

# Respiratory Syncytial Virus (RSV): FDA Fast-Tracks RSV mRNA ‘Vaccine’. “Are We Creating a Public Health Disaster”

By [Dr. Joseph Mercola](#)

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[Mercola](#)

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*Respiratory syncytial virus (RSV) — a respiratory virus that causes typically mild cold-like symptoms — is emerging out of season around the world*

*Most children have been exposed to RSV by their second birthday and recover without incident. In rare cases, RSV can progress to pneumonia or bronchiolitis (inflammation of the small airways of the lungs)*

*August 3, 2021, the U.S. Food and Drug Administration granted fast-track designation to Moderna for an mRNA-based injection against RSV*

*As with coronavirus, previous efforts to develop an RSV vaccine have met with failure as test subjects have a tendency to die or become seriously ill when exposed to the wild virus, thanks to paradoxical immune enhancement (PIE), also known as antibody dependent enhancement (ADE)*

*Moderna’s RSV shot uses the same lipid nanoparticle as its COVID-19 injection. The mRNA will encode for a prefusion F glycoprotein, a protein that mediates the RSV virus’ entry into your cells and is known to elicit a neutralizing antibody response*

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Respiratory syncytial virus (RSV) — a respiratory virus that causes typically mild cold-like symptoms — has apparently been selected as the next invisible boogey man. Most children have been exposed to RSV by their second birthday.

The fact that most children survive past the age of 2 tells you something about the risks involved. That said, in very rare cases, RSV can progress to pneumonia or bronchiolitis (inflammation of the small airways of the lungs).

## RSV Emerges Out of Season Around the World

According to reports, RSV is now raging around the world, from New Zealand<sup>1</sup> to Japan<sup>2</sup> and the U.S.,<sup>3</sup> where it hit so hard in June 2021 that the Centers for Disease Control and Prevention issued an emergency alert<sup>4</sup> for parts of the southern United States.

The CDC encouraged testing for RSV among patients who tested negative for COVID-19 but had “acute respiratory illness” symptoms. They also advised health care personnel, child care providers and staff of long-term care facilities to stay home from work if they had respiratory symptoms, even if they test negative for COVID, as they might have RSV.

Like coronavirus, previous efforts to develop an RSV vaccine have met with failure as test subjects have a tendency to die or become seriously ill when exposed to the wild virus, thanks to paradoxical immune enhancement (PIE), also known as antibody dependent enhancement (ADE).

In New Zealand, health officials said there were few cases of RSV in 2020 during the pandemic and, while it’s normally a winter disease, it’s now making a comeback off-season in 2021. According to Stuff.co.nz,<sup>5</sup> the outbreak “was more than twofold greater than the historical average from 2014 to 2019 for this time of year.”

Similar reports have been published in Japan where, in early July 2021, the National Institute of Infectious Diseases warned of RSV infections outside the normal peak period. According to the Japan Times:<sup>6</sup>

*“... the number of RSV patients per medical institution was 3.87 in the week ending June 27 — the highest number of cases since 2019. In 2018, the year the counting system was changed, the infection count peaked in September at 2.46, and it reached 3.45 patients per medical institution a year later.”*

August 3, 2021, U.S. health officials reported that RSV had started to taper off by midsummer, but a resurgence is now seen, with a “record-breaking 563 new RSV cases” reported in the week before August 3.<sup>7</sup>

### FDA Fast-Tracks mRNA Shot Against RSV

That same day, August 3, 2021, the Food and Drug Administration granted fast-track designation to Moderna for an mRNA-based injection against this common cold virus. As reported in a Moderna press release:<sup>8</sup>

*“... the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for mRNA-1345, its investigational single-dose mRNA vaccine against respiratory syncytial virus (RSV) in adults older than 60 years of age.*

*‘We are pursuing an mRNA RSV vaccine to protect the most vulnerable populations — young children and older adults,’ said Stéphane Bancel, Chief Executive Officer of Moderna.*

*‘We are studying mRNA-1345 in these populations in an ongoing clinical trial and we*

*look forward to sharing data when available ... We have accelerated research and development of our infectious disease therapeutic area and we will continue to advance our mRNA vaccines into new areas of high unmet need."*

Moderna's press release correctly points out that there's no approved vaccine available for RSV. What they don't mention is why. The reason there's no RSV vaccine on the market is the same reason why there has never been a coronavirus vaccine, and that is because none of them were able to pass trials.

As with coronavirus, previous efforts to develop an RSV vaccine have met with failure as test subjects have a pesky tendency to die or become seriously ill when exposed to the wild virus, thanks to paradoxical immune enhancement (PIE), also known as antibody dependent enhancement (ADE).<sup>9</sup>

### RSV Shot Builds on COVID Jab

Moderna's RSV shot uses the same lipid nanoparticle as its COVID-19 injection. The primary difference between the two shots is the coding of the mRNA. In the RSV shot, the mRNA encodes for a prefusion F glycoprotein.

Prefusion F protein is a protein that mediates the RSV virus' entry into your cells and is known to elicit a neutralizing antibody response.<sup>10</sup> Under normal circumstances, it's hard to imagine an RSV vaccine built on a novel mRNA platform getting fast-tracked, but we're no longer in normal times.

The rollout of mRNA COVID shots have, as predicted, paved the way for any number of new mRNA-based injections going straight to human trials. So, should you ever feel like your body lacks in synthetic mRNA, fear not. This is just the beginning. Those who embrace vaccine passports will surely find themselves called to the nearest vaccine center several times a year for mandatory refills.

### Are We Creating a Public Health Disaster?

The decision to fast-track yet another mRNA injection fails to take into consideration the possibility that we might already be creating an avalanche of ADE-related illness from the COVID shot. Adding another injection for a respiratory virus that has historically been associated with ADE could be extremely risky.

As noted in a September 9, 2020, Nature Microbiology paper titled "Antibody-Dependent Enhancement and SARS-CoV-2 Vaccines and Therapies":<sup>11</sup>

*"Data from the study of SARS-CoV and other respiratory viruses suggest that anti-SARS-CoV-2 antibodies could exacerbate COVID-19 through antibody-dependent enhancement (ADE). Previous respiratory syncytial virus and dengue virus vaccine studies revealed human clinical safety risks related to ADE, resulting in failed vaccine trials ...*

*ADE can increase the severity of multiple viral infections, including other respiratory viruses such as respiratory syncytial virus (RSV) and measles.*

*ADE in respiratory infections is included in a broader category named enhanced respiratory disease (ERD), which also includes non-antibody-based mechanisms such as cytokine cascades and cell-mediated immunopathology ...*

*Furthermore, ADE and ERD has been reported for SARS-CoV and MERS-CoV both in vitro and in vivo ... ADE pathways can occur when non-neutralizing antibodies or antibodies at sub-neutralizing levels bind to viral antigens without blocking or clearing infection ...*

*ADE has been observed in SARS, MERS and other human respiratory virus infections including RSV and measles, which suggests a real risk of ADE for SARS-CoV-2 vaccines and antibody-based interventions ...*

*Going forwards, it will be crucial to evaluate animal and clinical datasets for signs of ADE, and to balance ADE-related safety risks against intervention efficacy if clinical ADE is observed."*

In case you missed it, the authors specifically point out that ADE can worsen the severity of RSV. Theoretically then, if you get the COVID shot and end up with ADE, then contracting RSV could turn into a far more serious problem than it would otherwise.

#### Have COVID Policies Weakened Immune Systems?

While the COVID shot could play a role if we start seeing severe RSV in adults, it's unlikely to be part of the equation when it comes to children, as the shot is still not authorized for children under the age of 12. More than likely, the out-of-season rise in RSV among children is related to the easing of restrictions after not being exposed to normal pathogens for extended periods of time.

During the past 18 months, as most of the world has been masked up, locked down and otherwise distanced from one another, children and adults have not been exposed to viruses and bacteria as they normally would.

On the one hand, there has been a significant reduction in the number of people reporting colds, flu and other infectious diseases. On the other hand, some health experts are questioning if this lack of exposure may have increased the risk for some to experience more illnesses as children reenter school and adults reenter the workforce.<sup>12</sup>

The two main parts of your immune system are your innate immune system, which you were born with, and your adaptive immune system, which is developed as you're exposed to pathogens.<sup>13</sup> A healthy immune system keeps a record of every pathogen to which it has been exposed so that it can quickly recognize it if exposed again. Your immune system is activated when you're exposed to a protein it doesn't recognize, called an antigen.

Since the system is so complex, there are several potential ways in which things can go wrong. If your immune system doesn't work correctly it can result in immunodeficiency diseases, resulting in more and longer-lasting sickness.

Some health experts are concerned that children may have experienced greater harm to their immune system than adults since they have spent the better part of the last 18 months isolated from nearly every exposure.<sup>14</sup>

From what researchers are now finding, it is infants and children who may have the most detrimental response to social distancing.<sup>15</sup> Since the beginning of 2020, doctors and hospitals have noticed a significant reduction in the number of bacterial and viral infections children have been contracting. This includes bronchiolitis, measles, varicella, RSV and pertussis.

A paper<sup>16</sup> published in August 2021, from the Pediatric Infectious Disease Group postulated nonpharmaceutical interventions imposed during 2020 could result in larger epidemics of infectious diseases once these interventions are lifted.

### Rising Number of Infants With RSV Related to Immunity Debt

Some experts are calling a rising number of RSV infections in babies a “debt of immunity” created because infants born during 2020 had a lack of exposure to normal pathogens.<sup>17</sup> Once infants and children are introduced to these environmental pathogens en masse, it can instigate a precipitous rise in cases.

According to The Guardian,<sup>18</sup> New Zealand reported a 99.9% reduction in flu and 98% reduction in RSV during 2020. This nearly eliminated the spike of deaths that happens during the winter months from flu and RSV. In the short-term, it may have prevented an overload of the health care system while others were being treated for COVID-19.

However, in the long run, it may have created an additional problem in infants and children. When the immune system is not challenged at an early age, it can lead to larger outbreaks, which again taxes the health care system. As of early July 2021, New Zealand had reported nearly 1,000 cases of RSV over five weeks. The usual number reported is 1,743 over 29 weeks.

Doctors are hoping this doesn’t necessarily mean there will be more RSV cases, only that they are occurring in more rapid succession early in the season. The current outbreak has stretched the resources in New Zealand and Australia, which is also experiencing a surge in cases. New Zealand’s director general of health Dr. Ashley Bloomfield commented to a reporter from The Guardian saying he was:<sup>19</sup>

*“... certainly concerned about the sharp surge in RSV cases ... There’s some speculation that [the current outbreak] may be partly exacerbated by the fact we didn’t have any last year and so there is a bigger pool of children who are susceptible to it.”*

In Canada, Wellington-based epidemiologist Michael Baker warns that his country may also see a similar trend in cases of RSV in the next year, warning that babies who were born prematurely are most at risk.<sup>20</sup>

That said, while Canada may see a rebound in RSV infections, Baker does not think that a lack of exposure to pathogens at an early age will have “in any way impeded the development of a healthy immune system.”

### Is a Fast-Tracked RSV Shot the Answer?

Considering the multitude of problems associated with the gene-based COVID shots, I’m not

optimistic about the development of a fast-tracked mRNA “vaccine” against RSV. The risks are numerous. Already, we’re seeing trends that could signal that ADE is at play in older people who got the jab (but not younger people).

In the U.K., as of August 15, 2021, 68% of COVID patients admitted to hospital who were over the age of 50 had received one or two COVID injections. Mortality statistics reveal the exact same trend. In the over-50 group, 70% of COVID deaths were either partially or fully “vaccinated.”<sup>21</sup>

Could this be because older people are developing ADE and therefore suffer more serious infection when exposed to the SARS-CoV-2 virus? In the under-50 category, the unvaccinated make up a majority of hospitalizations and deaths in the U.K., so perhaps the shot affects different age groups differently.

Older people are also the target group of the RSV shot, and infants and young children are a target for both COVID shots and RSV shots. Time will tell what the ramifications of programming the bodies of the very young and the very old to produce more than one antigen might be. But my guess is it won’t be good.

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## Notes

<sup>1, 5</sup> [Stuff.co.nz July 21, 2021](#)

<sup>2, 6</sup> [The Japan Times July 7, 2021](#)

<sup>3</sup> [Vanderbilt University Medical Center June 23, 2021](#)

<sup>4</sup> [CDC Emergency Alert June 10, 2021 HAN00443](#)

<sup>7</sup> [Clinical Trials Arena August 3, 2021](#)

<sup>8</sup> [Moderna Press Release August 3, 2021](#)

<sup>9, 11</sup> [Nature Microbiology September 9, 2020; 5:1185-1191](#)

<sup>10</sup> [Nature Communications May 8, 2019; 10: 2105](#)

<sup>12, 18, 19</sup> [The Guardian, July 8, 2021](#)

<sup>13</sup> [Informed Health, July 30, 2020](#)

<sup>14</sup> [DW, February 8, 2021](#)

<sup>15, 16</sup> [Infectious Diseases Now, 2021;51\(5\)](#)

<sup>17</sup> [Independent, July 9, 2021](#)

<sup>20</sup> [Global News, July 13, 2021](#)

<sup>21</sup> [Evening Standard August 20, 2021](#)

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