|  |
| --- |
| Transcript: Webinar  |
| Respiratory Syncytial Virus Mother & Infant Protection Program (RSV-MIPP)Webinar held on: Wednesday 22 January 2025 |
|  |

0:0:27.3 --> 0:0: 33.443
**Christian McGrath (Health)**
We're just kicking off the meeting, just letting some people in who are waiting in the lobby. So, we'll just start in a moment.

0:1:2.753 --> 0:1:29.393
**Christian McGrath (Health)**
Good evening. Thanks everyone for attending. This is our session on RSV maternal infant protection program in Victoria. I just want to start; my name is Doctor Christian McGrath. I'm the Deputy Chief Health Officer for Communicable Diseases in Victoria and I will start the meeting with Acknowledgment of Country. I'd like to pay my respects to the Traditional Owners of the respective lands upon which we're all meeting. I'm sure there's a lot of different lands given the number of people in this meeting.

0:1:30.183 --> 0:1:37.443
**Christian McGrath (Health)**
So for me that's the Wurundjeri people of the Kulin nation, the Traditional Owners of the land.

0:1:38.943 --> 0:1:45.343
**Christian McGrath (Health)**
I pay my respects to their Elders, past, present and emerging, as well as any Aboriginal and Torres Strait Islander people today. Thank you for being at this meeting.

0:1:47.103 --> 0:1:57.423
**Christian McGrath (Health)**
I just said this is the second of two webinars that we're hosting on the new program, which is designed to protect mothers and infants in Victoria from RSV.

0:1:59.63 --> 0:2:7.333
**Christian McGrath (Health)**
And as you know, Australian mums and their newborn babies will have free access to one of the most comprehensive RSV protection programs ahead of winter this year.

0:2:8.903 --> 0:2:14.503
**Christian McGrath (Health)**
We were delighted with our first webinar to have Professor Michelle Giles and Nigel Crawford, who are joining us later on today.

0:2:16.183 --> 0:2:28.583
**Christian McGrath (Health)**
The first webinar presented on the disease impact of RSV and some of the clinical elements of the of the program, including Abrysvo and this will be available to watch online and we'll put a link to that in the chat as we talk tonight.

0:2:30.263 --> 0:2:45.383
**Christian McGrath (Health)**
But today, we're going to provide more detail - just delving into the logistics of the rollout of the program. We're in a position where we can announce some of those details of the Respiratory Syncytial Virus RSV Mother and Infant Protection Program, or RSV-MIPP for short, to make it a bit easier for everyone.

0:2:46.743 --> 0:3:25.743
**Christian McGrath (Health)**
We'll begin with Professor Giles from the Vaccine Research Group at the Doherty, who will give us an overview of the program, some of the program benefits and what each of the components offer, talk a bit more about the products themselves and a bit of a revisit of some of the earlier conversation in the previous meeting.

And then we'll hear from our immunisation lead, Senior Technical Specialist, Immunisation Program, Catherine Radkowski, with the details of the program rollout and delivery, and we'll cover things such as the eligibility criteria, commencement dates, who can deliver the program and what settings, how to order the vaccine and immunisation products.

0:3:27.303 --> 0:3:40.223
**Christian McGrath (Health)**
We’ll also cover the importance of reporting on the AIR as well as in fact a bit about vaccine administration errors and reporting things, tricks and things, etcetera to be aware of.

0:3:42.663 --> 0:3:46.903
**Christian McGrath (Health)**
And then we'll do a more prolonged question and answer session, we know that was pretty popular with the previous session.

0:3:47.453 --> 0:3:55.653
**Christian McGrath (Health)**
Then Professor Nigel Crawford, consultant paediatrician and vaccinologist will join us for that session as well and bring his expertise.

0:3:57.223 --> 0:4:23.713
**Christian McGrath (Health)**
So just for awareness, this session will be recorded, and we will make the link available so you can share with colleagues or to revisit later on because it will be put online as well. Online you'll also find there's some additional resources such as fact sheets or posters for patients, posters for the clinics and health services, as well as some of the clinical information we've discussed today.

It's a fairly packed program for Tuesday evening. So, thanks everyone for coming in.

0:4:25.223 --> 0:4:47.383
**Christian McGrath (Health)**
We'll kick off, by introducing Professor Michelle Giles. For those of you don't know her, she's the Clinical and Health Systems leader of the Clinical and Health Systems Research and Vaccine Research Group at the Doherty Institute. But she's also an infectious diseases physician and a clinician scientist with clinical appointments at the Alfred, Royal Women's and Monash.

0:4:48.723 --> 0:5:14.563
**Christian McGrath (Health)**
She also has academic appointments in the Department of Infectious Diseases at the University of Melbourne and the Department of Obstetrics and Gynaecology at Monash University, and she specialises in infections and pregnancy and maternal immunisation, and is very well qualified to talk on these topics and hopefully share a bit of her insights and knowledge. So, Michelle, thanks once again for doing this presentation. That's a real passion of yours and we really appreciate you being here to be able to talk about it. So, thank you.

0:5:16.173 --> 0:5:20.493
**Michelle Giles**
Great. Thanks Christian. Can I just check that my slides are being shared, OK?

0:5:21.423 --> 0:5:21.623
**Christian McGrath (Health)**
Yeah.

0:5:22.273 --> 0:5:57.583
**Michelle Giles**
Fabulous. Thank you. I just realised, actually, thanks for that really great introduction but my first slide is dated 2024 as you introduce me, I realise it's the same slide I used for the first webinar, so I apologise I haven't updated that to 2025. But it's great to be here and as Christians mentioned, there is a recording of our first webinar and I've tried to not to repeat exactly the same content, but because there may be some attendees tonight who haven't seen the first webinar or weren't able to attend, there is some slides that are similar.

0:5:58.423 --> 0:6:4.663
**Michelle Giles**
So, but it's really exciting because we're going to have a big focus tonight on actually implementing this program, so.

0:6:6.623 --> 0:6:23.103
**Michelle Giles**
Just starting with declarations of interest. So, as you may know I'm on ATAGI and have been a member there since 2016. As mentioned, I'm head of Vaccine Research Group with the Doherty, but tonight I'll be talking really in my professional capacity, not related to my other roles.

0:6:24.783 --> 0:6:38.223
**Michelle Giles**
So this is why we are all here. This is why we're so excited about this program and it's because of the burden of disease. So many of you will realise that paediatric RSV disease burden is huge.

0:6:38.783 --> 0:7:9.23
**Michelle Giles**
And it's the leading cause of severe respiratory infection globally, with 33 million episodes and you can see in that first pie chart that if you just look at all episodes, those infants under six months of age account for about 20% of all episodes. But when you when you go along this slide to the right hand side and you look at severe disease starting with hospitalisations and then death, you can see that that pink piece of the pie increases in proportion and that is because those infants under six months of age are so vulnerable.

0:7:9.563 --> 0:7:16.803
**Michelle Giles**
So they account for up to 39% of hospitalisations and nearly half of RSV deaths are in that age group.

0:7:20.913 --> 0:7:47.313
**Michelle Giles**
But it's important to remember that although RSV is associated with mortality, and we often think about that with premature infants that in fact most global RSV deaths occur in full term infants before three months of age. And although we're talking about an implementation of a program in a high-income setting, most of those deaths do occur in low and middle income settings and outside the healthcare system.

0:7:49.423 --> 0:7:49.823
**Michelle Giles**
So.

0:7:50.373 --> 0:8:18.733
**Michelle Giles**
Maternal immunisation. This is a new maternal vaccine, but maternal immunisation as a concept is not new. It's given to protect mother and, in some vaccines, just to protect infants and in some obviously both. And we've been vaccinating pregnant women safely since the 1960s and to great effect, actually. So, the tetanus containing vaccines, of course, have been pivotal in the elimination of maternal, neonatal tetanus worldwide.

0:8:19.543 --> 0:8:21.943
**Michelle Giles**
And have been proven to be very safe and effective.

0:8:22.443 --> 0:9:3.863
**Michelle Giles**
And our own setting, we obviously have data for influenza, pertussis containing vaccines and COVID. And obviously, even though we're talking about RSV tonight, it would be remiss of me not to put a plug in for the other maternal vaccines and particularly with the rise in pertussis cases that we're seeing in Australia. So, we'll focus on RSV. And also, just to flag another favourite vaccine, if you like, that's in the pipeline about to start phase three trials is Group B Streptococcus. So, we're going to have a quite we already have and will talk about this in the implementation. Quite a crowded space there of maternal vaccines with the addition of a new vaccine with RSV.

0:9:6.243 --> 0:9:16.283
**Michelle Giles**
So what happened on Sunday? So, the Minister, Minister Butler, our Minister for Health and Aged Care, held a press conference and announced this program.

0:9:18.263 --> 0:9:38.703
**Michelle Giles**
It was reported in the ABC free RSV vaccines for pregnant women's been announced. Here's what you need to know. So, if you all want to have your Wednesday night back and tune out, you can. I'll put the link there, but I am hoping that what you'll hear tonight will be a little bit more comprehensive than what you need to know from the ABC report.

0:9:39.333 --> 0:10:37.853
**Michelle Giles**
So the three key messages from this announcement, though, to just highlight is that what was announced on Sunday is the most comprehensive protection program for babies in the world, and the basis of making that pretty bold statement is because we have a program that uses two prevention products, the maternal vaccine and monoclonal antibodies. In countries around the world that have an RSV prevention program, countries have either introduced one or the other, but we are introducing what's been referred to as a comprehensive protection program because it has both of these products, it will be starting soon, February the 3rd, and will be available on the NIP. And in the press conference the language that's been used, if you like, the message from the press conference is as a backup to this maternal vaccine, there will be a backup treatment by way of monoclonal antibodies.

0:10:38.953 --> 0:10:50.913
**Michelle Giles**
So they're the three key messages announced only a couple of days ago. So, the timing of this webinar is excellent in light of this announcement. So, I just want to quickly run through the evidence for the maternal vaccine program, which some of you who have seen the first webinar would be aware of.

0:10:52.453 --> 0:11:13.413
**Michelle Giles**
So this is the study, the phase three pivotal efficacy study that was run in 18 countries, including Australia recruited and randomised over 7000 women between 24 and 36 weeks' gestation.

0:11:14.973 --> 0:11:43.673
**Michelle Giles**
And this is the key finding. So, in green you can see the efficacy through the 2-3 months or 90 days and the efficacy against severe medically attended RSV, lower respiratory tract infection was over 80%. And then on the right, you can see in blue their efficacy through to 180 days, so six months. So, it drops off a little bit as you go from three months through to six months.

0:11:47.573 --> 0:12:14.613
**Michelle Giles**
And so this maternal vaccine is developed by Pfizer and was approved in Europe and the United States in 2023 and in Australia in 2024. It's approved for the gestational window of 24 to 36 weeks in Australia and in Europe, and this gestational window reflects the clinical trial, it's approved for a more narrow gestational window in the United States between 32 and 36 weeks.

0:12:15.413 --> 0:12:20.653
**Michelle Giles**
And the product itself, I'm not going to go into great detail about. I know that Catherine's going to mention this in her slides.

0:12:21.483 --> 0:12:45.683
**Michelle Giles**
So this is just a nice summary of how both products protect the infants, they protect through passive immunisation, but there are some differences. So obviously the main difference is who you give this product to. So, it's obvious the maternal vaccine is given to the mother and those antibodies produced across the placenta to provide protection to the newborn.

0:12:47.293 --> 0:12:54.893
**Michelle Giles**
The monoclonal antibodies are given after birth, of course, and duration of action is at least five months.

0:12:55.723 --> 0:13:21.443
**Michelle Giles**
So one minor sort of detail that is a differentiating point, if you like between the two, is that the long-acting monoclonal antibodies act against a single site on the fusion protein whereas the vaccine actually induces multiple neutralising antibodies against multiple sites. Now this may not have significance clinically,

0:13:22.253 --> 0:13:31.763
**Michelle Giles**
but it may be relevant down the track if there is a virus mutation that may render the antibody ineffective because it's limited efficacy to a single point site.

0:13:35.163 --> 0:14:7.813
**Michelle Giles**
So what are the ATAGI recommendations? So pregnant women are recommended to receive this vaccine from 28 to 36 weeks. Abrysvo is the only RSV vaccine approved for use in pregnancy, not Arexvy, and we'll come back to that. I think you'll hear this message a number of times throughout the evening, and to date, we've already had a number of administration errors where a Arexvy, has been given to pregnant women so Abrysvo is the approved vaccine. It reduces risk of disease by about 70% in infants less than six months of age.

0:14:8.313 --> 0:14:32.513
**Michelle Giles**
I've shown you a summary slide of that data at this stage, we don't have advice on repeat vaccination. But when we get this data, we'll be able to provide advice, and ideally, we need two weeks post vaccination for adequate protection. This is the time really required often for production of those antibodies.

0:14:33.333 --> 0:14:39.813
**Michelle Giles**
But if inadvertently a woman is vaccinated under 28 weeks, a repeat dose is not indicated.

0:14:42.513 --> 0:15:13.693
**Michelle Giles**
So I just wanted to add a few extra slides on safety tonight and these slides were actually presented in the United States back in October, but they've looked specifically at use of this vaccine and the outcome of preterm birth and small for gestational age infants. And this these preliminary results are from the vaccine safety data link and it's always good to see what safety data is available, post licensure in countries, that have implemented vaccine prior to Australia.

0:15:14.473 --> 0:15:55.293
**Michelle Giles**
So for those of you who are not aware of what the vaccine safety data link is, it's essentially a collaborative project between 13 healthcare organisations in the United States and what these healthcare organisations do of course, is having really large databases of information on demographic information on intervention such as vaccination. In the setting of pregnancy, they have an annual birth cohort across all these sites of about 115,000. So, you can look at vaccination and birth outcomes.

0:15:57.693 --> 0:16:23.173
**Michelle Giles**
So this analysis was a matched analysis. What they did was to look at pregnant people aged 16 to 49, between 30 and 37 weeks, and they compared the outcomes, with the two outcomes of interest; in this preliminary analysis was pre term birth and small for gestational age, and they compared those pregnant people that received a vaccine and they matched them to the site to unvaccinated pregnant people during the same gestational week and looked at their birth outcomes.

0:16:23.973 --> 0:16:41.933
**Michelle Giles**
They used propensity scoring if you like. This is a statistical method to try and account for demographics and other variables that might influence the likelihood of that person being vaccinated.

0:16:43.533 --> 0:17:27.533
**Michelle Giles**
And the key findings, so they this is in almost 14,100 women. So, you'll remember I showed you that slide that was just over 7000 in the pivotal phase three studies. So, this is some additional safety data obviously not from a randomised controlled trial but on another 14,000 women vaccinated. And what you can see is that when you look at events like preterm birth, the number in the vaccinated group was 571 compared to 637 in unvaccinated. When you look at the overall percentage, it was quite low. The background rates of preterm birth actually sit, often a bit higher than that, particularly in some states. In the United States, closer to sort of 8%.

0:17:28.333 --> 0:17:55.63
**Michelle Giles**
But you can see for both groups they were low and there was not an increased rate of preterm birth.

So the reason I'm presenting this information is because for those of you online who are already talking to your patients about this vaccine or who will be talking to pregnant women about this vaccine in the coming days, weeks, months and even years, there'll be a lot more safety data, observational safety data that comes out. But there's another.

0:17:55.973 --> 0:18:3.573
**Michelle Giles**
Here's a study if you like. On almost 14,000 women and the outcome of preterm births, so very reassuring data.

0:18:6.813 --> 0:18:35.653
**Michelle Giles**
So the conclusion from this study is that this vaccine is not associated with the increased risk of preterm birth or small for gestational age infants. Obviously, this is from the United States, where they're vaccinating from 32 weeks, and we are recommending from 28 weeks. But I think it's incredibly helpful to have this data available to explain or to reassure not just healthcare providers, but also their pregnant people and their families.

0:18:36.343 --> 0:19:14.173
**Michelle Giles**
There's ongoing analysis for other safety outcomes, particularly things like preeclampsia, still birth and other syndromes. Here you can see the list, but clearly, it's important that we continue to watch this space.

So just mentioning one other change or update since the last presentation and this is probably more relevant to RSV vaccines for older adults, but it may be mentioned or come up or you may be aware of it. So, I just wanted to put this slide in tonight.

0:19:14.983 --> 0:19:40.743
**Michelle Giles**
And this is a recent requirement by the FDA that Guillain-Barre Syndrome has to be added to the warning and precautions section of both of Abrysvo and Arexvy. And this is the comment that will be added as the results of post marketing observational studies suggest an increased risk of Guillain Barre Syndrome GBS during the 42 days after vaccination.

0:19:41.533 --> 0:19:46.173
**Michelle Giles**
This is specifically seen in adults over 65 years of age.

0:19:47.43 --> 0:20:6.323
**Michelle Giles**
It has not yet been reported that there is an increased rate of Guillain Barre Syndrome in pregnancy, but you need to probably be aware of this and what this equates to. The FDA analysis was 9 excess cases of GBS per million doses for Abrysvo.

0:20:7.933 --> 0:20:41.693
**Michelle Giles**
And also just for those of you who maybe don't work in the antenatal space, if you refer to Guillain Barre syndrome as GBS in the setting. In a maternal setting, it will be interpreted as Group B Streptococcus. We abbreviate that to GBS all the time. So just be aware of that if you talking about Guillain Barre Syndrome GBS. OK, so let's get back to the program that's been announced and what that includes.

0:20:42.303 --> 0:21:11.263
**Michelle Giles**
So obviously, it includes the maternal vaccine on the NIP and it also includes a monoclonal antibody component and Nigel Crawford talked on this in the first webinar very comprehensively, so I'm just providing a really quick update using some of his slides that he's generously shared with me for tonight. But I know that Catherine will also talk about the practicalities and the timing of this in more detail.

0:21:11.983 --> 0:21:29.623
**Michelle Giles**
So just to highlight nirsevimab as the other component of this comprehensive program, it's a human immunoglobulin monoclonal antibody. As you all know and as I've already mentioned, it binds to a highly conserved epitope of the pre fusion protein of RSV.

0:21:31.653 --> 0:21:36.853
**Michelle Giles**
It has a half-life that's extended, so a single dose will last at least five months.

0:21:38.533 --> 0:22:13.133
**Michelle Giles**
I won't go through this in detail, but just like for the maternal vaccine, there is data from studies to support the efficacy of nirsevimab in preventing hospitalisation, severe disease in not just infants with comorbidities of heart or lung disease and prematurity, but also (full) term infants, and what's also really encouraging with this product is you can see in this slide up the top in blue are those clinical trials that showed vaccine efficacy of around 80%.

0:22:13.883 --> 0:22:36.763
**Michelle Giles**
And then underneath you can see what's been published as from observational data post roll out in other settings during the first RSV season. And although the studies are not exactly the same methodology, it's really encouraging to see that the vaccine effectiveness has been maintained where this product has been used to prevent RSV disease.

0:22:38.613 --> 0:23:11.973
**Michelle Giles**
So this was the state supply in 2024 where monoclonal antibodies were used in Queensland, WA and NSW and I'm really, really excited and pleased to be here tonight with this slide where we actually have a national RSV prevention program and although we're going to focus on Victoria, there are some subtle differences between jurisdictions.

0:23:12.603 --> 0:23:44.333
**Michelle Giles**
In terms of some of the timing of the monoclonal antibody products, when we're thinking about a maternal RSV vaccine, it is now free, and women are eligible on the NIP. So, we do truly have a national program. So, my last slide before I hand over to Catherine are some practical suggestions for implementation and we can get into this in a bit more detail later, but don't forget the other vaccines, and they can be co-administered with RSV.

0:23:45.623 --> 0:24:44.413
**Michelle Giles**
Professor Crowford has mentioned the only contraindication to RSV vaccines and immunisation products are currently anaphylaxis after a previous dose of the same product or a component of the RSV vaccine. And always we'll talk about AIR (Australian Immunisation Register). I think that's a really key consideration here in implementation because this is quite a unique program.

So it's really important that we think about how to identify infants, whose mothers were not vaccinated during pregnancy and would be eligible for monoclonal antibodies. AIR is going to be critical to monitor and evaluate the program, but also, really importantly, at the coalface, AIR is really important for actually making decisions about eligibility. So, and just to remind people that no RSV vaccine is funded for older adults and medically at-risk individuals so.

0:24:45.213 --> 0:24:50.133
**Michelle Giles**
The only RSV vaccine that is currently funded is for pregnant people.

0:24:51.83 --> 0:25:10.493
**Michelle Giles**
And this can cause some confusion. It's likely to raise some questions for immunisation providers who deal with people across the lifespan, but it's really, I just think that's really clear and it's important to highlight that that from the start.

0:25:12.133 --> 0:25:14.253
**Michelle Giles**
I will stop sharing.

0:25:18.613 --> 0:25:20.13
**Michelle Giles**
And hand back to you, Christian.

0:25:23.3 --> 0:25:28.243
**Christian McGrath (Health)**
Fantastic. Thank you, Michelle, for that whirlwind tour, I should have said at the beginning.

0:25:29.893 --> 0:25:43.573
**Christian McGrath (Health)**
We'll have opened up the Q&A, and if you have pressing questions, please put them in in the Q&A, and questions that you think are important. We'll try and address all of those in the Q&A at the end of the session.

0:25:45.213 --> 0:25:54.573
**Christian McGrath (Health)**
First, we're just going to bombard you with a lot of information. So, Michelle, thank you for getting that started and we're going to continue with Catherine's presentation now.

0:25:55.43 --> 0:26:52.293
**Christian McGrath (Health)**
So as I said, Catherine is our Specialist Technical Specialist. So, she's the lead at the Immunisation Program at the Victorian Department of Health and she's been responsible for the leadership, strategic planning and operational oversight of immunisation policy and programs in Victoria for a number of years. She likes to make it clear she's from Canada rather than the US, but she immigrated to Australia in about 2012 with a clinical background in clinical pharmacy and initially worked at the Alfred before being recruited to the department in 2016 to implement the Victorian pharmacist administered vaccination program.

Since then, she's been involved in the rollout of a number of government commitments on vaccine programs and delivered a number of innovative, safe and quality services to Victorian community, of which RSV-MIPP is just the latest. So, I'll hand over to Catherine to go through some of the logistics details and answer some of the questions about how the program is going to run in Victoria, so over to you, Catherine. Thank you.

0:26:53.563 --> 0:27:10.243
**Catherine Radkowski (Health)**
Thanks so much, Christian and thank you for everyone who is joining. This is a really exciting program and it's excellent that people are taking the time of such a nice evening during the Australian Open to learn more about our exciting new program.

0:27:11.813 --> 0:27:24.133
**Catherine Radkowski (Health)**
As Michelle mentioned, there's been a lot of development in the RSV space and now there's a number of products on the market and in collaboration with the Commonwealth and other jurisdictions.

0:27:24.643 --> 0:27:53.963
**Catherine Radkowski (Health)**
In 2025, we're going to roll out an RSV mother and infant protection program or as Christian said RSV-MIPP. This program is going to consist of two products. So, the first one being Abrysvo that was announced by the Commonwealth on Sunday, and it will be funded for pregnant women under the National Immunisation Program. I'll go into a bit more detail in the next slide about this. The 2nd component will utilise nirsevimab, also known as Beyfortus.

0:27:54.533 --> 0:28:20.533
**Catherine Radkowski (Health)**
Beyfortus is not a vaccine but a monoclonal antibody, and this component of the program will be funded by each jurisdiction independently, and in Victoria it will commence on the 1st of April this year. As Michelle said, this is the first program of its kind. It's a dual comprehensive program that utilises both the maternal vaccine and an infant monoclonal antibody.

0:28:21.333 --> 0:28:58.93
**Catherine Radkowski (Health)**
A lot of the other RSV immunisation programs that have been implemented around the world either use one or the other, but not both, so a really exciting time for Australia to be leading in this space. The cornerstone of the program will really be Abrysvo, and we want to encourage all expectant mothers to take up the opportunity to be vaccinated with it to ensure that their babies are protected from RSV the moment that they are born. But as a backup, we do have nirsevimab and nirsevimab will also be available for infants who are most at risk.

0:28:58.633 --> 0:29:21.873
**Catherine Radkowski (Health)**
For RSV, we've got a limited supply of this and being very open and honest, there's global demand for this and we really don't have enough supply for every baby that's born. So, we really need to make sure that we are utilising the product for the babies who need it most and making sure that we apply the eligibility criteria.

0:29:23.693 --> 0:29:58.933
**Catherine Radkowski (Health)**
All right, Abrysvo. So the Commonwealth announced that the program under the National Immunisation Program will commence on the 3rd of February of this year, so that's less than two weeks away. It's recommended as a single dose for all pregnant women between 28 and 36 weeks' gestation. It can be given post 36 weeks. However, if the infant is born less than two weeks after administration, they will require a dose of nirsevimab as not enough time would have lapsed to ensure passive immunisation.

0:29:59.693 --> 0:30:8.253
**Catherine Radkowski (Health)**
It is not recommended for use in women in pregnant women less than 28 weeks' gestation or women who are breastfeeding but are not pregnant.

0:30:9.813 --> 0:30:35.773
**Catherine Radkowski (Health)**
It's also important to note that, as Michelle also noted, there is another RSV vaccine with a very similar name called Arexvy that is registered for use in on the private market for adults over the age of 60 and older should not be given to pregnant women, and our Tassie colleagues today just thought of a really clever way of how to remember which RSV vaccine is for pregnant women.

0:30:35.853 --> 0:30:53.13
**Catherine Radkowski (Health)**
So think of so Abrysvo has B. B stands for baby and so if it has a B in it, that means you can give it to the mum. Arexvy does not have a B in it so can't give it to the mum. So, I thought that was a really clever way of remembering it so thought I'd share it.

0:30:54.573 --> 0:31:5.773
**Catherine Radkowski (Health)**
If Arexvy is given an error, please report any administration errors to SAEFVIC and I'll come back to reporting of vaccination errors a little bit later on in the presentation.

0:31:7.923 --> 0:31:32.443
**Catherine Radkowski (Health)**
So Abrysvo will be delivered as a year-round program and should not only be offered to pregnant women before or during RSV season. We're recommending that it should be offered at the 28-week antenatal appointment. However, all women who are already greater than 20 weight 28 weeks pregnant at the time of program commencement should be vaccinated as soon as possible.

0:31:33.253 --> 0:31:37.533
**Catherine Radkowski (Health)**
You can co-administer Abrysvo with other maternal vaccines, including pertussis, influenza and COVID-19.

0:31:38.253 --> 0:32:5.853
**Catherine Radkowski (Health)**
The lyophilized vaccine, which means it comes in a powder, must be reconstituted only with the diluent provided using the vial adapter and be given intramuscularly into the deltoid muscle. The preparation is slightly different to standard vaccine preparations and an Abrysvo preparation and administration fact sheet will be available for providers on our website so that you can use it as a quick reference guide.

0:32:6.653 --> 0:32:22.23
**Catherine Radkowski (Health)**
And because this is a vaccine that is under the National Immunisation Program, it is mandatory to report administration to the Australian Immunisation Register and I'll come back to this in a little bit with more detail later on.

0:32:23.613 --> 0:32:42.133
**Catherine Radkowski (Health)**
All right. So that was the maternal component of the program that covers the eligibility criteria. So now I'll go through the infant program. So, as mentioned, there will be an infant nirsevimab program implemented in every state and territory in Australia.

0:32:42.803 --> 0:33:6.523
**Catherine Radkowski (Health)**
We've tried to ensure national consistency as much as possible, but there are some slight differences between each jurisdiction, so it's super important that when you are delivering nirsevimab in Victoria that you do follow the Victorian eligibility criteria. Our criteria are completely aligned with the Australian Immunisation Handbook.

0:33:7.693 --> 0:33:13.853
**Catherine Radkowski (Health)**
If you need more clarity or more information, please just refer to the Handbook, because we do follow it.

0:33:15.133 --> 0:33:45.13
**Catherine Radkowski (Health)**
And for nirsevimab, the eligibility criteria are broken down into three main components. So, there's a neonate program. There's the first RSV season catch up and the 2nd RSV season catch up. The nirsevimab program will commence on the 1st of April and this is to coincide with the start of the Victorian RSV season, which typically runs from April to September each year. The program will conclude on the 30th of September this year.

0:33:46.323 --> 0:34:2.123
**Catherine Radkowski (Health)**
Other jurisdictions further north have a year-round nirsevimab program and that's because their RSV season is not seasonal like ours. So that's the reason for the difference and why Victoria does not have a year-round nirsevimab program.

0:34:4.93 --> 0:34:56.323
**Catherine Radkowski (Health)**
So I'm just going to go through each of the eligibility criteria for the three components of the infant program.

So, the neonatal program will be available from 1st of April 2025 until conclusion of the program for infants who meet the following criteria. So, they're born to mothers who did not have Abrysvo during pregnancy or Abrysvo was administered less than two weeks before birth, or infants who are identified as high risk for RSV, regardless of the maternal RSV vaccination status.

So, this includes infants with conditions associated with increased risk of severe RSV as defined in the Australian Immunisation Handbook and on the slide there, you'll see a list of conditions that would make them more at risk.

0:34:58.693 --> 0:35:40.133
**Catherine Radkowski (Health)**
The first RSV season catch up program will be available for infants born on or after 1st of October 2024 up to 8 months of age who meet the following criteria. So, they're born to mothers who did not receive Abrysvo or Abrysvo was administered less than two weeks before birth, or the infant is identified as high risk for RSV, regardless of the maternal vaccination status. And these conditions are defined in the Australian Immunisation Handbook.

Just one thing to note, if the infant does have one of these risk conditions, the threshold of eight months does not apply.

0:35:42.293 --> 0:36:14.953
**Catherine Radkowski (Health)**
And then the final component of the infant program is the second RSV season catch up program and this will be available for infants entering their second RSV season. So that means they were born on or after 1st of October 2023 and have the following eligibility criteria. They are Aboriginal or Torres Strait Islander, or they have conditions associated with increased risk of severe RSV, as defined in the Australian Immunisation Handbook.

0:36:17.73 --> 0:36:45.813
**Catherine Radkowski (Health)**
So administration of nirsevimab is likely to be most effective when given shortly after birth for infants born just before or during RSV season. But obviously there might be delays for neonates who are in neonatal intensive care or special care nurseries.

It's recommended that maternity units establish workflows for administration of nirsevimab that includes checking the maternal RSV vaccination status on the AIR.

0:36:47.573 --> 0:36:50.533
**Catherine Radkowski (Health)**
Nirsevimab comes in a prefilled syringe.

0:36:51.13 --> 0:37:7.213
**Catherine Radkowski (Health)**
It is available in two doses, there's a 50-milligram dose that comes in a 0.5ml prefilled syringe with a purple plunger, and 100 milligram dose that comes in a 1ml prefilled syringe with a blue plunger.

0:37:8.773 --> 0:37:19.533
**Catherine Radkowski (Health)**
For the neonate and 1st RSV catch-up program, if the infant is less than five kilograms, they should receive a 50-milligram dose intramuscularly.

0:37:20.363 --> 0:37:36.563
**Catherine Radkowski (Health)**
If they're more than five kilograms, they should receive the 100-milligram dose and it's advised that the 100-milligram dose is delivered utilising the 100-milligram prefilled syringe rather than giving two of the 50 milligram prefilled syringes.

0:37:38.133 --> 0:38:12.283
**Catherine Radkowski (Health)**
For the second RSV season, infants should receive a 200-milligram dose and this should be administered as two of the 100 milligram prefilled syringes, given at the same visit. Even though nirsevimab technically is not a vaccine, it should still be reported to the Australian Immunisation Register to ensure that the infant has an administration record and does not receive nirsevimab again in primary care. And I'll touch on this in a couple of slides.

0:38:14.133 --> 0:38:29.293
**Catherine Radkowski (Health)**
So nirsevimab should be given intramuscularly and the preferred side of administration is the anterolateral thigh region, and the pictures and figures here are taken from the Australian Immunisation Handbook that has more information available.

0:38:31.133 --> 0:39:0.693
**Catherine Radkowski (Health)**
Both Abrysvo and nirsevimab do not have unique storage requirements and should be stored typical to most vaccines in a purpose-built vaccine refrigerator at or between +2 to +8 Celsius and must be protected from light at all times.

The purpose-built refrigerator must be monitored continuously in accordance with the most current edition of the National Vaccine Storage Guidelines ‘Strive for Five’.

0:39:1.353 --> 0:39:7.313
**Catherine Radkowski (Health)**
And we've got a range of resources available on our website to support providers in cold chain management.

0:39:8.933 --> 0:39:30.613
**Catherine Radkowski (Health)**
All right, so I've gone through the two components of the program and the eligibility criteria, so now who can deliver this program in Victoria? What are the immunisation workforces?

So Abrysvo, being the cornerstone of the program, it will be accessible to all registered immunisation providers in Vic.

0:39:31.303 --> 0:40:0.943
**Catherine Radkowski (Health)**
So that includes GPS, nurse practitioners, pharmacies, local councils, Aboriginal health services and hospitals. We really want to make this vaccine as easily accessible as influenza vaccine is and to make it as easy as possible for pregnant women to access due to limited supply of nirsevimab. On the next slide I'll go over the certain settings in which nirsevimab will be available.

0:40:1.813 --> 0:40:37.183
**Catherine Radkowski (Health)**
In Victoria, we have recently authorised nurse immunisers and Aboriginal and Torres Strait Islander health practitioners to be able to administer nirsevimab. So, this slide is slightly busy, but it does highlight the key settings for delivery of nirsevimab. You'll see that maternity hospitals will play a big role in the neonate program, whereas GPs, certain nurse practitioners, pediatrician and specialist hospital immunisation services, Aboriginal health services and some local councils will play a greater role in the catch-up programs.

0:40:38.613 --> 0:41:18.383
**Catherine Radkowski (Health)**
From looking at this table, you'll see pretty much most authorised immunisers in Victoria will have access to nirsevimab. The exception is community pharmacies, who currently are not authorised to administer vaccines in children less than five, however, we see a big role for community pharmacy in delivery of the maternal Abrysvo program. Abrysvo is listed on the NIP and so it can be delivered at no cost to pregnant women as community pharmacies are eligible to claim administration cost payment from the Commonwealth as part of the NIPVIP. So, we're really hoping that this can help to decrease any barriers to access for the maternal vaccination component.

0:41:21.103 --> 0:41:23.823
**Catherine Radkowski (Health)**
OK, so ordering, how do we order?

0:41:25.543 --> 0:41:54.803
**Catherine Radkowski (Health)**
Some of you probably would have received an e-mail from us on Monday saying that ordering for Abrysvo has opened. The reason for this and why we've opened it up early is to make sure that you have stock available for program commencement on the 3rd of February. So, the actual National Immunisation Program and the eligibility criteria for Abrysvo, under the NIP doesn't commence until the 3rd of February.

0:41:56.343 --> 0:42:22.23
**Catherine Radkowski (Health)**
I'm going to put a little plug in to say how important it is to ensure that the e-mail address that you provide us when you sign up for a government funded vaccination account with us, is actually monitored, because we use that e-mail to send important information such as this as to when ordering opens or key changes. So please double check to make sure that the e-mail that you have registered with us is monitored.

0:42:23.763 --> 0:42:42.83
**Catherine Radkowski (Health)**
Providers can order Abrysvo just like any other vaccine from us. You can utilise your Onelink ordering template and there are currently order limits in place to ensure equitable distribution and to minimise any stockpiling. But we will be monitoring distribution patterns, and order limits can change.

0:42:43.623 --> 0:42:48.983
**Catherine Radkowski (Health)**
Providers should refer to their Onelink ordering template for the most up to date ordering information.

0:42:50.663 --> 0:43:4.223
**Catherine Radkowski (Health)**
And just also to mention that Pfizer did provide a shelf-life extension to several batches that are listed there on the slide and this information will be included when those batches are dispatched.

0:43:5.783 --> 0:43:24.983
**Catherine Radkowski (Health)**
For nirsevimab - we actually haven't received nirsevimab into our warehouse yet. So, it is not yet available to order, but we are anticipating that we will be able to open up ordering from mid-March to ensure that providers have nirsevimab on their premises for the program commencement date of 1st of April.

0:43:26.73 --> 0:43:42.633
**Catherine Radkowski (Health)**
More information will be available closer to the date and again because of the limited supply that we have. We will have strict order limits in place and there will be some strict monitoring just to make sure that we don't run out of this very valuable monoclonal antibody.

0:43:45.853 --> 0:44:10.893
**Catherine Radkowski (Health)**
All right, so I've mentioned a few times about the importance of reporting to the Australian Immunisation Register or AIR, and I just want to take the time to say why it's so important for this program. So, RSV-MIPP is very different to standard programs. We've got two products and we're relying heavily on accurate record keeping to know whether the mother received the maternal vaccine.

0:44:11.703 --> 0:44:15.743
**Catherine Radkowski (Health)**
Obviously the easiest way to check if someone has been immunised is to look at the AIR.

0:44:16.513 --> 0:44:42.273
**Catherine Radkowski (Health)**
However, historically, health services, who will play a very big role in this program, have issues accessing AIR and also reporting to AIR. And we currently see this with other maternal vaccinations and birth dose vaccinations, and the reason for this has to do with the software program that health services use, and it doesn't link up to AIR and this isn't a problem that's unique to Victoria. It's a national problem.

0:44:43.103 --> 0:44:45.463
**Catherine Radkowski (Health)**
There are solutions that are being worked through.

0:44:46.13 --> 0:45:11.773
**Catherine Radkowski (Health)**
There are some workarounds, but it's not implemented in every health service just yet, and it is inconsistent in terms of what each health service is doing. So how this becomes a problem is a mother goes and gives birth at a hospital and doesn't know if they received Abrysvo. The hospital isn't able to check AIR quickly and to be on the safe side, they decide to administer nirsevimab to the infant.

0:45:12.583 --> 0:45:16.543
**Catherine Radkowski (Health)**
They can't then upload a record of nirsevimab being given to the baby.

0:45:17.183 --> 0:45:50.973
**Catherine Radkowski (Health)**
And the baby goes and has a checkup, say at the GP or the maternal child health nurse. And that provider goes on to AIR and sees that no maternal vaccination was given and also sees that no nirsevimab was given and then gives nirsevimab. So, you can see how this can create an issue of double dosing. And you can see how we can run out of nirsevimab. So, it's super important that providers are uploading to AIR, and I urge you all to please do so, just so we can make this program a success.

0:45:52.543 nirsevimab
**Catherine Radkowski (Health)**
We've developed an AIR fact sheet to help provide support to providers and this will be available on our website, and we are continuing to work with health services to see what we can do to make sure that nirsevimab is uploaded to AIR. Also, just a quick note to say that AIR does not record multiple doses of nirsevimab an infant may have, and
only one dose will be shown as being recorded onto AIR.

0:46:25.123 --> 0:46:52.323
**Catherine Radkowski (Health)**
OK, so vaccine errors as mentioned previously, there are multiple RSV products on the market and it's important to double check that you are prescribing or administering the correct RSV product. As I previously mentioned, there's another RSV vaccine with a very similar name to Abrysvo called Arexvy that's registered for use in adults over 60. This should not be administered to pregnant women.

0:46:53.223 --> 0:46:59.73
**Catherine Radkowski (Health)**
Remember Abrysvo, B, baby. That's the one that you want to give to the pregnant woman.

0:47:0.623 --> 0:47:24.863
**Catherine Radkowski (Health)**
Abrysvo and Arexvy are also not approved for use in infants and young children, and also should not be administered. However, we're human, mistakes do happen and if an error does occur, please make sure that you report it to SAEFVIC, who are Victoria's vaccine safety and surveillance provider. More information is available on our website in relation to vaccine error management.

0:47:25.823 --> 0:47:38.453
**Catherine Radkowski (Health)**
And if anything does occur and you know, stuff can happen. You can always contact SAEFVIC, and you can always contact us at immunisation@health.vic.gov.au and we can help work through the best way forward.

0:47:40.23 --> 0:48:14.663
**Catherine Radkowski (Health)**
So finally this is my last slide. There are a number of resources that have been developed by both the Commonwealth and us to help support rollout of RSV-MIPP. All the information that I have provided today is available on our website <https://www.health.vic.gov.au/immunisation/respiratory-syncytial-virus-immunisation> and we've actually done quite a quite a big refresh on that website today, and it has a lot of new information that wasn't there yesterday. We'll also be doing some regular updates as more information becomes available, particularly for the nirsevimab component of the program.

0:48:16.223 --> 0:48:23.823
**Catherine Radkowski (Health)**
And I think that's it for me. So, thank you so much for taking the time to listen to me and I'll stop sharing my slide and hand back to Christian.

0:48:29.813 --> 0:48:44.653
**Christian McGrath (Health)**
Thank you, Catherine. Again, I'm passing information, so thank you. I think there's a lot of detail on that, which is when it’s new for some people will be quite confronting, but it does start to make sense after having a look at it.

0:48:46.223 --> 0:49:17.903
**Christian McGrath (Health)**
You know, there's a lot to the program, as you can see and appreciate. So hence why it's important for these sorts of sessions and for it to be backed up with a lot of resources online. But you can also see the complexity and the thinking that's had to go into design, the program, that sort of deals with the realities of how you know our service systems, but also global demand and global supply of the products have got, but hopefully as a result, we've been able to develop a program that will protect all the infants in Victoria and across the country from RSV.

0:49:19.663 --> 0:49:29.823
**Christian McGrath (Health)**
So thank you both to Michelle and Catherine and thank you to everyone who's put some questions into the Q&A, which we will go to in a second. It's great that there's been so many questions that have been asked already.

0:49:31.463 --> 0:49:37.623
**Christian McGrath (Health)**
We'll try and work our way through them, and we've left ourselves a bit of time to answer some of those questions, so bear with us.

0:49:38.203 --> 0:49:57.563
**Christian McGrath (Health)**
I should say that any of the questions you're asked if we don't think that they're being addressed in the Q&A, or we can't answer them today or not being addressed in FAQ fact sheet, then we're endeavoring to use those questions and answers to incorporate those into material. So that the materials we produce are relevant to the questions people are actually asking.

0:49:59.103 --> 0:50:8.903
**Christian McGrath (Health)**
But before we start the Q&A, just want to also introduce Nigel Crawford to join us. I understand he's available online, so if you're on, Nigel, feel free to switch your camera on.

0:50:10.813 --> 0:50:30.293
**Christian McGrath (Health)**
Nigel, for those who don't know, is a consult pediatrician and vaccinologist and is recognised as an expert in vaccination in all special risk groups, so much so that he's the director of SAEFVIC, which, as we said, is responsible for adverse effects following vaccination in the community in Vic.

0:50:31.863 --> 0:50:47.933
**Christian McGrath (Health)**
So in addition to that, he's also the head of the Immunisation Services at the Royal Children's Hospital and he has led the RSV surveillance project at the Royal Children's Hospital since 2016.

0:50:51.583 --> 0:51:4.303
**Christian McGrath (Health)**
So RSV and maternal vaccine to protect children, immunisation to children is one of his key goals. Sorry, I'm just trying to find him on the computer so we can give him access.

0:51:6.63 --> 0:51:16.223
**Christian McGrath (Health)**
Or if one of the team can have a look to do that to give him presenter right so that he can see the Q&A and switch his camera. That would be great. But Nigel will be joining us in trying to answer the questions.

0:51:19.223 --> 0:51:26.583
**Christian McGrath (Health)**
So I might just start from the bottom of the questions and work my way up and I'll just throw it over who I think's most appropriate to answer them.

0:51:27.493 --> 0:51:41.413
**Christian McGrath (Health)**
Please if I've thrown to the wrong presenter, feel free to call a friend or I'll pass it on. We'll try and work through the questions that have been raised, and the first question was where I can access the previous session and that's already been answered in the comment.

0:51:43.103 --> 0:52:3.143
**Christian McGrath (Health)**
This one, I think Catherine's for you. I think you sort of answered it, but we've already received our NIP Abrysvo, came in this afternoon. Are we able to offer it to our eligible pregnant women now? I do not have to wait until the official start date 3rd of February? I think I'll take it, they mean, are they able to offer it for free under the NIP at the moment or do I have to wait till the 3rd of February?

0:52:4.923 --> 0:52:8.603
**Catherine Radkowski (Health)**
So under the NIP, the program doesn't commence until the 3rd of February.

0:52:12.923 --> 0:52:19.163
**Christian McGrath (Health)**
Or so if it was delivered now, it'd be a private script. I'm guessing. Yeah, sort of implying. Yeah. OK, no worries. Thank you.

0:52:15.943 --> 0:52:17.863
**Catherine Radkowski (Health)**
Correct. Yeah.

0:52:21.183 --> 0:52:30.623
**Christian McGrath (Health)**
What if a vaccinated mother wants to access a private monoclonal antibody for a child, I’ll throw that one to Catherine as well?

0:52:31.333 --> 0:52:40.413
**Catherine Radkowski (Health)**
Yeah. So, we've been told, Sanofi is the supplier of nirsevimab in Australia and is not available on the private market.

0:52:42.43 --> 0:53:0.223
**Christian McGrath (Health)**
So it's only available for the state funded program, so there isn't any availability of the nirsevimab as a private script. Just to clarify, and that's partly as Catherine's already alluded to, there's global demand for this product and obviously the company makes decisions around that.

0:53:1.183 --> 0:53:18.903
**Michelle Giles**
Can I just jump in Christian also, just to make the point that as healthcare providers, we have a real responsibility to use these products wisely in the setting of you know, potential supply shortages, cost etc.

0:53:20.503 --> 0:53:29.63
**Michelle Giles**
And if a mother is vaccinated, there's not really other reason other than the high-risk situations that Catherine has mentioned, there's no reason for her infant to also get monoclonal antibodies.

0:53:29.593 --> 0:53:54.393
**Michelle Giles**
So I think it's really important that that we as a collective group of healthcare providers make sure we give those clear messages to pregnant women that that they there's not, they're not going to get that addition any additional benefit and it's not the best use of our resources. So, we shouldn't be supporting the use of both outside of those circumstances that Catherine has mentioned that are listed in the in the Handbook.

0:53:57.193 --> 0:54:12.263
**Christian McGrath (Health)**
Oh great. I think obviously we've seen examples of that in other medications that are circulating at the moment, like Ozempic, is a pretty common one, and making it available for diabetics. So there are examples of that. Obviously, we want to make sure we've got nirsevimab for those who do need it.

0:54:14.383 --> 0:54:22.183
**Christian McGrath (Health)**
OK. So I'll just continue working my way up. Michelle. I think this one's for you. Is past history of Guillain-Barré syndrome a contradiction to vaccination?

0:54:23.13 --> 0:54:27.333
**Michelle Giles**
Thanks, Christian, and hi, Nigel. Welcome. I've seen you just joined so.

0:54:28.903 --> 0:54:32.343
**Michelle Giles**
Thanks for joining us. So we can throw the really hard questions to you.

0:54:34.23 --> 0:54:53.463
**Michelle Giles**
So now Guillain Barre in itself is not a contraindication to vaccination, but I think it's important to have a discussion with anyone across the spectrum about Guillain Barre because it can occur in as a consequence or after infection.

0:54:53.763 --> 0:55:49.933
**Michelle Giles**
It can occur in other situations, so not just in relation to vaccination. In other scenarios such as influenza, we've been able to safely vaccinate many people with Guillain Barre with influenza who thought they weren't able to be vaccinated. So it's not a contraindication, but the reason I'm put that slide in about the FDA warning is because I still think it is important for us to be aware of and you will have people who will come and have a history of Guillain Barre. So it's really important to have that discussion about what their Guillain Barre looked like. Did it occur after a vaccine or after an infection? And what's their risk of the vaccine preventable disease or RSV that you're trying to prevent? And just to reiterate the point I made earlier in my slides, this signal was really seen in older adults. It's not a signal that we're seeing in young people or in pregnant people.

0:55:50.743 --> 0:55:52.503
**Michelle Giles**
So I just want to really emphasise that.

0:55:54.103 --> 0:56:0.263
**Michelle Giles**
Because I don't want people to leave this webinar thinking that pregnant that we've seen this signal with GPS vaccines in pregnancy.

0:56:4.493 --> 0:56:26.173
**Christian McGrath (Health)**
Question about monoclonal antibody in the second year privately, I think we've sort of answered that no private availability, but obviously that's available in the public scheme in the second year of life for those with the high risk criteria and we know for the average infant also that the highest risk period for RSV is in those first six months of life. Hence why the program really targeted towards them.

0:56:27.743 --> 0:56:33.503
**Christian McGrath (Health)**
Will it be able to give the RSV monoclonal antibodies to babies in general practices or will it be a hospital-based program?

0:56:34.263 --> 0:56:37.663
**Christian McGrath (Health)**
Catherine, I think you answered that question, but do you want to reiterate some of those points?

0:56:38.493 --> 0:57:3.13
**Catherine Radkowski (Health)**
No problem. So yes, we see general practices playing a key role in the catch up component of the program, so both for infants entering their first RSV season and infants entering their second RSV season, and there be more information, or it is already up on our website to detail through which providers can access nirsevimab. But short answer yes.

0:57:4.693 --> 0:57:25.463
**Christian McGrath (Health)**
Thank you. Just a comment can do a DVA script for 60+, 8 dollars. I think that's probably relevant to Arexvy in the over 65 age group because I think there was a line in there about it is not available, but I actually don't know the DVA prescribing criteria. Does anyone else on the call know? No? I don't expect the pediatrician to.

0:57:28.623 --> 0:57:36.823
**Christian McGrath (Health)**
So we will take that as a comment and we might be able to mention that if it's relevant, but obviously it's in older adults, not the not part of this program.

0:57:39.53 --> 0:57:47.813
**Christian McGrath (Health)**
This one I think I'll throw it to you Michelle. If mum misses Abrysvo in the 28 to 36 week window, can they get it after 36 weeks' gestation?

0:57:48.863 --> 0:58:2.783
**Michelle Giles**
Yeah, sure. So, the answer is yes. Nobody should be turning a pregnant woman away who is 36 and one day, 36 five days, 38 and not vaccinated them obviously.

0:58:4.343 --> 0:58:39.493
**Michelle Giles**
The exception to that might be if they've got an elective caesarean section booked at 38 weeks, or and they're 37 and you know that they're not going to be within that 14-day window, or they have a booked induction of labour so, in the exception of a very specific known date.

Obviously, deliveries are otherwise unpredictable, and they could go beyond 40 weeks. So, I would still vaccinate that woman and also advise her that if she then delivers within 14 days, her baby would be eligible to get monoclonal antibodies.

0:58:46.423 --> 0:58:54.863
**Catherine Radkowski (Health)**
The thing that I just remembered, sorry for jumping in Christian, but the question about niservimab in second year privately, I wonder if it…

0:58:54.33 --> 0:58:57.193
**Christian McGrath (Health)**
Catherine, I can see you're trying to look out whether that would be NIP funded.

0:59:0.63 --> 0:59:2.143
**Catherine Radkowski (Health)**
Oh, sorry, I think (IT) broke I think.

0:59:3.183 --> 0:59:4.623
**Catherine Radkowski (Health)**
It's breaking up for me at least.

0:59:5.973 --> 0:59:6.853
**Christian McGrath (Health)**
You're dropping out. Sorry.

0:59:7.293 --> 0:59:8.653
**Catherine Radkowski (Health)**
I think you're dropping out Christian.

0:59:9.53 --> 0:59:9.253
**Christian McGrath (Health)**
Oh.

0:59:11.823 --> 0:59:20.743
**Catherine Radkowski (Health)**
You're sort of back. I just wanted to perhaps, maybe Michelle or Nigel could elaborate about nirsevimab in second year and why.

0:59:22.383 --> 0:59:38.383
**Catherine Radkowski (Health)**
There wouldn't be benefit, I guess a benefit for infants who do not have the risk factors for severe RSV to get nirsevimab and why it's only funded for those at risk for severe RSV, because I think that's important to clarify.

0:59:40.643 --> 1:0:10.523
**Nigel Crawford**
Yeah, thanks. I'm happy to talk to that. So I was listening to the presentations earlier, but just yeah, turn my screen on and join now. So yeah, the key thing is the second season is really prioritising the high risks groups. I think, Catherine, you sort of alluded to that as part of the initial roll out this year, so 2025 in Victoria is the first time we're going to have broad access to nirsevimab.

So, the key is, that you know under three months is really the main group that we see hospitalised, but out to six months, really common presentation for all infants including healthy, but is higher in those higher risk groups.

1:0:10.733 --> 1:0:39.93
**Nigel Crawford**
And then going into the second season, again, those groups remain at high risk, so you still have RSV disease potentially in those populations. It's more about the more likely to have severe disease including hospitalisation, which is one of the key endpoints we'll be measuring as part of the implementation and measuring the impact of the program. So definitely will provide benefit potentially for all, but you've got to target those at most at high risk.

1:0:39.903 --> 1:0:53.663
**Nigel Crawford**
And the key thing is the dose, I think I know you alluded to that in the table essentially it's four times the dose of 50 milligrams you give to an under 5kg, in the second season, we're saying it's 200 milligrams or two 100 milligram me injection. So a substantial increase in in the amount you're using and therefore the cost, you know financially of that product.

1:0:53.853 --> 1:1:23.573
**Nigel Crawford**
So we're in a situation where we know we're fiscally constrained both at a state and a national level. So it's really about using the product for the maximum benefit. Hence, that second season, I'll just briefly comment too. There's a question here around the Aboriginal and Torres Strait Islanders. They definitely access the vaccine in the first season because it's for all children. It's more that they're being called out as a group that definitely has higher risk moving into that second season. So they're also funded for that second season dose. So, it's really just trying to call out those key groups for the second season but priority's still the first, hope that helps clarify a little bit.

1:1:23.933 --> 1:1:24.613
**Nigel Crawford**
Thanks.

1:1:25.723 --> 1:1:29.83
**Christian McGrath (Health)**
Thanks Nigel.

1:1:30.583 --> 1:1:37.903
**Christian McGrath (Health)**
Someone's asked a question about for each pregnancy, like pertussis. I think that's about the vaccine. I think Michelle and Catherine touched on it. But Michelle, did you want to add anything else?

1:1:39.43 --> 1:2:10.823
**Michelle Giles**
Yeah, I think watch this space at the moment it's not funded or there aren't recommendations for subsequent pregnancies. But we know based on our experience with other maternal immunisations, that usually a dose is required each pregnancy because some pregnancies are three years apart, five years apart, you know, eight years apart for me, so that the likelihood of needing other doses to protect the infant at the same level is high, but until we have that data, we don't have recommendations or funding for subsequent pregnancies.

1:2:13.73 --> 1:2:32.153
**Christian McGrath (Health)**
OK, someone's written a comment. I think, Catherine, we should follow offline. Don't suppose there is a tool to calculate like a pneumo tool. That's something we might be able to develop if the department's got the technology to have on the page. But that might be something to help people work through the eligibility criteria of their infants. So that's a good suggestion. Thank you.

1:2:34.23 --> 1:2:42.663
**Christian McGrath (Health)**
Is nirsevimab only given in hospital. Will the supply be given to put a second RSV season as well?

1:2:44.133 --> 1:2:45.853
**Christian McGrath (Health)**
Catherine I might go to you first, but let Nigel add anything else additional.

1:2:49.203 --> 1:3:13.683
**Catherine Radkowski (Health)**
I just do want to touch in terms of a tool, we will have a flow chart, so not a calculator, but a nice flow chart and the Australian Immunisation Handbook, also, we reuse the same flow chart, but that will be available and so providers can print it out, and it's pretty easy to follow in terms of figuring out who's eligible and what dose to give.

1:3:14.903 --> 1:3:49.463
**Catherine Radkowski (Health)**
So nirsevimab. No, it's not only going to be given in hospitals. Obviously hospitals will play a really big role in that neonate dose but first season catch up and 2nd season RSV catch up, there'll be much greater input from primary care and will be available from you know, GPs, maternal child health nurses, and so forth, Aboriginal health services, some local councils, so we're hoping it still will be easily accessible and you won't have to go into hospital to get that dose.

1:3:52.863 --> 1:3:53.863
**Christian McGrath (Health)**
Did you want to add anything, Nigel?

1:3:55.63 --> 1:4:28.13
**Nigel Crawford**
Yeah. Now just to say that definitely those high-risk groups are already actively involved in this RSV space, bronchiolitis such a common admission. We've been giving the short acting monoclonal, palivizumab, which was the monthly injection to these high-risk groups for a period of time. So, we know both the specialists and the parents are really aware, but it's only ever been the first season.

So maybe for Catherine and the team, maybe if you're giving the first dose and you know they're high risk, you could mention you know you could be recommended to dose in your second season for future years because we do need to get awareness out around those high risk groups. But there will be targeted work on those key populations. Thanks.

1:4:29.373 --> 1:4:39.133
**Christian McGrath (Health)**
Thank you. I think this is in relation to the vaccine site of administration, is that far in over a one year age. So these site of administration. Catherine I will throw to you on that one as well.

1:4:40.233 --> 1:4:55.833
**Catherine Radkowski (Health)**
I was going to throw to hopefully Nigel and Michelle because it's usually in the arm over 12 months and I might have to take that one offline as well. So if it's not the arm and we still continue in the thigh, do you know Nigel and Michelle?

1:4:57.633 --> 1:5:15.713
**Nigel Crawford**
Yeah, often in the thigh 6 months and under. So into the anterolateral thigh would also be, you know, appropriate for this product. Again, some children may be presenting for their 2, 4, 6 month vaccines at the same time. So you have to work out, you know, the location. But I think the thigh or deltoid would both be appropriate, but we'll make sure it's really clear for providers the different options.

1:5:19.973 --> 1:5:20.573
**Christian McGrath (Health)**
Thank you.

1:5:20.123 --> 1:5:20.723
**Catherine Radkowski (Health)**
Thank you.

1:5:22.543 --> 1:5:27.903
**Christian McGrath (Health)**
I think as an adult physician, I'm not so good at this one. Will the at risk stickers for the green books be updated?

1:5:31.103 --> 1:5:59.823
**Catherine Radkowski (Health)**
No, the green books are not going to be updated, so we've tried to do a bit of work on this and the green books are not consistently used and we won't make it for the next print date either. But on one of the pages you can write in, you know, nirsevimab was given. The problem is it is I think on the second page.

1:6:0.333 --> 1:6:18.863
**Catherine Radkowski (Health)**
Also it's inconsistent whether it's carried around and we want to really push that AIR should be the source of truth and we want to provide fact sheets in terms of how parents can, you know, access AIR to check whether their child’s record has been uploaded.

1:6:22.643 --> 1:6:23.843
**Christian McGrath (Health)**
Thank you.

1:6:27.903 --> 1:6:28.223
**Christian McGrath (Health)**
OK.

1:6:30.63 --> 1:6:34.423
**Christian McGrath (Health)**
Will any of your slides be available for use in upscaling maternity stuff?

1:6:36.913 --> 1:6:57.863
**Catherine Radkowski (Health)**
Yes. So the slides well, my slides at least I shouldn't say my slides because there was a whole heap of people that worked on this slides. But we will make them available on our website for exactly that reason, that you can use it to educate staff in terms of how to access the program and just to make it really clear to run through everything.

1:6:59.833 --> 1:7:4.73
**Christian McGrath (Health)**
You what is the definition of a second RSV season?

1:7:5.623 --> 1:7:8.263
**Christian McGrath (Health)**
Throw it at anyone, I'll say Nigel here.

1:7:9.543 --> 1:7:34.343
**Nigel Crawford**
Yeah, essentially, it's 2026. So I think as Catherine alluded to our main season is April till September, we do see a little bit of out of season RSV and hence the maternal program all year round, you know it's going to be the key cornerstone of the national approach. But the six-month window covers those main times and essentially, we're saying the second season, you know, for the majority will be 2026 or for those that are into their second year this year they were born you know in 2024 essentially.

1:7:35.143 --> 1:7:41.263
**Nigel Crawford**
So again, there will be calculators and dates to look around that, but essentially can think of it as an annual event. Thanks.

1:7:42.573 --> 1:7:47.853
**Christian McGrath (Health)**
RSV season is generally in our annual event in the Southern states, as Catherine said.

1:7:47.523 --> 1:8:13.323
**Michelle Giles**
So just to jump in, so we talk about second season for the infants born now, their second season is 2026, but then this RSV season may be the second season for already born infants. So you have to think about two different cohorts this year, the future, next 2nd season and the current 2nd season.

1:8:14.593 --> 1:8:34.953
**Christian McGrath (Health)**
So simplify newborn infants born this year in their first RSV season are at risk and therefore eligible for a product, and infants who are in their second season this year who are high risk are eligible for products because they're unwell. Nigel, do you want to comment on the duration of protection for the seven that because that's probably relevant to that question?

1:8:35.713 --> 1:9:17.453
**Nigel Crawford**
Yeah, it's definitely looking good out to the six months, a little bit of data may even be longer out to 9 to 12 months. Obviously our colleagues in WA and Queensland have run programs that sort of monitoring the impact. Again, they tend to see a more seasonal program apart from the northern, you know parts of those states, and we're also getting some data out of our European and US colleagues around that duration but definitely minimum of six months, potentially out to nine months, but won't be enough. Again talking about that second season, thinking you want at least 18 months of protection to take you round it, won't provide into that second season, a little at a maximum, we would have thought, you know, from first principles be diminishing protection out to potentially a little bit out to 12 months, but certainly not the second season protection from that first dose.

1:9:18.423 --> 1:9:28.143
**Christian McGrath (Health)**
So that explains why you want the product given, obviously during that RSV high-risk season and why it might need to be repeated in the second season for those high-risk individuals.

1:9:24.483 --> 1:9:24.763
**Nigel Crawford**
Right.

1:9:28.513 --> 1:9:28.713
**Nigel Crawford**
Yeah.

1:9:30.563 --> 1:9:43.843
**Catherine Radkowski (Health)**
There will be dates, so I did mention the birth dates when I was going through and that will be in the flow chart as well. So it can be easy to follow in terms of, you know, which infant is eligible for what component of the nirsevimab program.

1:9:45.753 --> 1:10:14.943
**Christian McGrath (Health)**
Thanks Catherine. There's a couple of questions about AIR and newborns. I know that's going to be addressed in some of the facts sheets online, but just there is matching based on details like address, etc. And ‘mother of’ and that, but it's a bit complicated. So the details will be online in our fact sheets in more detail, and I can see that someone's requested a link to the AIR fact sheet and Donna - wonderful Comms person, has put that link in the chat as well.

1:10:16.623 --> 1:10:18.543
**Christian McGrath (Health)**
I think I answered the next one as well.

1:10:19.53 --> 1:10:28.493
**Christian McGrath (Health)**
Alright. Can we place another January order with Onelink for this if we have already used our monthly order for January, as it wasn't available when we ordered, Catherine?

1:10:28.913 --> 1:10:39.353
**Catherine Radkowski (Health)**
Yeah. So I popped the answer in the chat. A short answer is yes. You can place a one off of Abrysvo order to make sure that you've got stock ready for the start of the program.

1:10:45.183 --> 1:10:49.783
**Christian McGrath (Health)**
It's trying to get up to date with the questions because my screen is updating, sorry.

1:10:51.303 --> 1:10:53.423
**Christian McGrath (Health)**
If someone's ready to read the next one, by all means.

1:10:53.863 --> 1:11:7.403
**Michelle Giles**
Yeah, there's a question about co-administration. I think Nigel's already mentioned it with nirsevimab with other vaccines. So Nigel, did you want to just reiterate that? I'll keep watching Christian. I can see them easily. Just let me know when they come back for you.

1:11:7.863 --> 1:11:33.383
**Nigel Crawford**
Yeah, definitely. Co-administration is fine. And I think again from the sort of neonatal maternal hospital we've been giving hepatitis B vaccine at birth, vitamin K, you know as a preventative therapy.

So I think the antenatal very aware of giving products and it's fine to give the nirsevimab at the same time as those products as well as I mentioned earlier, if they're presenting for their 2, 4, 6-month other vaccines, it's fine to give them monoclonal antibody at the same time. So, there's also a question around some of the safety.

1:11:34.183 --> 1:11:36.663
**Nigel Crawford**
Definitely very good safety profile, as a monoclonal.

1:11:37.453 --> 1:11:57.133
**Nigel Crawford**
Working different on the immune system, but no sort of major flags or side effects, you know, flagging from international national data at the moment, but obviously ongoing surveillance ongoing, important to have that 15 minutes observation post any product and notify, if you do have a reaction, if you're not sure it's causative to SAEFVIC and we'll help follow up or answer any queries if concerns. Thanks.

1:12:0.293 --> 1:12:7.493
**Christian McGrath (Health)**
I've got the questions back, will both Abrysvo and nirsevimab be funded for those not eligible for Medicare?

1:12:9.23 --> 1:12:13.183
**Christian McGrath (Health)**
I think this is best to throw to you, never an easy question unfortunately with immunisations.

1:12:13.613 --> 1:12:28.53
**Catherine Radkowski (Health)**
Yeah. So we will put a more detailed answer in the frequently asked questions, but because there's two sort of programs at play, one that's funded under the National Immunisation Program, one that's not.

1:12:29.623 --> 1:12:44.103
**Catherine Radkowski (Health)**
National Immunisation Program you do need to be a Medicare card holder, but we'll provide a bit more of a detailed answer in the FAQ's. They're not yet up on the website because we wanted to wait until after this webinar.

1:12:44.603 --> 1:12:47.323
**Catherine Radkowski (Health)**
But they will be posted soon.

1:12:49.33 --> 1:13:6.903
**Michelle Giles**
Can I just jump in just with a little bit of extra information for some population. Some population within maternity who are not Medicare holders but are potentially on working visas, or students who have private health insurance that covers maternity care.

1:13:8.543 --> 1:13:18.823
**Michelle Giles**
There is the option for them to pay for it (Abrysvo) on a private script, of course, and some depending on their level of private health insurance cover that they come with their visa.

1:13:19.413 --> 1:13:32.343
**Michelle Giles**
They may or may not be able to get that covered or reimbursed, so I just think that's another bit of information to be aware of, for a population within a larger population of non-Medicare holders.

1:13:35.773 --> 1:13:48.773
**Christian McGrath (Health)**
So another question on the Medicare and AIR check, which I said I think the team's going to make sure it’s addressed in all the AIR fact sheets with some tricks etc.

1:13:50.343 --> 1:13:55.703
**Christian McGrath (Health)**
I think we've already answered the question about vaccine orders before ordering opened.

1:13:57.343 --> 1:13:58.543
**Christian McGrath (Health)**
And ordering it once again.

1:14:0.223 --> 1:14:4.183
**Christian McGrath (Health)**
What do we advise parents?

1:14:2.203 --> 1:14:33.333
**Michelle Giles**
Sorry, Christian, can I just add, there's a, I can't I emphasise why there's a huge amount of focus on checking the AIR and for infants at the six-week check. But I just want to bring everybody's focus and attention back to the cornerstone of this program is the maternal vaccination. If a mother brings the infant to you at six weeks or comes for a six weeks check to the GP.

1:14:34.783 --> 1:15:3.103
**Michelle Giles**
First thing to check would be the mother's vaccination status to see if she actually got Abrysvo, that's the cornerstone of the program, as opposed to whether the infant got monoclonal antibody in birth suite. So just really trying to bring people's focus back to, as Catherine really, I loved your transparency and honesty Catherine at the start about the fact that monoclonals there's limited supply, there's global demand.

1:15:3.863 --> 1:15:5.943
**Michelle Giles**
The cornerstone of the program is maternal vaccination.

1:15:6.583 --> 1:15:31.983
**Michelle Giles**
So that should be the first point for of checking right checking at birth, checking at six weeks is to see whether Mum received the maternal vaccination. So sorry to sort of put that in, but I think that's because if mum did in the right time and there's no risk factors, then you don't need to be worrying about whether the baby got monoclonal antibody or not.

1:15:20.623 --> 1:15:21.663
**Christian McGrath (Health)**
Alright, that's good.

1:15:33.773 --> 1:15:54.303
**Christian McGrath (Health)**
All right. And I was going to add, hopefully the mum will know whether she's been vaccinated or not. We like to see these things documented, obviously. But you know, as part of informed consent when giving a vaccine etc, it's important to make sure mum can recall what she's been vaccinated against and why. So, I think that would be helpful as well.

1:15:56.103 --> 1:16:2.823
**Christian McGrath (Health)**
I think this one's for you, Nigel. What do we advise parents about the common and rare side effects of Beyfortus?

1:16:5.493 --> 1:16:27.893
**Nigel Crawford**
Sort of alluded to that's it's very well tolerated. Common side effects. Obviously local reaction don't tend to see much of a fever. You know this particular product obviously with co-administration you may see that from the other vaccines. I'm always on the lookout for any allergic, you know, hives or other reactions but again extremely uncommon and not highly reported. So there will be some advice that comes with the information as we flow through.

1:16:29.463 --> 1:16:34.983
**Nigel Crawford**
But the overall Information is that it's very well tolerated, not too many side effects, so minimal concerns on that side.

1:16:37.463 --> 1:16:45.623
**Christian McGrath (Health)**
Thank you. This question is slightly out of the RSV-MIPP program, but can adult older than 60 be given an Abrysvo, Michelle?

1:16:47.643 --> 1:16:49.283
**Michelle Giles**
Yes, but it's not funded.

1:16:50.663 --> 1:16:52.503
**Christian McGrath (Health)**
I think that's probably the important distinction.

1:16:55.343 --> 1:16:56.63
**Christian McGrath (Health)**
OK.

1:16:57.743 --> 1:17:2.423
**Christian McGrath (Health)**
This is a comment about.

1:17:4.503 --> 1:17:10.183
**Christian McGrath (Health)**
Being told by midwife that hospitals were not required to upload maternal vaccines to AIR, and it’s not correct.

1:17:12.343 --> 1:17:19.663
**Christian McGrath (Health)**
In short, if it's a NIP funded vaccine, it must be recorded on AIR.

1:17:21.263 --> 1:17:39.543
**Christian McGrath (Health)**
But as Catherine had alluded to earlier, there is technical issues and some health services with transfer from like electronic health records in the AIR that is a national problem, but there's been work done to try and rectify it with some health services and individual levels to try and improve that record keeping, but also for programs like this, saying that acknowledging it's really critical.

1:17:40.723 --> 1:17:46.763
**Catherine Radkowski (Health)**
It is actually mandated as well, it's legislated under the AIR Act. And the reason, I guess.

1:17:48.743 --> 1:18:3.343
**Catherine Radkowski (Health)**
The Commonwealth has not been as maybe heavy-handed is because it's a national issue in terms of this, these EMR uploading to AIR, but it is mandated. So they really should be, so that's incorrect. Sorry I just had to add that.

1:18:3.463 --> 1:18:33.983
**Michelle Giles**
And also I think there's just some confusion here about it, it really needs to be entered or uploaded via software at the point of where that woman receives it. And so vaccination status is sometimes captured on EMR in maternity settings, but that's not where it's administered. So I think we're lucky in Victoria because we do have a widespread of vaccinators for in pregnancy.

1:18:35.53 --> 1:18:55.383
**Michelle Giles**
So hopefully, over time, many of them already do upload. They know it's mandated to report to AIR, and I think that as Catherine's already articulated, most of a lot of the software problems sits with actual the health services rather than pharmacies and primary care in terms of putting on the AIR.

1:18:58.103 --> 1:19:5.623
**Christian McGrath (Health)**
I think shout out to GPs and pharmacies because they by far doing AIR better than anyone else.

1:19:7.703 --> 1:19:20.983
**Christian McGrath (Health)**
If a pregnant woman receives Abrysvo and then an infant is born of ABO incompatibility, then receives a blood transfusion, does the infant receive nirsevimab? Thank you, Nigel. I'll let you take that one.

1:19:23.123 --> 1:19:48.883
**Nigel Crawford**
Yeah. No, it's not normally a concern in terms of transfusion, other things that often comes up with live, you know, vaccines, older, you know, children one year old, if you had a transfusion, obviously, intravenous immunoglobulin, more for the infant rather than the adult. But from the maternal point of view, I don't think that would change your risk of RSV in the infant. And we'd still expect some protection. So I don't think that would change our recommendations. We'll have to look at Catherine's flow chart. But I think that would be fine just to follow it as per the standard guidance.

1:19:50.263 --> 1:19:50.703
**Christian McGrath (Health)**
Thank you.

1:19:52.863 --> 1:20:2.503
**Christian McGrath (Health)**
A question about payment to local government providers for administration of vaccine.

1:19:58.423 --> 1:20:1.103
**Catherine Radkowski (Health)**
We can take that one.

1:20:3.393 --> 1:20:23.73
**Catherine Radkowski (Health)**
Yeah. So local councils are only paid for certain childhood and adolescent vaccines. And so there is no payment similar to if councils choose to administer influenza vaccines for adults, there is no payment provided by the department for that.

1:20:26.373 --> 1:20:28.373
**Christian McGrath (Health)**
You I think Nigel's answer the next one.

1:20:31.63 --> 1:20:33.383
**Christian McGrath (Health)**
And that's the same question.

1:20:34.933 --> 1:20:43.13
**Michelle Giles**
Just to be really clear, and as I've made it is available for Aboriginal Torres Strait Islanders in the first season.

1:20:44.583 --> 1:20:49.303
**Michelle Giles**
I'm not sure why that question was asked, but just to be really clear, it is available.

1:20:49.433 --> 1:21:13.633
**Christian McGrath (Health)**
Yeah. So both the vaccine product, it's the same eligibility criteria in the first season And I think it's probably just worth calling out amongst Aboriginal and Torres Strait Island children and or infants and their mothers in the first season. But the second season, as Nigel called out, is just given that there's a higher burden of RSV disease in that population the second year of life, hence why they're also covered by the program in the second RSV season.

1:21:15.323 --> 1:21:30.603
**Christian McGrath (Health)**
This one's directed to you, Michelle. It's regarding the GBS again, not Group B strep, Guillain Barre. Would you rather let them refer back to specialist and let the specialist decide. That's from a GPasking that question.

1:21:31.53 --> 1:22:4.433
**Michelle Giles**
So, I think it depends on the confidence of the person who's providing the medical advice about and their knowledge about the implications of having a vaccine or the risk. So that discussion, the risk benefit discussion with the individual, I think I wouldn't limit to only one provider, so that the neurologist who's diagnosed the GBS, in the past might be someone who is willing and able to give that advice about a new RSV vaccine.

1:22:5.663 --> 1:22:31.23
**Michelle Giles**
Someone like myself or Nigel, who runs specialist immunisation services who provide this sort of advice all the time about future vaccinations in the setting of particular past medical history, could provide that advice. Some GPs and you know, I guess I don't think there's a black and white answer to that question about who should provide and have that risk benefit discussion.

1:22:31.833 --> 1:22:34.833
**Michelle Giles**
I think the most important point is it (discussion) needs to be had.

1:22:35.343 --> 1:22:51.513
**Michelle Giles**
And I think there should be. There is available, I suspect Catherine, on the website sort of some contact details and safety could be maybe a starting point if GPs were interested in trying to find out who they could refer to, if that's what they wanted to do.

1:22:56.853 --> 1:23:0.493
**Catherine Radkowski (Health)**
Yeah, there is some contact information and we'll make sure it's nice and clear.

1:23:1.403 --> 1:23:27.203
**Nigel Crawford**
Just adding Christian to that for the GBS, it's really been a concern if you've had that vaccine and within 42 days had GBS within the window to then have another dose. So that obviously came up with COVID vaccine. If you had had GBS that was in the vaccine potential window similar for influenza vaccines as a direct question, you know, would you give that product again to someone who's had potential temporal association, but our neurology colleagues generally been very supportive of other vaccines, definitely want to be protected.

1:23:27.993 --> 1:23:40.663
**Nigel Crawford**
Because you can get GBS from those infections themselves, so you know that's been a general approach, but totally agree with Michelle. We're very happy to have those consultations through, the specialist or SAEFVIC. And we do loop in neurology specialists, you know, as required. Thanks.

1:23:43.643 --> 1:23:49.993
**Christian McGrath (Health)**
Thank you and just noting again, the GBS signals in the over 65 group too.

1:23:52.793 --> 1:23:58.353
**Christian McGrath (Health)**
So nirsevimab is only for eligible kids, not healthy baby? If mum not vaccinated during pregnancy?

1:23:59.173 --> 1:24:1.853
**Michelle Giles**
No, it's for all (infants) if mum’s not vaccinated.

1:24:3.633 --> 1:24:25.793
**Christian McGrath (Health)**
So any child where mum's not vaccinated. But obviously we're keen to see as many mums vaccinated as possible. I think if I read the question the other way, again, no, you do not need to give nirsevimab to a healthy baby if mum was vaccinated. There's no additional benefit from giving nirsevimab in addition to Abrysvo and that would be not a good use of the vaccine.

1:24:28.553 --> 1:24:40.193
**Christian McGrath (Health)**
A baby that is born the cusp of the RSV season. So, the end of March would not be eligible for the neonatal program. Would they be considered under the first catch-up criteria? The answer is yes. Yeah, so.

1:24:39.103 --> 1:24:39.623
**Catherine Radkowski (Health)**
Correct.

1:24:41.383 --> 1:25:1.703
**Christian McGrath (Health)**
That would be obviously, if they haven't received maternal vaccine and entering their first RSV season, then they would be eligible for the nirsevimab for protection. So, I'm just going to, there's a lot of questions which is really great. It's great to have such an engaged audience, but I'm getting conscious now. We're going to start running out of time so.

1:25:3.273 --> 1:25:13.873
**Christian McGrath (Health)**
Given the 90 and 180 day data, do we aim for just 28 weeks or 32 to 36 weeks for longer term efficacy in newborn? Michelle.

1:25:14.593 --> 1:25:44.473
**Michelle Giles**
Yeah, love this question. The most important thing is you just give it so and if you have someone who's 28 weeks and there's the opportunity to vaccinate, you absolutely should take that opportunity, because you don't know at 28 weeks if she's not going to deliver at 34 weeks. So if you miss that opportunity, that baby, then I guess there is that backup of monoclonal antibodies. But I think it's an implementation problem. We have a narrow window, there's multiple vaccines. We want to give in pregnancy recommended.

1:25:44.713 --> 1:25:58.953
**Michelle Giles**
So I personally think that you should have the discussion given at 28 weeks if you can. If the woman wants time to think about it or to have it at another visit, that's fine, but I don't think we should be pushing it later.

1:26:0.513 --> 1:26:6.513
**Michelle Giles**
To try and max it like to try and push out the protection beyond the six-month window.

1:26:9.533 --> 1:26:10.53
**Christian McGrath (Health)**
Thank you.

1:26:12.833 --> 1:26:22.713
**Christian McGrath (Health)**
Like just going through all the questions, I'm trying to figure out a couple of the the good ones to follow up, one for you know that might be a good answer.

1:26:24.513 --> 1:26:27.993
**Christian McGrath (Health)**
As I'm just going through it, I'm sorry. And they're not in order anymore. Guys, I apologise for that.

1:26:29.913 --> 1:26:35.873
**Christian McGrath (Health)**
If there's past history of RSV infection before the 2nd season, does a high risk baby still need them on monoclonal antibody?

1:26:37.553 --> 1:27:3.713
**Nigel Crawford**
Yeah, they do. RSV infection doesn't actually give you longer term protection. Overall in terms of season. So, we actually see some infants present to the hospital twice in the one year. So while we're trying to optimise protection or not it won't 100% effective. So there will be some breakthrough cases and we know that duration of protection will also wear off. So regardless of both status and previous infection, you still need to proceed with that second season dose for those that are eligible.

1:27:4.153 --> 1:27:10.673
**Christian McGrath (Health)**
No worries. Thank you. And can you co-administer with infant immunisations?

1:27:11.993 --> 1:27:12.673
**Nigel Crawford**
Yes it can. Yeah.

1:27:13.133 --> 1:27:22.413
**Christian McGrath (Health)**
Yeah. And just one last question on the dosing. How critical is the five kilograms requirement for which dose is given? Do we need accurate weights from parents?

1:27:23.483 --> 1:27:53.323
**Nigel Crawford**
Yeah, I think we're lucky. We're pretty good at getting weights in that newborn period. So, I think you know, obviously most newborns will be under 5 kilos, but in that sort of one to two months can get a little bit tricky. It's it is double the dose that we're administering for those over 5 kilos, it's 50 up to 100 milligrams.

So there might be a little bit of leeway around 5 kilos, but once they're over five and a half, six, you really want to make sure you're knowing the weight and giving that appropriate dose and the appropriate vial as Catherine's outlined. So yeah, it is important to check the weight. But as I say, most babies coming in, you know, for a check or other things will have a weight to hand.

1:27:53.583 --> 1:27:58.863
**Nigel Crawford**
So would recommend that that's looked at prior to deciding on the on the dose. Thanks.

1:27:59.903 --> 1:28:15.983
**Christian McGrath (Health)**
And then if you have a question, sorry about the dosing regimen for nirsevimab, but you might just skip over, but we'll try and ensure that we covered in the FAQ's that are up on the website for people so they can refer to those just because it is getting to 7:29pm. I'm just looking if I can sneak in one more question.

1:28:18.833 --> 1:28:31.313
**Christian McGrath (Health)**
Can high risk infants be vaccinated outside the April to September window, so immunised with nirsevimab. No, it's only just during the RSV season for bang for buck for the monoclonal antibody.

1:28:34.813 --> 1:29:5.593
**Nigel Crawford**
And I agree, Christian, it's really trying to maximise that six month. That's the window we prescribed. I think it was alluded to other jurisdictions. So Darwin has an all year round season, a little bit of a different program, and for us, we want to maximise the impact of this product and really get it to those most vulnerable in April, May, so everyone on the calls obviously aware of all the information and the data now. So we want to maximise uptake to our peak seasons. Normally June and July we're seeing most of our RSV cases. So, let's work hard to get all those doses out to those vulnerable groups in those that six month period. Thanks.

1:29:6.823 --> 1:29:19.463
**Christian McGrath (Health)**
Thank you. And our apologies, I should give a shout out to council programs for their excellent AIR upload as well. So, I'm sorry for missing that, that's the danger when you praise anyone, you might miss several other people and worthy of praise, so I apologise.

1:29:21.33 --> 1:29:39.313
**Christian McGrath (Health)**
Speaking of praise, thank you to all our presenters this evening. It's really, really appreciated for sharing your expertise and insights to the program, but also to a few people who are working in the background to get the presentation up and running for us all really appreciate that. Thank you. But my biggest praise is thank you to everyone who's come as part of the audience, to come and learn about this program.

1:29:39.863 --> 1:30:13.913
**Christian McGrath (Health)**?

It's got a lot of potential benefits for the community and we really thank you for being here and encourage you to speak to your clinical colleagues etc about this program to ensure maximal uptake, because we know from interstate and overseas experience that protection against RSV makes a massive difference to children's hospitals, to GP practices just because of the really significant change in clinical presentations during the RSV season over autumn winter. So thank you for all being champions of the program basically.

1:30:14.543 --> 1:30:41.263
**Christian McGrath (Health)**
We know we haven't got to all the questions tonight despite leaving, I think 40, 45 minutes for questions, which you really just represents the engagement from this audience. So it's really exciting and thank you. We'll do our best to try and take them offline and answer them in our resources and materials because a lot of them are really, really great questions. So thank you for that. And for paying attention. So just one last, thank you to our presenters, really, really appreciated and thank you everyone. Have a enjoyable rest of your evening.

1:30:42.313 --> 1:30:42.633
**Christian McGrath (Health)**
We'll wrap up.