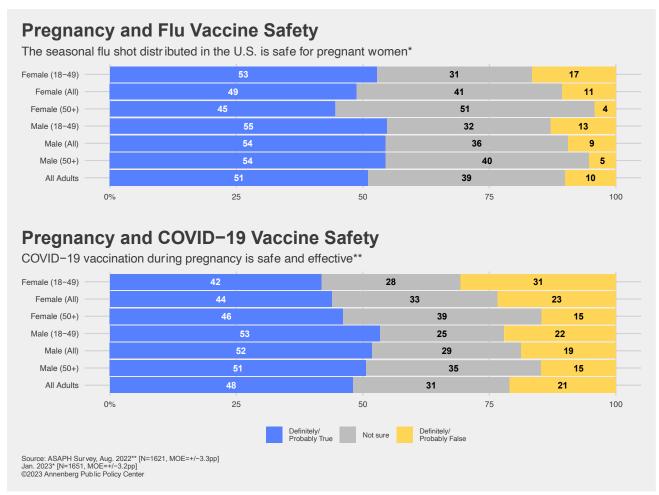
<u>CDC 2018-2019 data</u> indicated that only 65% of pregnant people had received both the flu and Tdap vaccines (Centers for Disease Control and Prevention, 2019). Subsequent <u>research</u> suggests that Tdap vaccination may have declined among pregnant people during the pandemic (Smith et al., 2022). In a small "cross-sectional study of a convenience sample of recently delivered women," <u>Martinez et al.</u> found that "fear of side effects of both vaccines was the most common reason for vaccine hesitancy" (Martinez et al., 2023).

The Annenberg Public Policy Center (APPC) data show that higher percentages of women of childbearing age (18 to 49 years old) do not think that vaccination against COVID-19 and the flu during pregnancy is safe, when compared with women age 50 and older and all adult men. (See APPC's second <u>ASAPH Knowledge Monitor</u> (*Annenberg Science Knowledge/ASAPH Surveys Archives*, n.d.).

Although a majority (53%) of women of childbearing age know that the seasonal flu vaccine "is safe for pregnant women," 17% of women of childbearing age incorrectly think that is false. Doubts that the vaccine is safe for pregnant women are held by a much larger percentage of women of childbearing age (17%) than women 50 years old and older (4%) or adult men (9%).

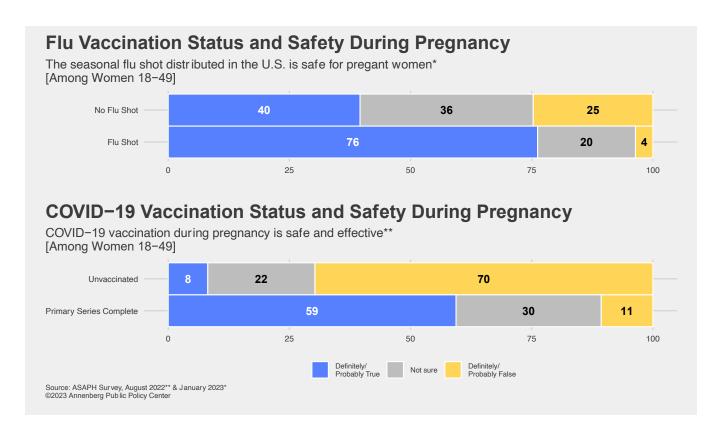
This trend is even more pronounced with the COVID-19 vaccine. As seen in a prior wave of the survey, in August 2022, just over 4 in 10 women (42%) of childbearing age report that Covid-19 vaccination during pregnancy is safe and effective. But nearly a third (31%) of women of childbearing age incorrectly think it is false to say that this is the case. Many more women of childbearing age doubt the safety and effectiveness of COVID-19 vaccination during pregnancy (31%) than do older women (15%) or adult men (19%).

Figures 3a & 3b. Responses to questions on whether vaccines are safe for pregnant women, specifically the flu vaccine (3a, top) and COVID-19 vaccine (3b, bottom). Source: <u>ASAPH Knowledge Monitor</u>, August 2022 and January 2023 ("Women of Childbearing Age More Doubtful About Safety of Flu, Covid-19 Vaccines During Pregnancy," 2023). See Appendix for full methodology.



The report finds differences among women of childbearing age depending on vaccination status.

Figures 4a & 4b. Responses to questions on whether vaccines are safe during pregnancy varied depending on the respondents' vaccination status, with more vaccinated respondents indicating correctly that both the seasonal flu vaccine (4a, top) and COVID-19 vaccines (4b, bottom) are safe for pregnant women. Source: <u>ASAPH Knowledge Monitor</u>, August 2022 and January 2023 ("Women of Childbearing Age More Doubtful About Safety of Flu, Covid-19 Vaccines During Pregnancy," 2023). See Appendix for full methodology.



In May, the Food and Drug Administration (FDA) <u>approved</u> access to <u>two</u> RSV vaccines for older adults (Pfizer, 2023b; U.S. Food & Drug Administration, 2023b), and this summer is likely to approve distribution of a maternal RSV vaccine for pregnant people to pass antibodies on to fetuses to prevent the illness in infants from birth up to at least six months of age.

The June 2023 ASAPH survey of more than 1,600 adults found that less than half of Americans (49%) were likely to recommend the vaccine against RSV, if approved by the FDA, to a pregnant friend or family member. By contrast, most Americans (63%) would recommend a vaccine against RSV to a friend or family member aged 65 or older. (When the survey was fielded, the FDA had already approved the vaccine for adults 60 and older, although the shots were not yet available.)

Figure 5. Survey respondents' likelihood to recommend a potential RSV vaccine to a friend or family member who was either pregnant or age 65 and up. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.

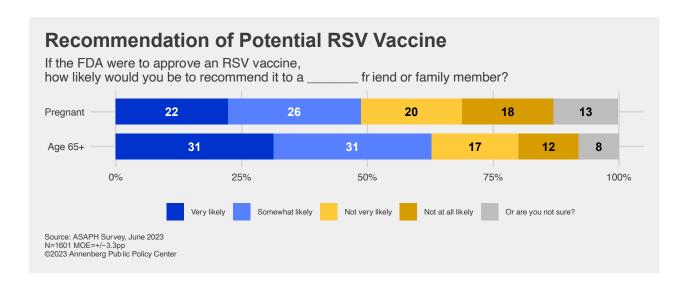


Figure 6. Survey respondents' likelihood to recommend the flu vaccine during pregnancy. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.

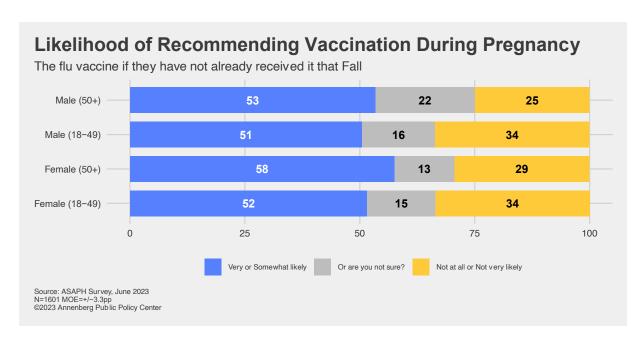


Figure 7. Survey respondents' likelihood to recommend the COVID-19 vaccine during pregnancy. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.

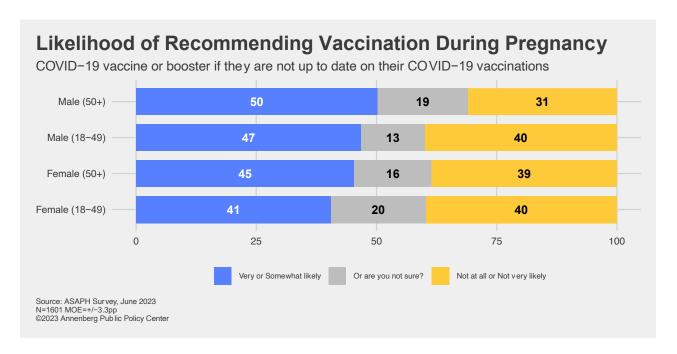


Figure 8. Survey respondents' likelihood to recommend the Tdap vaccine during pregnancy. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.

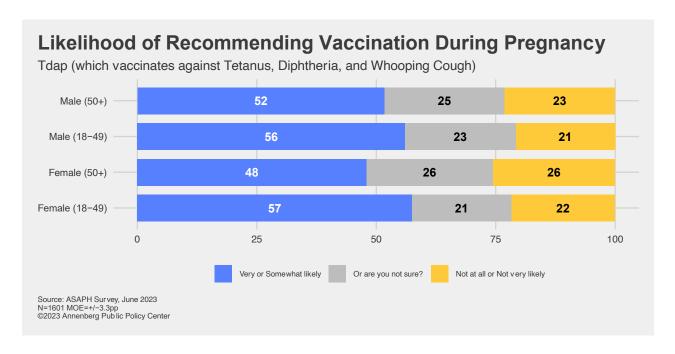
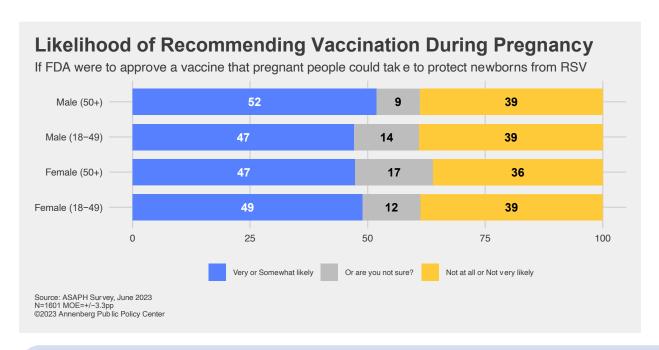


Figure 9. Survey respondents' likelihood to recommend a potential RSV vaccine during pregnancy. Source: <u>ASAPH Knowledge Monitor</u>, June 2023 ("RSV Is a Serious Health Threat, but the Public Knows Little About It," 2023). See Appendix for full methodology.



Findings from ASAPH Knowledge Monitor, April 2023

- **Flu:** The U.S. seasonal flu shot is considered safe for pregnant women by three-quarters (76%) of women of childbearing age who indicate they are vaccinated against the flu but only by 40% of those who did not report having a flu shot.
- **COVID-19:** The COVID-19 vaccination during pregnancy is considered safe and effective by 59% of women of childbearing age who report having had the primary series of COVID-19 vaccine shots but only 8% of those who did not report taking COVID vaccines.
- **Uncertainty:** Large numbers of people especially, women age 50 and older are not sure if the two vaccines are safe during pregnancy.
 - o Among women 50 and older, 39% are not sure if the COVID-19 vaccine is safe and effective during pregnancy, and over half (51%) are not sure if the flu shot is safe for pregnant women.

Finding from ASAPH Knowledge Monitor, June 2023

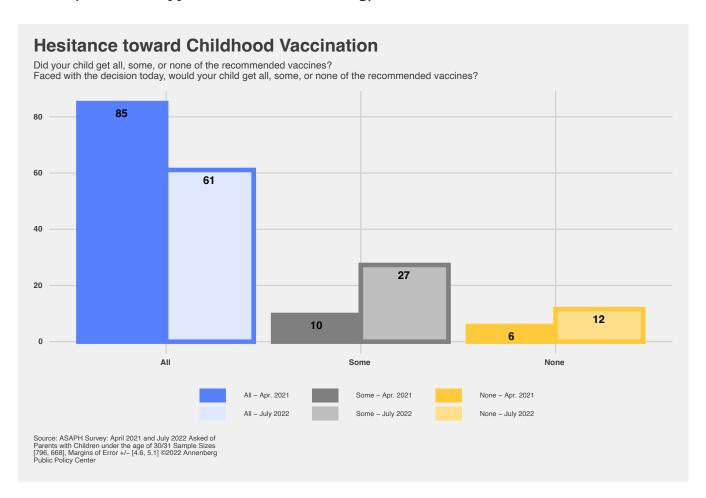
 There is no age-related difference in willingness to recommend an RSV vaccine for a pregnant person.

The context shaping public perceptions of a new vaccine

Hesitance to vaccinate children has increased

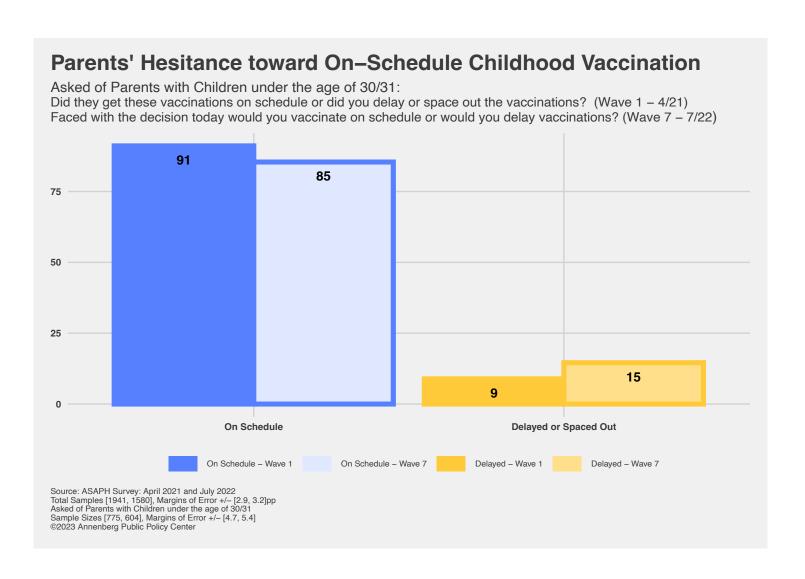
Questions asked of parents in 2021-2022 show a change in the extent to which they have had their children vaccinated – and what they would do today. In April 2021, 85% of parents with children up to age 30 said their child had received *all* the recommended childhood vaccines, while 10% said their child received *some* of the vaccines and the children of 6% received *none*. But in July 2022, when parents on the same panel were asked what they would do if faced with the same vaccination decision today, only 61% would have their children get all of the vaccinations. The percentage of parents who would have their children given only some of the vaccinations grew over 2 ½ times, to 27%, while 12% would give their children none.

Figure 10. Parents' hesitance toward childhood vaccination. Source: ASAPH Survey, April 2021 and July 2022. See Appendix for full methodology.



Hesitance to give children on-schedule vaccination also is greater today than when parents had their own children vaccinated. Whereas 91% of parents surveyed in April 2021 said their children received vaccinations on schedule, when asked in July 2022 what they would do today, 85% said their children would get the vaccinations on schedule.

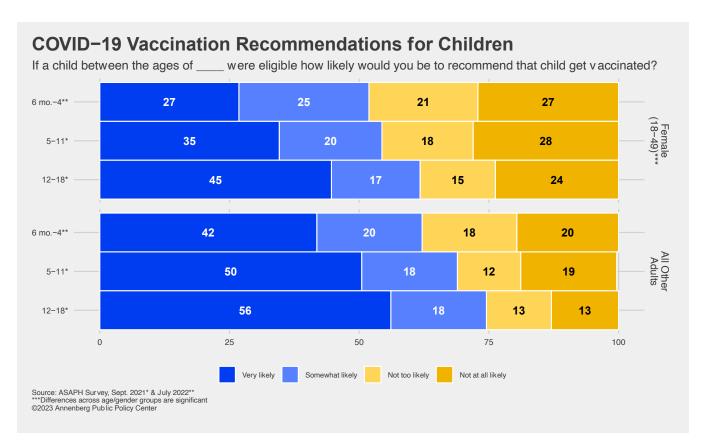
Figure 11. Parents' hesitance about on-schedule childhood vaccination. Source: ASAPH Survey, April 2021 and July 2022. See Appendix for full methodology.



As the age of the child decreases, public reluctance to vaccinate against COVID-19 increases, including among 18- to 49-year-old women

Surveys fielded in 2021 and 2022 show that the public's willingness to vaccine children against COVID-19 increases with the age of the child – and that, conversely, the younger the child, the greater the hesitation about vaccination. This trend is even more pronounced among women of childbearing age, 18 to 49 years old. While 45% of women of childbearing age would be very likely to recommend that a child aged 12-18 get vaccinated against Covid-19, only 27% would be very likely to do so for a child six months to 4 years old. And while 56% of other adults – adult men and women 50 and older – would be very likely to recommend vaccination against Covid-19 for a child aged 12-18, only 42% would do so for a child six months to 4 years old.

Figure 12. Public understanding of COVID-19 vaccination recommendations for children. Source: ASAPH Survey, September 2021 and July 2022. See Appendix for full methodology.



Correcting or contextualizing problematic information about RSV & vaccination *

Questioning the need for an RSV vaccine

Corrective context

RSV is common in children. While many infants will only have a cold from RSV, it can be dangerous for some.



The CDC <u>estimates</u> that 58,000 to 80,000 children under 5 are hospitalized each year because of RSV and that among every 100 babies under 6 months of age with RSV, 1 to 2 may need hospitalization (Centers for Disease Control and Prevention, 2022d). There are half a million emergency department visits and 1.5 million visits to outpatient clinics for kids under 5 each year. Deaths are "uncommon" in the U.S. — an <u>estimated</u> 100 to 500 each year for kids under 5 (Centers for Disease Control and Prevention, 2021), though the CDC says RSV-associated deaths are likely undercounted due to a lack of testing. In lower-income countries, death in infants is more of a concern; an estimated 45,700 babies up to 6 months of age worldwide died due to RSV in 2019, according to a systematic analysis of hundreds of studies <u>published in the Lancet</u> (Li et al., 2022).

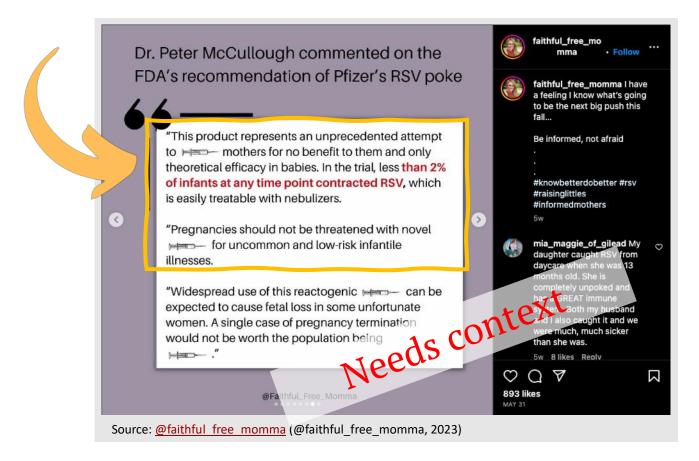
Problematic content

Among claims that are circulating about RSV vaccination, a recurring suggestion is that the risk of RSV isn't significant enough to justify any vaccination that comes with risk.

Cardiologist Dr. Peter McCullough has said misleadingly that RSV in infants is "uncommon," "low-risk," and "easily treatable with nebulizers" (Nevradakis, 2023b). McCullough, who has previously made false and misleading claims about the COVID-19 vaccines ("Peter McCullough Archives," n.d.), was quoted in The Defender, a publication of Children's Health Defense, a group that has spread vaccine misinformation and was founded by Robert F. Kennedy Jr.

^{*} The content in this section is adapted from a FactCheck.org/SciCheck article <u>published</u> on June 12, 2023, written by Lori Robertson (Robertson, 2023c).

McCullough's comments have also been disseminated on social media, including in a carousel of slides posted to Instagram by the user @faithful_free_momma on May 31, 2023 (Angela [@faithful_free_momma], 2023).



Distortions about available treatments for RSV

Corrective context

The CDC <u>indicates</u> that most RSV infections "go away on their own in a week or two" (Centers for Disease Control and Prevention, 2022b). People with RSV should manage fever and pain with over-the-counter medicines and drink plenty of fluids; some individuals may experience more severe symptoms that require hospitalization. A <u>drug</u> called "palivizumab (pah-lih-VIH-zu-mahb) is available to prevent severe RSV illness in certain infants and children who are at high risk for severe disease" (Centers for Disease Control and Prevention, 2022e) and the FDA has approved two monoclonal antibody products to help protect young children and infants from severe RSV. The CDC indicates that "nirsevimab (Beyfortus) and palivizumab (Synagis) – can help protect babies and young children from severe disease from an RSV infection," adding that, "[t]hese

products are not treatments for a child who already has RSV infection" (Centers for Disease Control and Prevention, 2022e).

Problematic content

However, online posts contend that <u>colloidal silver</u> should be considered as an option (Kaylee Marie [@conspiracy.kay], 2022), as should <u>coconut oil and garlic</u> (Bekah Christine, 2022).



Contextualizing concerns about safety of RSV vaccine for pregnant individuals

The state of the s

Preterm births

Corrective context

In its <u>briefing document</u>, the FDA said there was a "numerical imbalance of 1%" in premature births between the vaccine and placebo groups, noting that the difference was not statistically significant (U.S. Food & Drug Administration, 2023a). In the vaccine group, 5.7% of participants had a preterm birth, compared to 4.7% of the placebo group.

The difference for low birth weight also wasn't statistically significant: 5.1% in the vaccine group and 4.4% in the placebo.

The difference for preterm births wasn't statistically significant, though the FDA indicated its advisory committee — the Vaccines and Related Biological Products Advisory Committee — could discuss the imbalance in its May 18 meeting, which the committee did.

The rates of preterm birth in the trial were lower than the <u>background rate</u> of 10% of all births globally for 2020 (WHO, 2023).

<u>Problematic content</u>

The Instagram post by <u>@faithful_free_momma</u> (Angela [@faithful_free_momma], 2023) <u>described</u> the trial results as having "about 20% more preterm babies and low birth weight babies" in the vaccine group. There is a 20% difference between the two groups for the number of preterm births, but the figure requires the context that we provided above.



Adverse events

Corrective context

The peer-reviewed trial results <u>said</u> (Kampmann et al., 2023): "No safety signals were detected in maternal participants or in infants and toddlers up to 24 months of age. The incidences of adverse events reported within 1 month after injection or within 1 month after birth were similar in the vaccine group (13.8% of women and 37.1% of infants) and the placebo group (13.1% and 34.5%, respectively)."



The FDA <u>briefing document</u> on the vaccine said that within 30 days after vaccination, 0.4% of adverse events reported in the vaccine group and 0.1% of adverse events in the placebo group were considered to be related to the injection by the investigator (U.S. Food & Drug Administration, 2023a). For the infants, no serious adverse events "were considered related to maternal vaccination," the briefing document said. But in one case of an infant death, the investigator assessed that it wasn't related to vaccination while the FDA was "unable to exclude the possibility of the extreme prematurity and subsequent death being related."

In all, there were five infant deaths (0.1%) in the vaccine group and 12~(0.3%) in the placebo group.

Problematic content

One slide in the Instagram carousel from @faithful_free_momma <u>listed</u> percentages for adverse events reported in Pfizer's clinical trial after vaccination (Angela [@faithful_free_momma], 2023) but didn't explain that the percentages were similar for those in the placebo group. And these adverse events are any health events that occur after vaccination, not necessarily events caused by the vaccine.



Unsupported concerns about vaccine ingredients

Problematic content

The Instagram post also highlighted a description of the placebo from the FDA briefing document that said the placebo was similar to the vaccine formulation "minus the active ingredients." The post pointed to those words and misleadingly commented, "basically everything but the virus" (Angela [@faithful_free_momma], 2023). The inaccurate implication of the post is that the RSV vaccines contain the whole virus. They do not.

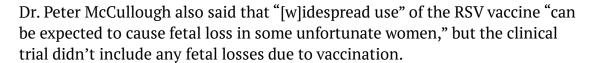


It's possible some may wrongly conclude from the post that the vaccine shot could infect people with the virus. It can't.

Pfizer's RSV vaccine is a <u>protein subunit vaccine</u>, which uses part of a protein of a virus, not the whole virus (Gavi, the Vaccine Alliance, 2020). Other vaccines, including those for hepatitis B and pertussis, are also protein subunit vaccines.

Distortions about the effects of the RSV vaccine

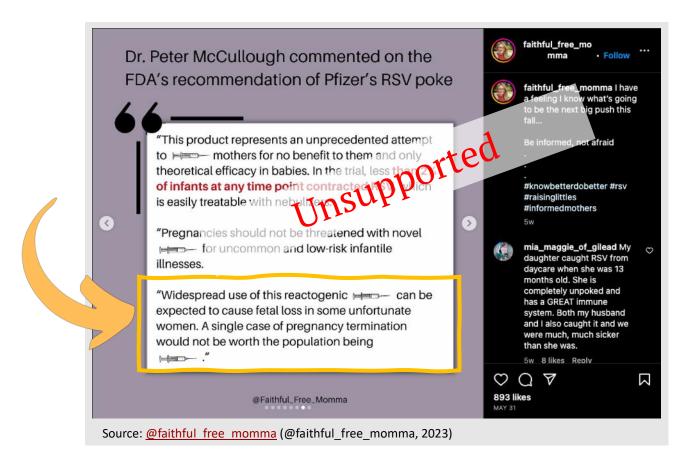
Context and correction





In the trial, there were 10 fetal deaths in the vaccine group and eight in the placebo group, the FDA briefing document said. These were due to "various clinical conditions and presentations." The FDA agreed with the assessment of the study investigator that none was related to the vaccine, "based on review of available case narratives and evident lack of temporal relation of vaccination to the fetal loss events."

Problematic content



Reducing susceptibility to misconceptions about a new vaccine

Because concerns raised about the COVID-19 vaccines have shaped public perceptions of new vaccines, we can anticipate the ones that will be raised by a new vaccine that will deliver protection to infants by vaccinating during pregnancy.

Unwarranted safety concerns seeded by misconceptions about earlier vaccines

Of the more than 6,000 claims fact-checked by eight national and international fact-checking organizations over the first three years of the pandemic, Annenberg Public Policy Center researchers found that just over 1,250 or over one in five asserted that the COVID vaccines were unsafe. Here we indicate ways to reduce susceptibility to three of those claims: unwarranted fears about vaccine testing; the false assertion that vaccines cause autism; and the false claim that COVID-19 vaccination changes one's DNA.

Unwarranted fears about vaccine testing

Addressing concerns raised about COVID-19 vaccination for those who are pregnant

Individuals who were pregnant at the outset of the COVID-19 clinical trials were excluded from them. But studies conducted afterward showed that taking COVID-19 vaccination while pregnant reduced the risk of severe COVID-19 (Lipkind et al., 2022; Magnus et al., 2021; Moro et al., 2022; Sadarangani et al., 2022). There is evidence as well that taking the two primary doses of the mRNA vaccine while pregnant confers benefits on newborns and infants who are less likely to be hospitalized in the six months after delivery (Halasa et al., 2022; Shook et al., 2022).

And importantly, getting infected with COVID-19 poses real risks. Those who are pregnant are more likely to experience serious illness if they contract COVID-19 than are those who are not pregnant (Centers for Disease Control and Prevention, 2022a).



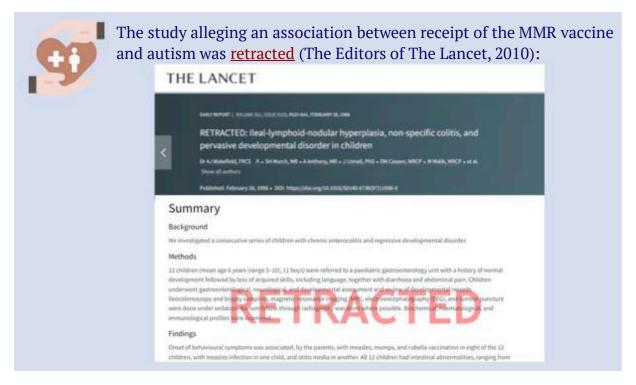
The RSV vaccine's clinical trial did include pregnant individuals. And the randomized, double-blind, placebo-controlled clinical trial, which enrolled roughly 7,400 pregnant individuals who were between 24 and 36 weeks of gestation, found that the maternal RSV vaccine reduced the risk of severe disease in infants. The trial didn't identify any safety concerns.

Some of the hesitancy about any new vaccine is its newness. Put another way, some are afraid that there may be "long-term" consequences of new vaccines that are not captured in clinical trials or shortly after the vaccine is rolled out. Importantly, although the "history of vaccines shows that severe effects following vaccination can occur...when they do, these effects tend to happen within two months of vaccination" (Children's Hospital of Philadelphia, 2021; see also Davids Landau, 2021). And the federal health agencies have systems in place to watch for and assess effects that may occur after vaccination (see APPC's first white paper in this series, "Minimizing public susceptibility to misconceptions about the effects of vaccination: Vaccine Adverse Event Reporting System [VAERS]," published in May 2023).

Debunking bogus claims about vaccinations in infants: The alleged autism association

Fears that the MMR vaccine causes autism, a claim unsupported by evidence, and that the number of vaccines given to children accounts for the rise in autism diagnoses, also debunked by extensive research, both play a role in current hesitancy to vaccinate children against COVID-19. In addition, acceptance of the incorrect assumed MMR-autism association predicted a reduced likelihood during the 2016-2017 Zika virus outbreak of intended vaccination if a Zika vaccine were approved by the FDA (Ophir & Jamieson, 2018).

Message from the public health community:



The National Academies of Science, Engineering, and Medicine report that "Many scientists have studied this question, but no credible studies show that autism is caused by vaccines" (National Academies of Science, Engineering, and Medicine, 2019). They say, as a result, that based on all that science knows at this time, the claim that vaccines cause autism is false.

Understanding the mRNA vaccine



The messenger RNA vaccines work by telling our cells to build protection against COVID-19. DNA is in the nucleus of our cells. The messenger RNA COVID -19 vaccines do not enter the nucleus of the cells.

Safety concerns about the new RSV vaccines are already being highlighted online (see, for example: Dr Panda, 2023; Nevradakis, 2023a). There are also some safety worries specific to childhood vaccination. Unwarranted claims that the COVID vaccine changed DNA and affected fertility played a role in the hesitancy of vaccinated adults to recommend vaccinating a child against COVID-19 (Romer et al., 2022). Those concerns are unfounded. And the RSV vaccines do not employ mRNA.

Recommendations

1. Visualize the effects of RSV and offer clear & accurate information on the benefits & risks of vaccination compared to likelihood of infection & its risks

Opponents of vaccination frequently feature possible, often rare, side effects. As individuals consider vaccination, they need to ask not whether possible side effects exist but whether the risks of vaccination outweigh the risks of the disease. To keep this comparative frame in focus, visualize the effects of the disease while also reporting the likelihood of contracting it and the nature and possible effects of doing so.

Dr. Jay M. Portnoy, a pediatrician at Kansas City's Children's Mercy Hospital, and member of VRBPAC, the FDA advisory committee, did this when he talked about the role that the dangers of RSV for very young infants played in his vote. "So if I compare the very small risk of earlier birth with the almost certain risk of getting RSV and a very high risk of ending up in the hospital, I have to on balance say that the risk is much greater if we don't give the vaccine then if we do, so that's why I voted yes," he <u>said</u> (U.S. Food and Drug Administration, 2023).

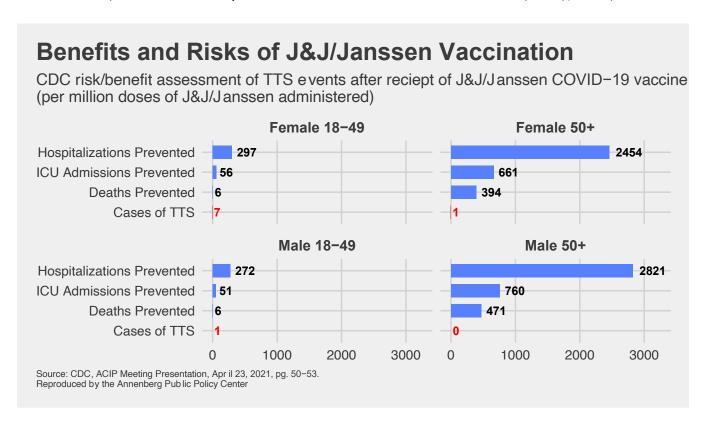
The experiment reported in Appendix 1 demonstrates that exposure to the following information about RSV risk increases the disposition to recommend RSV vaccination:

"RSV can be dangerous for some infants and young children. Each year in the U.S. an estimated 58,000-80,000 children younger than 5 years old are hospitalized due to an RSV infection. One to two out of every 100 children younger than 6 months of age with RSV infections may need to be hospitalized."

Among sites that visually represent the potential severity of RSV are the current <u>CDC page</u> on RSV in infants and young children (Centers for Disease Control and Prevention, 2022d) and an <u>informational page</u> on RSV in infants that indicates when to contact a doctor (Sanofi, n.d.).

Figure 13 compares the risk of a specific complication, thrombosis with thrombocytopenia syndrome (TTS), from receipt of the Johson & Johnson (J&J)/Janssen COVID-19 vaccine to the benefits of taking the vaccine. The J&J/Janssen vaccine has been linked to the blood clotting condition TTS (Oliver & Advisory Committee on Immunization Practices (ACIP), 2021).

Figure 13. Risk/benefit assessment of TTS after receipt of the COVID-19 vaccine from J&J/Janssen (Oliver & Advisory Committee on Immunization Practices (ACIP), 2021).



2. CDC should create a page that complements existing information on RSV but focuses on vaccination during pregnancy

Individuals cannot use information they can't find.

See the existing <u>CDC</u> webpage on <u>RSV</u> and their infographic on protecting children from infection below (Centers for Disease Control and Prevention, 2022c).





The CDC <u>page</u> on the safety of the MMR vaccine is a model that a future page pertaining to RSV vaccination for pregnant individuals could emulate, albeit with visual illustrations (Centers for Disease Control and Prevention, 2023c).



3. Pre-emptively communicate about the changing nature of science by noting that guidance may be updated as more is learned about the RSV vaccine

Science is an iterative process. After FDA approval, vaccines undergo the usual process of post-approval monitoring. Pre-emptively highlighting this routine scientific process can help ensure the public is not surprised if other safety issues come up during that process and lead to additional guidance.

4. Increase public understanding that multiple stages exist in the FDA vaccine review process

It also is important to communicate the stages involving independent review included in vaccine approval, and how the FDA and CDC decide whether the benefits of a vaccine outweigh the risks associated with infection and with vaccination.

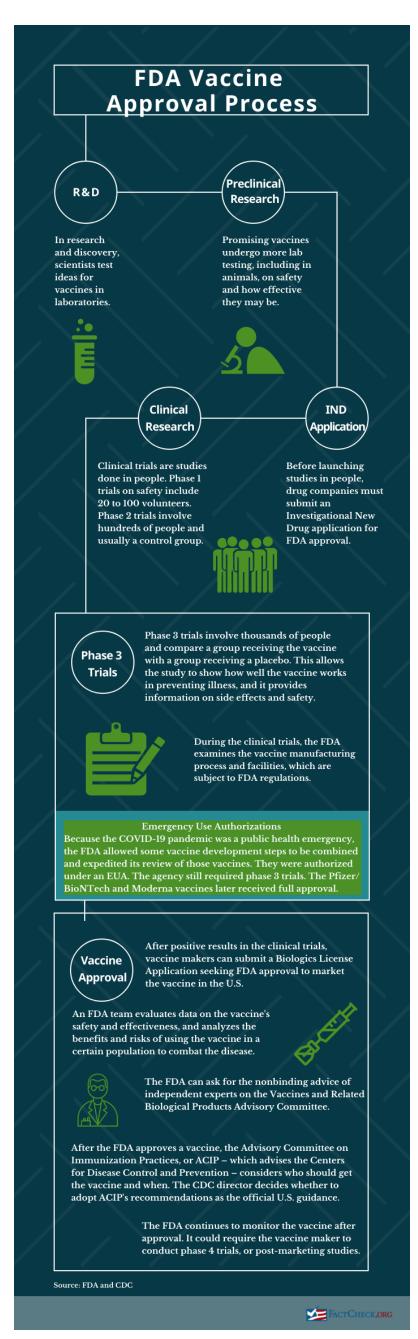
Overall confidence in the federal health agencies, including the FDA, remains high. When the APPC national ASAPH sample was asked in June 2023, "In general, how confident, if at all, are you that the following are providing the public with trustworthy information about matters concerning public health? / The Food and Drug Administration (FDA)," 77% percent reported that they were somewhat or very confident in this federal health agency.

Effect of exposure to an FDA vaccine-approval pathway diagram

Importantly, a study conducted by APPC researchers provided evidence that exposure to a chart showing the stages through which a vaccine passes before approval increased willingness to recommend RSV vaccination to a pregnant friend or family member. See Appendix 1 for more details.

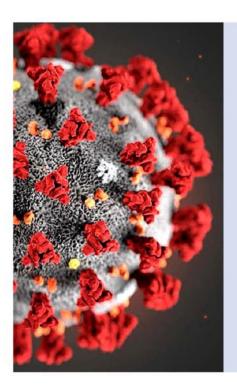
Survey respondents treated either with a visual description of the FDA's vaccine approval process (see Figure 14 below) or a description of the risks associated with RSV (see Recommendation 1 above) were more likely to recommend RSV vaccination to a friend or family member who was pregnant.

Figure 14. Flow-chart of the FDA vaccine approval process used in the experiment. Information source: U.S. Food and Drug Administration. Chart: <u>FactCheck.org</u> (Robertson, 2023b).



5. Remind potential vaccine recipients of the ways in which the FDA and CDC protect the vaccination review process from outside influence

Because those who wish to discredit vaccination often allege that the pharmaceutical industry dictates which medications and vaccines are and are not approved by the federal health agencies, it is useful as well to remind audiences of the ways in which the approval process protects review of data from outside influence.



Communicating the ways in which the evaluation of vaccine evidence is protected from outside influence

In the United States:

- Blinded, randomized, controlled studies with large, diverse populations
- Independent data and safety review board
- Independent statisticians review data at pre-set times
- Pre-set thresholds for continuing or ending trials
- Multiple stages of review before final authorization

6. Address a wait-and-see reluctance to be the first to vaccinate

We know that some of the reluctance of the U.S. population to take the COVID-19 vaccine was not motivated by opposition to vaccination but by a wait-and-see attitude. After large numbers took the vaccine without serious side effects, those individuals rolled up their sleeves. The same pattern characterized uptake of the HPV vaccine. By 2020, more than seven out of ten girls and boys had gotten at least one dose (Mozes, 2022). Of course, if everyone adopted this attitude, we never would achieve large-scale vaccination. But as vaccination uptake increases, it is important to remind those who are watchfully waiting that vaccination is becoming the norm.

Appendix 1: Experimental study of effects of exposure to an FDA pathway diagram

In the study, the Annenberg Science and Public Health (ASAPH) panel was randomly assigned to one of five conditions, three of which we analyze here. The prompts used in each of the three conditions are described below.

Data for this experiment came from wave 11 of the Annenberg Science and Public Health (ASAPH) panel, which was conducted between May 31 and June 6, 2023. Wave 11 had a sample of 1601, a margin of error of +/- 3.3 percentage points, and an overall design effect of 1.85.

Condition 2 presented respondents with a figure describing the FDA's approval process for vaccinations, in either English (see Figure 14) or Spanish.

After each of the three conditions, respondents were asked "how likely, if at all, would you be to recommend that a friend or family member who is pregnant take the [RSV] vaccine?" on a four-point Likert scale ranging from "Not at all likely" to "Very likely."

Survey respondents treated either with a visual description of the FDA's vaccine approval process or a description of the risks associated with RSV were more likely to recommend RSV vaccination to a friend or family member who was pregnant.

Condition 1: *Control*

An RSV vaccine is currently under review by the Food and Drug Administration (FDA). If the Food and Drug Administration (FDA) were to approve a new vaccine that those who are pregnant could take to protect their newborns from RSV from birth to 6 months of age, how likely, if at all, would you be to recommend that a friend or family member who is pregnant take the vaccine?

Condition 2: *Process*

An RSV vaccine that would be given to pregnant individuals to protect their newborns from RSV is currently under review by the Food and Drug Administration (FDA). The FDA approval process involves the stages of review shown in the following chart.

An RSV vaccine is currently under review by the Food and Drug Administration (FDA). If the FDA were to approve a new vaccine that those who are pregnant could take to protect their newborns from RSV from birth to 6 months of age, how likely, if at all, would you be to recommend that a friend or family member who is pregnant take the vaccine?



Condition 3: *Risk*

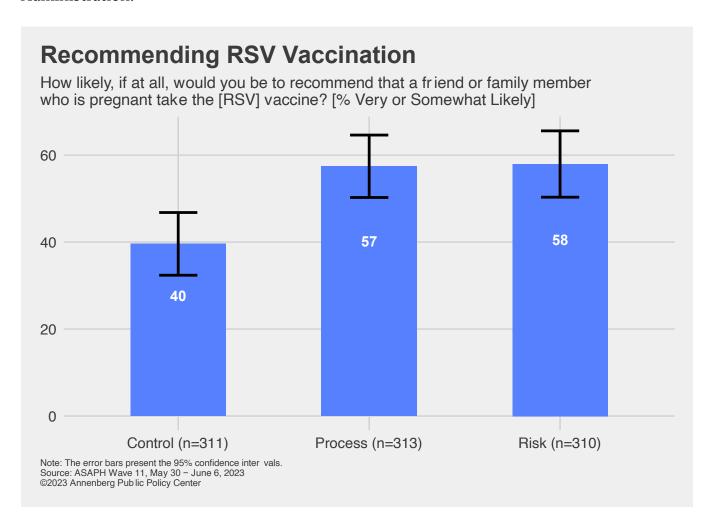
RSV can be dangerous for some infants and young children. Each year in the U.S. an estimated 58,000-80,000 children younger than 5 years old are hospitalized due to an RSV infection. One to two out of every 100 children younger than 6 months of age with RSV infections may need to be hospitalized.

An RSV vaccine is currently under review by the Food and Drug Administration (FDA). If the FDA were to approve a new vaccine that those who are pregnant could take to protect their newborns from RSV from birth to 6 months of age, how likely, if at all, would you be to recommend that a friend or family member who is pregnant take the vaccine?

MORE likely to recommend RSV vaccination to pregnant friend or family member

MORE likely to recommend RSV vaccination to pregnant friend or family member

Figure 15. Effect of exposure to the three conditions. Information source: U.S. Food and Drug Administration.



The experiment was created by Patrick Jamieson, Ph.D., and the data analyzed by Shawn Patterson, Jr., Ph.D. The FDA-CDC approval pathway diagram (Figure 14) was created by Lori Robertson of FactCheck.org.

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Methodology

The data for the Annenberg Science and Public Health (ASAPH) survey were collected from a nationally representative probability panel survey drawn randomly from the SSRS Opinion Panel of U.S adults, 18 and older. SSRS Opinion Panel members are recruited randomly based on nationally representative address-based sample design (including Hawaii and Alaska). Additionally, hard-to-reach demographic groups were recruited via the SSRS Omnibus survey platform, a nationally representative (including Hawaii and Alaska) bilingual telephone survey designed to meet standards associated with custom research studies.

Both the phone and online surveys were available in Spanish with about 1.7% of the panel using this language. Panel members in our study were not selected for any other studies conducted by SSRS and are considered proprietary. Panelists were invited by email or telephone to participate in the panel and were compensated the equivalent of \$15 for their time at each survey wave. The median length of the surveys was 20 minutes. The survey was deemed exempt from review by the Institutional Review Board of the University of Pennsylvania.

Of the 3,476 U.S. adult panelists invited to participate in wave 1 of the survey, 1,941 completed that wave's survey in April 2021 (56% completion rate). The majority completed the survey online rather than by telephone (97% online and 3% by telephone). These 1,941 panelists were recontacted at each subsequent wave unless they dropped from the panel. Post-wave 1 panelist completion rates were high, averaging 84 percent between waves 2 and 11.

Between waves 8 and 9, The Annenberg Public Policy Center of the University of Pennsylvania (APPC) engaged SSRS in recruiting additional panelists to the ASAPH panel to increase the sample size, account for attrition, and improve the representativeness of the panel. Additional panelists were recruited again via address-based sampling in similar fashion to the initial recruitment as described above. From these recruits, ASAPH randomly selected 74 additional panelists with an educational attainment of a high school degree or less to participate to improve representativeness.

Between waves 9 and 10, APPC engaged SSRS to conduct an engagement survey with the purpose of recruiting additional panelists. The survey was conducted via the SSRS Opinion Panel and invited only newly recruited panelists with an educational attainment of a high school degree or less to participate to improve representativeness. Data collection was conducted from December 6 – December 12, 2022 by web in English only. The survey obtained 60 completes, among which 33 were recruited to the ASAPH Panel. In total, 107 new respondents were added. The reduction in design effect between waves 8 and 10 reflects the improved representativeness of the sample post-replenishment.

The battery on RSV was included in Wave 11. Wave 11, conducted between May 31 and June 6, 2023, obtained 1601 responses with a margin of total sampling error of +/- 3.3 percentage points. ASAPH panelists are quarantined from other survey panel membership to avoid being affected by the content of other surveys. Data from Wave 11, however, contains 19 respondents who self-reported membership in other opinion panels. Diagnostics revealed no significant differences in the responses of these 19 panelists and the results presented in this report are unaffected by their exclusion.

About the Annenberg Public Policy Center

The Annenberg Public Policy Center of the University of Pennsylvania was founded in 1993 and created FactCheck.org in 2003. By conducting and disseminating research, staging conferences and hosting policy discussions, its scholars have addressed the role of communication in politics, science, adolescent behavior, child development, health care, suicide prevention, civics, and mental health, among other important areas. The center's researchers have drafted materials that have helped policy makers, journalists, scholars, constituent groups and the general public better understand the role that media play in their lives and the life of the nation.

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APPC's ongoing funding comes from an endowment established for it by the Annenberg Foundation in 1993.

SciCheck's COVID-19/Vaccination Project is made possible by a grant from the Robert Wood Johnson Foundation. The views expressed here do not necessarily reflect the views of the Foundation. The goal is to increase exposure to accurate information about COVID-19 and vaccines, while decreasing the impact of misinformation.