

# Immunization Umbrella Options to Reduce the Burden of RSV

Susan Hepworth, L.J. Tan, MS, PhD, Chelsea Woosley



*The National Coalition for Infant Health is a collaborative of more than 200 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCFIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCFIH prioritizes safety of this vulnerable population and access to approved therapies.*

## **Susan Hepworth:**

Thank you, everybody, for joining today's webinar under the Immunization Umbrella Options to Reduce the Burden of RSV. This is hosted by the National Coalition for Infant Health and co-hosted by the Alliance for Patient Access. My name is Susan Hepworth, and I serve as executive director of the National Coalition for Infant Health. Joined today by our speakers, Dr. L.J. Tan of Immunize.Org and Dr. Chelsea Woosley of the National Association of Pediatric Nurse Practitioners. I want to thank our co-host, the Alliance for Patient Access, for helping to make today's webinar possible. I want to review a few objectives before we get into the meat of our discussion today to level set.

There are four things I want to bring to your attention. The first is a better understanding of the impact of the burden of RSV. Then, we will learn about current vaccines, immunizations, and development to prevent RSV in infants and young children. The last two items identify some policy barriers that may impact equitable access to new immunizations coming to market. And then, lastly, a call to action for those interested, related to a CDC advisory committee on Immunization Practices meeting scheduled for August 3rd to discuss a new immunization for RSV.

Before discussing this with L.J. and Chelsea, I want to share this short video from our co-hosts, the Alliance for Patient Access. This video is helping to educate on the different types of immunization and why the policy will be essential to ensure timely and equitable access and ensure that the procedures we have in our current vaccine pathway and vaccine infrastructure system can adapt to new technology and innovations.

## **Video**

All infants, children, and adults need protection from infectious diseases. That's why immunizations are so necessary. There are two types of immunizations. The first is active immunization, which trains the body to create antibodies to fight diseases. These immunizations are commonly called vaccines. They protect against diseases like polio, whooping cough, and the flu. The second type

of immunization is passive immunization, which provides the body with antibodies to fight infections. This type of immunization can help protect against diseases that traditional vaccines cannot address, whether a vaccine or a long-acting preventive monoclonal antibody. Immunizations are critical for public health. That's why they must be accessible promptly and equitably to boost public health and maximize disease prevention. All immunizations should be treated the same. Ensuring coverage and access for vaccines and long-acting preventive monoclonal antibodies with good policy. Families can have more opportunities to stay safe, healthy, and protected against infectious diseases.

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## **Susan Hepworth:**

I want to start with you, L.J. to help set the stage. I want you to talk about RSV; many people here are probably familiar with it. Firstly, why is it something that healthcare providers and parents need to be aware of?

## **L.J. Tan:**

To set the stage here, like the flu, RSV has a U-shaped impact on epidemiology. In other words, it dramatically impacts the young infants on one side of the curve, and then it dramatically affects those who are 60 and older on the other side of the curve. When we want to target protection, those are the populations we start with—but recognize that we still want to protect many people in the middle. It is the leading cause of hospitalizations in U.S. infants. About 2 to 3% of all infants will be hospitalized for RSV, and the hospitalization rate in infants five months of age and younger is almost 16 for 1,000 persons. This is a significant hospitalization rate for these younger infants who catch RSV, hence the need to protect them. It is also an important cause of hospitalizations in 60 adults 60 years and older. The 60 to 79 age group is 2.3 for every thousand. If you are over 80, it increases to 2.6 per 1000 persons in terms of hospitalization rates. Because there are so many more

adults, even though those rates are lower than we see in infants, the number of hospitalizations is more significant. Adults tend to be at about the same rate as we saw with infants five months of age and younger—finally, the population in between that. There are high-risk adult populations, including those with immunocompromised people, with diabetes, cardiovascular disease, and asthma, that we also want to protect. I hope this gives an idea of the impact of this disease. And again, Susan, Charles's comments will also be significant.

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**Susan Hepworth:**

Chelsea, what real-world impact do you see, mainly from a clinical perspective? What are you seeing these infants and young children experiencing when they come to the hospital with RSV?

**Chelsea Woosley:**

It can range, be severe or minor, but hospitalization is unsuitable for anybody. I work in a pediatric intensive care unit and care for kids from 0 to 17. My PICU is a level-one trauma center, and we see a lot of trauma patients. We also see medical-type patients such as those with seizures, asthma, or respiratory viral illnesses, and babies, kids, and toddlers can get very sick when they have a respiratory virus or an infection.

We see just a tiny percentage in the ICU. These patients may be with us for a day or several weeks to months. Unfortunately, if we see a patient in the ICU overnight, even if just one overnight stay in the ICU, they may still end up in the hospital. Because of that lingering oxygen requirement, they may still need hospitalization outside our ICU for several days or two weeks. But it varies from patient to patient. We also see many patients with chronic illnesses, an increasing population. We know a lot of those kids in our hospital. Once we see one chronic child in our ICU, the others come because the viruses impact many of these patients. It's not just the babies and the smaller kids for us. It's also a significant stressor for families with a chronically ill child because they must deal with this chronic illness. And then, on top of this, it's not easy getting to the hospital. It means putting them in their wheelchair and the van, etc., and getting them to the hospital.

It's also a significant stressor for families of previously healthy children because they've never dealt with hospital systems or hospitalizations. It is challenging for chronically ill children and their families because a respiratory illness can put them over the top and end up hospitalized. It is a heavy burden for patients and their parents, whether it's a first-time hospitalization or a chronically ill child with a respiratory illness exacerbating their chronic illness.

**Susan Hepworth:**

We've just talked about the impact on the patients and their families. But I wanted your perspective on the impact on the health care system and providers. Last year, we experienced the “triple-demic;” COVID-19, flu, and RSV; talk about the burden of having an additional illness like RSV on the healthcare system and our most precious resource, our actual healthcare providers.

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**Chelsea Woosley:**

RSV before COVID was primarily seasonal; we saw it in the winter and early spring, and we were generally swamped at times when we wouldn't be able to accept patients anymore. All this in a city where there are three children's hospitals. And even then, if our beds were full, the other hospitals were also full. We'd often have to transfer patients to other cities, including Texas, a big state, and many hospitals. Additionally, we'd have to transfer to other states, which is a massive burden for families. There's a family that comes with it and a parent who may or may not have other children or who may or may not have support to help with a family they leave behind.

COVID-19 was impactful in the hospital, but we saw fewer other viruses during COVID-19. The pediatric units were not stressed to the adults' level. However, since COVID-19, hospitalizations due to respiratory illnesses have become less seasonal. This led to this RSV illness going differently and being year-round. Include RSV, COVID-19, and flu, it wasn't just an RSV season in the winter months. Once the quarantine was lifted, we noticed an unbelievable burden of respiratory illnesses and hospitalizations in the summertime. Summer has become overwhelming in the last couple of years. The first summer, we saw more medical patients, resulting in a big bed availability problem. It overwhelmed healthcare providers and hospital staff. Caring for these patients and coordinating with other facilities to get beds for these kids was stressful.

**Susan Hepworth:**

I will cite some statistics before I ask you my next question. Last year, the National Coalition Group on Health and the Alliance for Patient Access, who is co-hosting today's webinar, conducted a

national survey of parents who had had at least one child become ill with RSV. We wanted to understand the indirect impact better. There were a few jaw-dropping statistics we got from that survey. More than two-thirds said RSV was a financial burden or crisis for their family. More than one-third said their experience with RSV put a strain on their marriage or relationship. And this, to me, was the most shocking of all. 10% left their job, and 7% reported being fired because they had to take so much time off work to care for their children with RSV. That's almost 20% who lost their job due to this. My question is this: do these statistics align with what you see in the hospital setting?

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**Chelsea Woosley:**

Absolutely. I have yet to mention the social workers we've had to rely on to help these families. The impact of RSV goes beyond just the clinical implications for the patient and their family. I've cared for many babies and children in the ICU who sometimes have required intubation, which is a super stressful event for our family. I've had to talk to the parent and say, this is the next step, what we will do. They won't say no because they know that's the right thing, but I can see the stress on their face. Many have required a long time in the ICU to recover from their illness. The emotional impact on the family is enormous.

It's a burden for the families who may or may not have the risk. I live in an area where many indigenous people may not have the support or the resources they need because they might not have extended family here. Also, many parents cannot go to work because they have to be here. We might have a parent who may have one or five children, and they may or may not have somebody helping care for them. It is a burden to the family to figure out where they will put their other children. Leaving your child in the ICU is an emotional struggle, impacting the infant or child to be there without a parent. I cannot imagine leaving my child, but some parents have to because they have no choice. It's a substantial financial burden. Some parents lose their jobs because they have to miss a day or more here, and some positions are not forgiving. Communication is vital. Talking to the parents and families every day and trying to explain to them the course of an illness or the severity of the illness are things that we could do differently for them because it pains me if we're unable to help them.

**Susan Hepworth:**

We had a neonatal nurse practitioner review the survey results and provide her expert analysis as part of the survey report. She brought up a good point: we didn't screen for socioeconomic status; we didn't look at household income, whether rural, urban, or suburban. She deduced that even these jaw-dropping statistics might be painting a rosy picture, in fact, of what's going on in our economy.

We've discussed the burden and how scary this can be. And there's nothing other than supportive care you can offer, oxygen, etc. There's no actual medication to treat this. However, good news came out at the FDA last week with the approval of a new immunization to prevent RSV in infants. L.J., can you discuss what's currently available for prevention, what's just been approved, and what could be approved soon?

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**L.J. Tan:**

Absolutely. It supports infants, except those most vulnerable, those born prematurely, younger than six months, or under six months. We had Palivizumab for them; the brand name was Synagis. Unfortunately, that is a passive immunization. You give an antibody, but it's a very short-lived antibody; it only lasts a short time in the body. For these highly vulnerable children and infants, you must give it once a month. Generally, you start right before the RSV season and continue to provide it once a month until the risk has passed. Research and development in RSV immunization techniques have been ongoing for over 60 years.

In the last 20 years, we have significantly increased our understanding of RSV's biology. Specifically, the F protein has been essential in how the RSV and the virus reproduce. We have multiple active and passive RSV immunizations by coupling that knowledge with new technology to provide vaccine immunizations.

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As of July 17<sup>th</sup>, we have a new product, a long-acting preventive monoclonal antibody called the Nirsevimab. The Nirsevimab acts long-acting and persists in the body throughout the season for about six months. Therefore, you give it once, and it protects through the RSV season. From the clinical trial data, it's about 70% effective at cutting the risk that a baby would need to visit an RSV physician. It was about 78% effective at preventing hospitalizations due to RSV. Now, I think I would be remiss not to mention that there is another way to protect infants, and the FDA is currently looking at another vaccine, in this case for pregnant women, that would also protect babies. In this situation, we give the vaccine to the mom. The mom makes the antibodies, which cross the placenta to protect the fetus and continue to last through the infant's first few months when they're most vulnerable to RSV complications. The FDA is currently looking at this vaccine for approval. The vaccine will protect babies from the moment they're

born. This is a benefit if you have an infection that shows up out of season, and the vaccination will also prompt the mother to make a broader response against RSV.

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**Susan Hepworth:**

It’s a unique time because this is the first immunization of its kind, presenting some policy challenges that many organizations like Immunize.org face. The National Coalition for Women’s Health and the Alliance for Patient Access have been paying attention to this for the last couple of years because we know that it has significant implications related to equity and policies that could exacerbate existing disparities or ensure that all infants have equitable access. Can you talk more in-depth about some of those policy challenges we’ve been looking at?

**L.J. Tan:**

Yeah, definitely. Whenever we have something new, we want to ensure we’re thinking it through and implementing the policy changes to ensure access is not an issue. Let me start by speaking first about a program called Vaccines for Children. The program provides underinsured and uninsured children with free vaccines that the provider administers. The provider then receives a payment for giving the vaccines out of the state’s Medicaid program, which the state determines. The Nirsevimab is not technically a vaccine but a long-acting preventive monoclonal antibody that behaves like a vaccine. It acts similar to a seasonal vaccine, such as the flu vaccine, where you give it to your infants at the beginning of RSV season and lasts throughout the seasons. Since it is not technically a vaccine, the Vaccines for Children’s Program must consider whether it can administer it. And if it can, how will it provide coverage for the Nirsevimab to these under-insured and uninsured children? It’s essential to recognize that we have so few disparities in our pediatric population for vaccines because of the Vaccines for Children program. The Vaccines for Children program has done a fantastic job of creating an infrastructure where people who are uninsured and underinsured children can get vaccinated. As a result, our coverage rates are very high among our disparate populations. If we don’t get Nirsevimab protection coverage under the VFC, you can immediately see that there might be some dis-

parities in equity challenges regarding access. We want to ensure that providers are adequately paid for an essential service when they give this long-acting monoclonal antibody. We need to make sure that we have a policy in place that also allows our providers to be adequately paid for providing this new product. This is brand new, and we must work through some policy changes.

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**Susan Hepworth:**

We’re increasing exponentially with innovation and technology. And how important it is for our vaccine infrastructure system and other parts of our health care system, even unrelated to vaccines, to adapt to innovation to continue fostering innovation. Do you have anything to add to that?

**L.J. Tan:**

Oh, absolutely. That’s an important concept, too. It shows us that we must show that we are nimble and can address precedents. We can set up new precedents for new technology and innovations that come down the pipeline. This is important to our manufacturing colleagues, as it’d be challenging for them to continue to innovate and develop new technologies if we cannot adapt our public health policies to use these innovations in the best way possible for our patients. We want to ensure that whenever something new comes along, we can assess its worth of safety and its effectiveness in the populations we’re looking at. Then, most importantly, we can ensure that it gets recommended and used in a way that allows the broadest access and best equity. Suppose we can make those policy changes rapidly, nimbly, and collaboratively. In that case, we’ll continue to create an environment in the United States for innovation and development.

**Susan Hepworth:**

I’ll talk about the meeting that’s been called by the CDC on August 3rd. But I will flag that this year, September, is the 30th anniversary of the Vaccines for Children program, a fantastic milestone. However, it will be crucial to see if they can adjust policy to account for innovation.

**L.J. Tan:**

When we talk about VFC, this innovation since it sounds like a duck, walks like a duck, quacks like a duck. It isn’t a duck, but this is what we have here. We have a long-acting preventive monoclo-



nal antibody that behaves like a seasonal vaccine. So, we must treat it like a seasonal vaccine, which means we must get it in season to address the burden of RSV disease in infants. If we do not do this, if we reduce access and, as a consequence, equity, we're not doing our country a service; we're not doing our public health vaccine infrastructure service. We need to create a policy that allows that access and equity. The Vaccines for Children program is a significant part, and they will vote on including this in the Vaccines for Children program.

**Susan Hepworth:**

Chelsea, from the families you care about, how do you feel they will receive news of a new immunization to prevent RSV, and do you think there might be any challenges?

**Chelsea Woosley:**

There is always going to be challenges. There's not ever going to be 100% agreement on something. But, the great thing is, in the past, the preventative vaccine was limited to just the high-risk patients, and now it's not. We can give these vaccines that will decrease hospitalizations dramatically. There may be some hesitancy, and it could be because of vaccine fatigue. Educating and recognizing that having a preventative vaccine is the key to lowering the severity of illness is imperative.

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It can mean having just a clinic visit versus then having to be hospitalized if they had been given this preventative. It might keep them away from the ICU, which is enormous. At the same time, I do not think that 100% of everybody is going to say, “Yay,” another vaccine; I think it's going to be up to us, the educators and the health care providers, to let people know that this can be the difference in a child's life.

**Susan Hepworth:**

L.J., I'll give you the last question. Given your work and passion for public health, what will the challenges be to ensure we have a good uptake of something that many people may not understand because it's not technically a vaccine, as you mentioned?

**L.J. Tan:**

I will reiterate some of what I said earlier, Susan, but those are significant policy barriers. A long-acting monoclonal antibody that works like a seasonal vaccine but is not a vaccine can be included in VFC. Wow. How cool is that? If we do that, we will reduce many access issues that result in inequity. The other one is that we want to ensure that our providers will get adequately reimbursed. They must be fairly paid for that critical work if they give the immunizations. And so, we need to ensure that the providers' payments will be fair. Then there is some of the nitty-gritty work we're doing that will come into play because this vaccine, this immunization, because it's not technically a vaccine, will not be coded

like a vaccine for billing. It means that providers will be billed for their insurers, the payers, in the traditional vaccine-type manner. They're going to have to learn a new way of doing this. New codes will have to be used. We want to make sure that we educate our providers on that so that they know how to bill for this further intervention and make sure that they get paid right away without any rejected claims. I can think of a lot of little other ones. For example, monitoring the safety of the server, rest assured that's happening with a new product; we need to ensure that we've got all our eggs in place as it goes forward and that this immunization will be monitored for safety. It is also approved for those high-risk infants' second year of life when their hospitalizations are not just overnight but for a more extended period when they will be in the hospital as they get over illnesses. It will significantly impact the burden on our safety and our infants, and we need to make sure that we remove any policy that makes that impact less.

**Susan Hepworth:**

I talked about a call to action, and we've mentioned it several times. The CDC, the Advisory Committee on Immunization Practices, is the committee that, after the FDA has approved an immunization or vaccine, reviews it and recommends it. They study whether it should be included in the vaccine regimen. Are there any guidelines around who should be eligible for it? After the approval from the FDA came out on the Nirsevimab, the Advisory Committee on Immunization Practices announced an ad hoc meeting to go ahead and, among other things, have a vote on whether to include that in the vaccine. And for those organizations and advocates like Chelsea, L.J., and I, we look forward to the outcome. It's something that we have been working on advocacy-wise for several years now. We will be submitting comments and it will be to thank the committee, which has been extremely busy since 2020, since COVID. We will thank the committee for taking this up and urging them to include it in the VFC because we want broad equity, and equitable access is so important. Those are the two major themes that the National Coalition for Health will include in their comments.

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We have a couple of questions that have come in. The first is about cost.

**L.J. Tan:**

The cost will not be revealed until after the ACP votes on the product, which will be out on August 3rd. If you look at the cost-benefit analysis they've run, as part of the ACP process, they have to run cost-effectiveness studies on whether the interventions can be worth the recommendation. Then, they looked at price ranges from 150 to \$300. Which was based on the modeling; however,

we'll have to wait till the manufacturers announce that cost.

**Susan Hepworth:**

Next question. Can a newborn baby receive the immunization, or must it be a few months old? Or would it be better for me to receive the antibodies they recommend?

**L.J. Tan:**

Nirsevimab is indicated for newborns through 24 months of age. It is going to be recommended to be used in newborns. Then, in the second year of life, it will be recommended for those high-risk patients. They also suggest that she get a vaccine to help her generate antibodies that she'll pass to her infant, but the FDA has not yet approved it.

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**Chelsea Woosley:**

I'll reiterate that we used to think of RSV season as November, October through April, but now it's year-round. So, a preventative vaccine is crucial and imperative.

**Susan Hepworth:**

That's great. Well, L.J. and Chelsea, thank you for this informative conversation and your expertise and insights into what happens at the bedside when somebody is hospitalized with RSV. Thank you, and have a great afternoon.

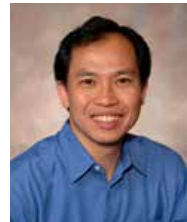
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**National Coalition for Infant Health Values (SANE)**

**Safety.** Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

**Access.** Budget-driven health care policies should not preclude premature infants' access to preventative or necessary therapies.

**Nutrition.** Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

**Equality.** Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.



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