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### ReachMD

[www.reachmd.com](http://www.reachmd.com)

[info@reachmd.com](mailto:info@reachmd.com)

(866) 423-7849

## Taking Action Against RSV: No Child Unprotected

### CHAPTER 1

#### Dr. Maldonado:

Hello and welcome. This is CE on ReachMD. I'm Dr. Yvonne Maldonado, and today we're diving into a topic that's top of mind for many clinicians this season—protecting our infants and young children from respiratory syncytial virus, or RSV. With new prevention strategies now available, including maternal immunization and long-acting monoclonal antibodies, we have powerful tools to reduce the burden of RSV, but understanding who's at risk, how these options differ, and when to act is key.

#### Dr. Tan:

And hi, I'm Dr. Tina Tan, and today we will walk through the latest insights on RSV prevention, seasonality, and how we can help safeguard the most vulnerable patients right from birth.

#### Dr. Maldonado:

Well, great. Thank you, Dr. Tan. Let's get started. So first, can you give us a brief overview of who's at risk for RSV?

#### Dr. Tan:

So everyone of all ages is at risk for RSV. However, we know that all infants, especially those under 2 years of age, are at the highest risk for RSV and severe disease. And there are even some other infant populations that are at even higher risk for severe RSV disease, especially preterm infants. And the more preterm you are, the higher risk you are for severe disease and hospitalization. And studies have consistently shown that up to 12% of these young infants require hospitalization for their RSV disease.

Now also, we know that infants with chronic lung disease, congenital heart disease, Down Syndrome, and weakened immune system from any cause, as well as neuromuscular diseases, severe CF, and American Indian and Alaskan Native infants are all at very high risk for severe RSV disease. And we also know that nearly every child will get RSV by the age of 2 years.

#### Dr. Maldonado:

Thank you, Dr. Tan. How does RSV impact both patients and the healthcare system?

#### Dr. Tan:

Well, RSV occurs so commonly that we know that the vast majority of the cases are being seen in the outpatient pediatric practice, and it's 1.6 million of these cases every year. We also know that there are about 472,000 ED visits, and this can lead to 70-80,000 hospitalizations, and about 300 deaths a year.

And when you look at how much all this costs on an annual basis, we're looking at over \$1.5 billion. RSV is the leading cause of infant hospitalization in the U.S., and it causes about 50% of all acute lower respiratory tract infections in U.S. infants. And basically, when you look at both pediatric and adult RSV, it's very expensive on the healthcare system, where costs exceed \$7 billion.

So you can see that this is a disease that's very common, and we really need to try to protect individuals against it.

#### Dr. Maldonado:

Thank you for that information. Clearly, this is an important burden of disease, not only for children, but for our entire healthcare system.

So why don't we go forward and break down the available prophylactic and preventive strategies. What are the current options for preventing RSV in infants, and how do they differ?

**Dr. Tan:**

That's a great question. So basically, there are two different ways that we can prevent RSV: we can vaccinate mom, and we can also give two different monoclonal antibodies to infants to basically protect them against RSV.

So if you look at maternal vaccination, there's only one vaccine that is approved for use in moms, and that is the RSVpreF vaccine administered between 32 and 36 weeks gestation, and is very effective at preventing severe, medically-attended RSV disease in infants.

And then for infants, there are monoclonal antibodies, and there are two different ones. You have nirsevimab, which is a human IgG1 kappa monoclonal. It basically works at site zero of the RSV F protein-directed inhibitor and has a half-life of 71 days. And the studies that were done show that it is incredibly effective, with an 87.2% effectiveness against RSV lower respiratory tract disease, 98% effectiveness against hospitalization for lower respiratory tract disease, and 71% effective against PCR-confirmed RSV.

And basically, the other monoclonal antibody is clesrovimab, which is a human IgG1 antibody that targets site IV of the RSV F protein and has a half-life of around 44 days. And basically, when you look at its effectiveness, it shows that it does reduce RSV lower respiratory tract infection and hospitalization by 84%.

And basically, when you look at its effectiveness at 150 days and 180 days, you can see that for severe medically-attended RSV, it's about 92% effective, and for all-cause hospitalization, it is 81-84% effective. And depending on the number of severe indicators, it has an effectiveness that ranges anywhere from 60% to 88%.

So basically, this particular monoclonal also is very effective, and both of them are very effective at protecting against RSV disease.

**Dr. Maldonado:**

So thank you, Dr. Tan. Clearly, we have two very effective ways to prevent RSV hospitalization and severe disease in children. However, RSV seasonality remains a critical driver. What should clinicians know about timing and preparedness?

**Dr. Tan:**

That is a great question. So we know that, in general, RSV tends to circulate between September and March every year. However, we had an unusual year in 2022 when we saw multiple peaks of disease after the pandemic. And so clinicians also need to be aware that seasonality does vary depending upon where you live in the U.S., with the southern portion of the U.S. having RSV seasons that start earlier than the northern and western parts in the U.S.

So it's generally recommended that we give protection somewhere between September and March. However, you need to be aware of what the seasonality is in your area of the U.S., and you need to talk to your Public Health Department about whether or not you may need to start giving RSV prophylactic protection earlier than September.

**Dr. Maldonado:**

Well, Dr. Tan, that was really helpful, really great overview of this important disease and the way to prevent it. So thanks to all of you.

In Chapter 2, we'll be discussing the latest recommendation on RSV vaccination. Thank you.

## CHAPTER 2

**Dr. Tan:**

Well, welcome back to Chapter 2, which is recommendations for RSV immunization. So let's now turn to the practical question on every clinician's mind: who should get RSV immunization, when, and how? And based on AAP guidance, what are the current recommendations for RSV immunization in infants and young children?

**Dr. Maldonado:**

Well, thank you, Dr. Tan. So as we know, RSV is a critically important disease to prevent. We don't have any great treatment strategies, and the American Academy of Pediatrics is really our first source for understanding what to do about prevention. Now, right now, routine RSV vaccination is really recommended for all children in the first RSV season. So, for example, infants born during their first RSV season, were born between October through March, which is during the season itself, should be vaccinated. Or those babies who are under 8 months of age who are now entering their first RSV season. So, for example, if they were born in April, when they get to September/October, they should be vaccinated, they should receive prevention during that period of time entering the season.

So preferably for children born during the RSV season, October through March, they should receive prophylaxis during the birth

hospitalization. And if not during the birth hospitalization, then shortly after discharge and by 1 week of age in the outpatient setting. And this should really be done during a scheduled well-child visit before the start of the RSV season as well. Now, I'm talking about the monoclonal antibodies there.

Now, if the mother did not receive the RSV vaccine during her pregnancy, or if her status is unknown, or she was vaccinated in a previous pregnancy, then that baby should still be considered as not protected. So that baby should be given one dose, ideally again during the birth hospitalization, with either nirsevimab or clesrovimab, within 1 week of birth or in an outpatient setting.

If the mother received the RSV vaccine during pregnancy but received it within 14 days before delivery, then it's likely that the baby may not have sufficient transplacental antibodies after birth, and so then that baby should get a dose of nirsevimab or clesrovimab within 1 week of birth.

And then finally, if the mother received the RSV vaccine greater than 14 days before delivery, then it's considered that the baby should have sufficient protection from transplacental passage of those antibodies, and therefore no additional monoclonal antibody is needed for that baby.

Infants with prolonged birth hospitalization should be given either nirsevimab or clesrovimab upon discharge from the hospital if they're going home between October and March.

Now, there are special situations for the second RSV season—and I should say that the preventive strategies are really only meant for the first season that baby has lived through. So the first RSV season that they're living through for all babies.

So, nirsevimab and clesrovimab can be used for the first RSV season for all infants. However, in a very select group of babies, they can get a second dose of nirsevimab only during the second RSV season. And those are babies 8 to 19 months of age who are high-risk infants with either chronic lung disease of prematurity, severe immunocompromised, or cystic fibrosis with severe lung disease, American Indian or Alaska Native children, as well, and then finally, there's another group who are age-eligible and undergoing cardiac surgery with cardiopulmonary bypass, who can get one additional dose of nirsevimab after surgery.

Now, in addition, routine maternal RSV vaccination with the bivalent RSV pre-fusion vaccine is available for pregnant individuals 32 to 36 weeks gestation, if they have not been previously vaccinated during a prior pregnancy. And the timing there is generally September through January. Either maternal vaccination or infant immunization is recommended to prevent severe RSV disease in infants, but not both. So, for example, if the mother has been vaccinated during that pregnancy, then the baby does not need to receive nirsevimab or clesrovimab. However, if the mother has not been vaccinated, then the baby should be considered for one of those monoclonal antibodies.

For all other pregnant individuals, RSV vaccination is not recommended. And at this time, we have insufficient data to know what to do about subsequent pregnancy. So no additional doses are currently recommended because we don't have that data yet. And again, infants born to those mothers should receive nirsevimab or clesrovimab after birth.

**Dr. Tan:**

So that was fantastic, Bonnie. Can we also talk about logistics? How should clinicians be thinking about immunization in the birth hospitalization setting?

**Dr. Maldonado:**

Well, we're well into our third year now of having these amazing monoclonal antibodies and vaccines. So the administrative aspects are really starting to work themselves out.

It's really important for providers to know at the birth hospitals where they work what the policies are for administering either nirsevimab or clesrovimab. Also the policies for understanding what documentation they have around the maternal immunization status, because you really want to know this information very early on. Preferably some providers and families talk about these issues before the delivery of the baby, so that they can understand the setting that that baby will need once the baby is born and in the hospital.

Just understanding what your local hospital logistics might be, and we know that many of you work in multiple hospitals, so you may just want to know what that is.

I think, at this point, because this is a universal recommendation and it's been going on now for now into our third year, most of you should have access to that information from the hospitals where you work.

**Dr. Tan:**

So what are the dosing considerations for infants under 8 months of age for the monoclonal antibodies?

**Dr. Maldonado:**

That's a great question, Dr. Tan. So we have two different dosing schedules depending on which monoclonal antibody you're going to use. Now, I'll start with clesrovimab, because it's really just one dose that is needed for all age groups, and that is a single 105-mg IM dose that is weight independent.

For nirsevimab, it is broken up by weight. And for babies under 5 kg, the dose is 50 mg IM, whereas for infants greater than or equal to 5 kg, the dose is 100 mg IM. And for babies who are high risk in their second RSV season, who are 8 to 19 months of age, their nirsevimab dose is 200 mg IM, and that is two 100-mg doses.

**Dr. Tan:**

And what about for children age 8 to 19 months of age who are at high risk and need another dose for the second RSV season

**Dr. Maldonado:**

Yeah, so as we talked about before, those—that is really an indication only for nirsevimab. We don't have a current indication for a second dose of clesrovimab at this point because it has only just been approved in June of 2025. So at this point, nirsevimab can be used for infants under 8 months of age, under special situations, for example, children who have underlying chronic conditions that we outlined before, or if they are Alaskan Native or Native American children, or again, if they are undergoing cardiopulmonary bypass surgery between 8 and 19 months of age.

**Dr. Tan:**

Excellent. So, as you heard, we have very effective ways of preventing RSV in children, either through maternal immunization or by monoclonal antibodies. And they are very effective means and are ways to basically protect these young infants against severe RSV and hospitalization.

So thank you so much for joining us, and thank you, Dr. Maldonado, for the excellent information.

### CHAPTER 3

**Dr. Maldonado:**

Welcome. RSV prevention isn't just about timing and tools; it's especially about trust. In this chapter, we'll explore how to have effective, respectful conversations with parents and caregivers, especially when navigating new immunization options.

**Dr. Tan:**

That's great. And one of the major questions that always comes up is that RSV immunization may be new to many families, so how can the clinicians have effective, respectful conversations with the parents?

**Dr. Maldonado:**

Thank you, Dr. Tan. I think we all know that pediatric providers are really great communicators, first and foremost. They really know how to engage with their families on a variety of topics, not just infectious diseases. We know, for example, that modeling shared decision-making is really important for them and their families, so listening to their concerns, acknowledging misinformation, and tailoring explanations is really important. Equip your learners with empathetic language by giving real-life examples is really helpful. And then addressing uncertainty around situations when maternal vaccination status is unknown.

So we really understand that the providers are being faced more and more with lots of questions, lots of misinformation that might come up, but it's important for the provider to be kept up to date. And I would recommend that one way to stay up to date, always, is the American Academy of Pediatrics website and getting their daily briefs. And I know we're all busy, but even with our busy schedule—or my busy schedule, I watch the AAP briefs every morning before I start work. Really helpful in knowing what's going on and what talking points I can use.

And there's also the HealthyChildren.org website, which is outwardly facing for parents, families, and children to take a look at.

So, Dr. Tan, when should these conversations ideally take place, and what should they include?

**Dr. Tan:**

That's a fantastic question. And I would say, take advantage of any visit that you have. So you can speak to them when they come in for their prenatal visit to determine whether or not they want to use your practice to take care of their child. You can speak to your OB/GYN colleagues and basically talk to them about the importance of vaccines, and basically talk to the parents when you meet with them for them to ask their OB/GYN for an RSV vaccine to protect their babies.

And you know, anytime you are talking to parents, you really should talk to them about the importance of immunizations and include RSV protection with the monoclonal antibodies as part of that discussion.

**Dr. Maldonado:**

Absolutely. One of the things that I think we are just learning about as families is that even though pediatricians know what RSV is, we all grew up in our medical training understanding what RSV is, most families don't really know what RSV is, how important it can be, how severe it can get. And so, really spending the time to talk about how important this disease is, and how effective and especially how safe these preventive measures are, is really important.

So when we talk to our families, we should try to really encourage them to take some of this information home and learn about it. And as you said, bringing it to families before the baby is born is especially helpful, but for those families who don't do that—and many of them don't—really just spending those first visits very early on—because this is something that has to be done within the first week of life. So preparing families as early as possible.

And the other issue, I think, is really bringing it to daycares, teachers, and school districts, really trying to get the message out into communities and not just to providers, is really helpful because they can actually reinforce the trust that these families might need.

**Dr. Tan:**

Excellent point.

**Dr. Maldonado:**

So, Dr. Tan, what are some common parental concerns about RSV immunization have you heard, and how do you approach those?

**Dr. Tan:**

So that's a great question. As you brought up, many parents are not aware of RSV, and so they don't think that it's going to affect their child, so it's really important to talk to them about how common RSV is and the problems that it can create.

The other thing is that because of the increasing amount of vaccine hesitancy, many parents are very reluctant to just accept getting vaccinated with a vaccine against a disease that they're not aware of. And so it just really is important, as you pointed out, to talk to them about RSV, explain to them how common it is, how severe it can be, and why it's important to protect their babies with what we have against this disease.

The other thing is that to explain to them that you're not giving them a vaccine that the baby needs to respond to, but you're giving them antibodies that are already made that will protect the baby against the disease.

**Dr. Maldonado:**

Thank you for that. And I think another issue that really is helpful, given that this is a new product that they may not be familiar with, and as we said before, they may not even know what RSV is, even though they've probably all of their kids have had it, they've all had it, is to really get a chance to talk about the fact that we have been using monoclonal antibodies to prevent disease in children for decades.

These are very safe alternatives. Again, vaccines are very safe as well, and that's a separate conversation that people can have, but to include the fact that at this very early age, the monoclonal antibody is something that we have a lot of experience giving with very few side effects.

It is also an opportunity, I believe, to bring up other vaccines that might be important in the family, such as influenza vaccine, and for those families who wish to do so, COVID vaccines for people at high risk as well. So it's a real opportunity, I think, to really bring this whole protection discussion together especially around respiratory virus season.

And also one other consideration, I think, is families may get a little confused if their baby is born, say, in April or May, and then they have to remember to bring their baby in for vaccination in the fall. And now the best thing would be to try to make sure that your schedules in your office and reminders are available for the family so that they know that they can come back in. And maybe if you have clinics where you can just have them vaccinated, get their monoclonal antibodies before the respiratory season, would make it a lot easier for these families so if they don't need to—they may not need an actual visit; they may be able to get the monoclonal in a very easy, quick visit to the provider's office.

So, this is something else that I think practices are starting to try to figure out, how do we incorporate this as easily as possible for families so that they don't have to remember that there's one more thing they have to do for their baby.

Well, thank you so much, Dr. Tan. Any other comments or concerns that you think that families might bring up?

**Dr. Tan:**

Well, I mean, I just think that we need to take the time to address any questions and concerns that the families have. Because I think if we provide them with information that they understand that if they choose to give the babies the monoclonal antibody, they're protecting

their infant, and I think that's really important for them to understand.

**Dr. Maldonado:**

Absolutely. Well, I know in these days of so much access to social media misinformation and disinformation, it is really hard for our young families to know what the right thing is to do for their children. We do know that when you look at poll after poll, parents still trust their healthcare providers, especially their pediatricians. And so as pediatric providers, we know that families have their trust in you, and that's a really important way to really anchor the message about how important RSV disease is in babies and how highly effective and safe these new preventive strategies are. And they are—they have been around about through almost two to three seasons now, but we are still in infancy in terms of getting the word out to our families.

So I think that's a great call to action, Dr. Tan, to really make sure that our families do trust us and know that we are going to be there to take care of their children and answer any questions that they might have.

**Dr. Tan:**

Yeah, and to basically take advantage of every single time they come into the office, to basically asking them if they have any questions, and to tell them which vaccines the baby is getting.

**Dr. Maldonado:**

Absolutely. Well, thank you so much, Dr. Tan, and thanks to all of you. That's all the time we have today. I want to thank our audience for listening in and thank you, Dr. Tan, again, for joining me and for sharing all of your valuable insights. It was great as always, to speak with you today.

**Dr. Tan:**

Well, thank you. It was wonderful.