Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report on the results of the public consultation on the health technology assessment on immunisation against RSV in Ireland: Statement of outcomes

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.

  Health technology assessment — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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1 Introduction

A health technology assessment (HTA) is intended to support evidence-based decision-making regarding the optimal use of resources in healthcare services. Measured investment and disinvestment decisions are essential to ensure that overall population health gain is maximised, particularly given finite healthcare budgets and increasing demands for services provided.

The aim of this HTA is to provide advice to the Minister for Health and Health Service Executive (HSE) to inform a long-term policy decision regarding an RSV immunisation strategy for infants and older adults in Ireland.

The draft HTA report was published for public consultation in December 2025. This Statement of Outcomes report summarises the feedback received during the public consultation period and outlines HIQA's responses to the issues raised, including any changes that were made to the report as a result.

2 Methods

The aim of the public consultation was to seek feedback to identify any issues with the draft HTA report, to consider that feedback, and to amend the report as necessary.

2.1 The consultation process

The draft HTA was published on the HIQA website on 9 December 2025 and was available for public consultation until 20 January 2026. The consultation webpage contained a link to the draft report, a link to the online survey (using the Qualtrics platform) for online submission of feedback, and a consultation feedback form that could be downloaded. To ensure wide accessibility, feedback could be submitted via an online survey, email, or by post.

A press release was issued to a wide range of media outlets at the beginning of the consultation period, and notifications of the public consultation were posted via social media sites (X, Facebook, Instagram and LinkedIn). To maximise awareness, social media notifications were posted on the day of publication, mid-way through the consultation period, and towards the end. The findings of the draft HTA were publicised in the media. Email requests for feedback were sent to a targeted list including 48 stakeholder organisations with relevant expertise and or representing individuals who are likely to be affected by the proposed introduction of an RSV immunisation programme.

2.2 Feedback form

The template for submission comprised a general request for feedback to enable respondents to flexibly provide their submission for any aspects of the report. A copy of the submission template is provided in Appendix A.

2.3 Synthesis

Each submission was recorded (excluding personal information), read in its entirety and, where appropriate, broken down into individual components. In cases where a question was skipped by the respondent, it was assumed that there were no issues of concern specific to that question. Incomplete responses provided via the online survey platform (for example, due to someone opening the survey but not completing it) were excluded.

The submissions were stratified according to whether they were submitted on behalf of individuals or stakeholder organisations. Feedback considered broad in nature was described narratively. Due to the large quantity of feedback submitted on behalf of individuals, these responses were individually coded and categorised according to different themes. Where amendments were made to the report based on feedback, this is highlighted in the HIQA response.

3 Results

Overall, 1,290 unique and complete submissions were received during the public consultation period through the online survey on Qualtrics (n=1,256), email (n=33) and post (n=1). Of these, 1,247 were submitted on behalf of individuals and 43 were submitted on behalf of organisations. In addition, 208 incomplete responses were received via the online survey on Qualtrics and have been excluded from the summary below.

All 1,247 submissions from individuals were summarised and coded according to several themes that were identified among the submissions. A breakdown of these coding groups and corresponding themes is provided in Section 3.1, including examples of verbatim representative feedback. Feedback submitted by organisations and institutions is outlined in Table 2 Feedback submitted by organisations and institutions .

3.1 Summary of feedback

Summary of general feedback

There were 1,247 valid submissions on behalf of individuals received through Qualtrics, email and post. Respondents comprised members of the general public

(n=536; 43%), parents (n=635; 51%), and healthcare professionals (n=111; 9%) including nurses, clinicians and allied health professionals. Responses were categorised and coded into four broad thematic groupings (Table 1), relating to the burden associated with RSV, perceived benefits of RSV immunisation; RSV programme related comments and opinions; and attitudes and opinions towards costs associated with RSV immunisation.

Table 1 Themes and sub-groups recorded from public consultation survey respondents (n=1,247)

Themes and sub-groups	Coding frequency*
The burden of RSV on children, families and the healthcare system	
Burden of RSV in children	399
Burden of RSV on healthcare system	334
Burden of RSV on families	307
Personal experience of RSV illness	221
Experience of severe RSV or complications	122
Reduced severity following RSV immunisation	87
Long-term consequences of RSV (on children and family)	53
Burden of RSV on emergency departments	54
Burden associated with complications, such as travel to Dublin	21
Burden of RSV on labs due to testing of samples	<5
RSV immunisation – valuing RSV immunisation and providing resilience to the healthcare system	
RSV immunisation seen as effective	797
The benefit of RSV immunisation to the healthcare system	445
RSV immunisation providing peace of mind to parents	354
Positive experience of RSV immunisation among parents	324
The benefit of RSV immunisation to families	292
Comparing experience of an immunised and non-immunised child	146
RSV immunisation seen as safe	31
Programme of RSV immunisation (support, access, expansion, suggestions)	

Themes and sub-groups	Coding frequency*
Support for the continuation of RSV immunisation	891
Removing RSV immunisation would be bad for infants and for hospitals (due to the avoidable burden)	151
Sense of unfairness and injustice at ending access to RSV immunisation	123
Belief that their child's RSV illness could have been prevented through immunisation	79
Impression that HIQA recommended not to continue RSV immunisation	71
RSV immunisation should be expanded to more groups of children	48
Missed out on RSV immunisation due to the cut-off for eligibility for their child	31
Support for the RSV vaccination of older adults	30
Willing to pay privately for RSV immunisation	21
Support for RSV maternal vaccination	5
Prioritise infants over older adults	5
Provide immunisation in clinics instead of at home visits	<5
Suggest that RSV should be made available at a reduced cost for older adults or free for groups at increased risk	<5
Costs – the benefits of RSV immunisation are worth the cost	
The cost is worth it given the benefits	308
Concerns regarding whether the economic evaluation captures the indirect costs associated with RSV infections	246
Problem with the focus on monetary cost instead of protecting the health of infants	234
Try to lower the cost (such as through price negotiation)	22
Impression that RSV immunisation is relatively cheap	<5
Adults could pay privately for RSV immunisation if they choose	<5

*Numbers refer to the number of times the sub-theme was identified in the submissions received through the Qualtrics survey and via emails
Note: Each response may have included multiple sub-themes.

The burden of RSV

Respondents referred to the burden that RSV places on children, families and the healthcare system.

Some respondents shared their personal experience of RSV illness (n=221/1,247, 18%). Most of these responses were received from parents (n=191/221, 86%). Among parents who reported in relation to their child's experience of RSV, more than half revealed that their child had experienced severe RSV and or complications (n=108/191, 57%).

"My eldest was hospitalised as an infant in early 2022 and it was a terrifying position to be in to see your child suffering like that."

Some parents felt that thanks to RSV immunisation, their child experienced much milder illness than they otherwise could have during the RSV season (n=78/635, 12%).

"My own son received the vaccine and still contracted RSV at just six weeks old, but thankfully his illness was mild and he recovered quickly."

Almost a third of respondents (n=399/1,247, 32%) commented more broadly on the burden of RSV in children. In addition to the burden of RSV on children, many respondents highlighted that RSV places a considerable burden on families (n=307/1,247, 25%). Respondents highlighted potential long-term consequences arising from RSV illness (n=53/1,247, 4%) such as associations with asthma and wheezing in children and considerable emotional, mental and or financial strains for families.

"My daughter was hospitalised for RSV at 6 weeks old in November 2023. This resulted in a 5 night stay. She was tube fed and placed on oxygen. This was very traumatic for us as first-time parents. The emotional impact it had on us as a family is unquantifiable"

The heavy emotional and logistical burden associated with complications, such as a requirement for the transfer to Dublin for specialist care and families needing to travel, was also highlighted (n=21/1,247, 2%).

"…as she became progressively more ill it was decided she would have to move to ICU at Temple Street. We had to follow her as she was brought in an ambulance (we were unable to travel with her as a doctor and nurse needed to be on board with her) and leave our other children with family while we spent the next week in Dublin. It was such a distressing time for us all and still upsets me to this day when I think of it. When she was well enough to leave ICU she was put on a ward for the

remainder of the time she spent there. Nearly every single child on that ward had RSV".

Beyond the burden on children and families, some respondents also commented on the burden that RSV places on paediatric critical care units (n=54/1,247, 4%) and the wider healthcare system (n=334/1,247, 27%).

"Bed capacity was always limited during RSV season, difficult decisions had to be made daily regarding elective admissions and ICU admissions with ICU beds at capacity. Staff burnout and fatigue were commonplace at this time of year. The increased demand on the system from RSV infection each year pre RSV immunisation placed a significant clinical risk for the care of all children attending the hospital."

RSV immunisation

Broadly speaking, three sub-themes were identified with respect to the public's responses concerning RSV immunisation: valuing RSV immunisation, support for an RSV immunisation programme, and the potential for RSV immunisation to provide resilience to the healthcare system.

Valuing RSV immunisation

Most respondents (n=797/1,247, 64%) specifically expressed the view that RSV immunisation is effective at preventing RSV infections and or severe RSV infections.

"I believe that the RSV vaccine has saved my newborn baby from a severe RSV infection, including hospitalisation."

Compared with effectiveness, there was very little mention of safety, with only a small number of respondents specifically referring to the safety of RSV immunisation (n=31/1,247, 2%).

"*My child tolerated the vaccine well, with no significant side effects."*

Respondents included parents whose infant had been immunised with nirsevimab as part of the 2024-25 or 2025-26 HSE RSV Pathfinder Immunisation Programme (n=324/635, 51%), all of whom shared a positive experience of RSV immunisation with no negative experiences noted in the responses.

"Incredible to have this immunisation available for my son when he was 5 weeks old this year. Felt incredibly lucky hearing stories from many mothers who previously didn't have this option and ended up with babies and young children hospitalised with RSV"

"The immunisation has been instrumental in keeping my baby, a NICU baby, safe and healthy since being born in September. It's essential it's kept for future babies in the same situations"

Many parents (n=146/635, 23%) shared how their experience of the RSV season had differed when considering an infant who was immunised through the Pathfinder programme compared with their older siblings who were not offered immunisation as infants. Others talked to the benefit of RSV immunisation for parents in multi-child households with an older child in school or creche.

"My daughter nearly died at 4 months from RSV. We had been sheltered in newborn bubble with minimal visitors, she was our first baby. We didn't realise just how sick she was, nor could we fathom who she had caught it from. We were almost a month in hospital with her. Our boy had the vaccine, we were not as sheltered as it was Christmas time, he was in fact exposed to RSV and did get some mild symptoms but it didn't get worse and he recovered within a week."

Some respondents commented (n=354/1,247, 28%) that RSV immunisation provides peace of mind to parents during the RSV season, taking away what can be a period of stress, concern and or anxiety.

"Knowing he had that protection during his most vulnerable months gave me enormous peace of mind as a parent."

In addition, almost one in four respondents (292/1,247, 23%) referred to the benefit of RSV immunisation for families.

"As a parent of two young children, I have seen the benefit of the RSV vaccination. It can be a worrying time having a newborn in a house during RSV season where a sibling is in crèche/daycare and exposed to a high level of germs. I have seen severe reactions in young family members to RSV prior to the introduction of the vaccine."

"Please take into account the positive impact that this has had. As a new mother of a summer baby in 2025, I was so relieved to be able to get my son the RSV vaccine after September. This helped my mental health tremendously as I suffer with health anxiety and this settled my brain. Also, it needs to be mentioned the impact on families with babies with RSV. The financial, emotional, physical strain that it can put on parents when their small kids are hospitalised has to be worth noting"

Support for a programme of RSV immunisation

There was widespread support for a programme of RSV immunisation among respondents. The most frequently recorded code was "support for the continuation of RSV immunisation" (n=891/1,247, 71%), highlighting that almost three in four

respondents expressed support for the continuation of RSV immunisation for newborns and infants. This refers to the successful HSE RSV Immunisation Pathfinder Programme that ran during the 2024-25 and 2025-26 RSV seasons, and highlights a strong desire for it to be continued in some form going forward.

"As a paediatrician working in Ireland (CHI at Temple St) the RSV immunisation programme has been a game-changer over the past two winters… I would highly advocate for continuation and expansion of the immunisation programme."

"As a mother, I believe the RSV immunisation programme provides real, tangible benefits that go beyond what can be fully captured in models or spreadsheets. It protects babies during their most fragile months, reduces anxiety for parents, and helps prevent avoidable strain on hospitals. I strongly urge that the RSV immunisation programme be retained. Its value is evident not only in data, but in the lived experience of families like mine."

Beyond supporting RSV immunisation, there was a sense of unfairness and or injustice among some respondents (n=123/1,247, 10%) towards the suggestion that access to RSV immunisation would not be offered to newborns or infants in future seasons, along with an impression that HIQA has recommended not to continue RSV immunisation (n=71/1,247, 6%).

"The RSV immunisation programme is extremely valuable and it is extremely concerning that the cessation of the programme is being considered."

Some respondents also shared that they had missed out on RSV immunisation as part of the Pathfinder programme due to the eligibility cut-off (n=31/635, 5%), while there was a belief among some that their child's RSV illness could have been prevented through RSV immunisation (n=79/635, 12%).

"I had a baby end of August 2024 and he was not offered RSV immunisation as he was born three weeks before the date of the rolling out of the immunisation. He got RSV/bronchiolitis at 3 months old and just about avoided hospital admission. If he had received the immunisation I don't think he would have been as unwell."

Notably, very few respondents referred to support for either maternal vaccination against RSV (n=5/1,247, <1%) or for RSV vaccination for older adults (n=30/1,247, 2%). Those that did, expressed clear support for these immunisation strategies.

"I would have been equally happy to receive the vaccine myself while pregnant (as under the NHS in the UK) to pass immunity on to my child that way."

"Extremely worthwhile investment in this vaccination, for both infants and elderly. Please provide for all, regardless of the cost"

Within the HTA, different strategies for RSV immunisation were considered including the passive immunisation of infants with an extended half-life monoclonal antibody or by maternal vaccination and the immunisation of older adults. The difference in the quantity of submissions relating to various strategies is likely influenced by awareness and support for the HSE RSV Immunisation Pathfinder Programme which provided immunisation for infants with the extended half-life monoclonal antibody, nirsevimab, in the 2024/25 and 2025/26 RSV seasons. To date, there have been no such immunisation programmes in Ireland for older adults or that provided maternal vaccination for the passive immunisation of infants.

Other codes that received support from a small number of respondents included support for infants to be prioritised over older adults (n=5/1,247, <1%), and a preference for RSV immunisation to be expanded to more children (n=48/1,247, 4%). Most responses related to the immunisation of infants against RSV with nirsevimab as part of the RSV Pathfinder Programme.

RSV immunisation providing resilience to the healthcare system

Some respondents also noted that RSV immunisation provides benefits to the healthcare system in Ireland (n=445/1,247, 36%). By reducing the burden on the healthcare system, RSV immunisation can be seen as a means of providing resilience to the healthcare system.

"The impact of infant RSV immunisation extends beyond direct health gains to infants. Reductions in RSV-related hospitalisations meaningfully support hospital surge capacity and winter resilience, particularly in paediatric and emergency care settings"

"The RSV immunisation has been a wonderful breakthrough, one of the greatest advancements in Paediatric medicine over the last 10 years, resulting in a dramatic reduction in severe cases of RSV and reduction in the need for intensive care."

Some respondents also commented that removing RSV immunisation would place what could be an avoidable burden on infants and hospitals (n=151/1,247, 12%).

"This immunisation has reduced the amount of sick babies admitted to hospital. The HSE is already under immense pressure, why add to it? This is preventable"

The cost of RSV immunisation

Respondents expressed the belief that the HTA fails to capture indirect or societal costs associated with the burden from RSV and or expressed a view that RSV should be provided irrespective of its cost given its benefits.

"*fails to take into account the additional clinical, economic and societal benefits of reducing paediatric RSV infections. There are additional parents' days of productivity due to reduced childhood illness and increased hospital capacity to respond to waiting lists and surge, these are not recognized correctly in the document. Nirsevimab has been a game changer for paediatric care and should continue, unquestionability.*"

Some respondents had issues with the perceived focus on the monetary cost of RSV immunisation at the expense of protecting newborns and infants from RSV (n=234/1,247, 19%).

"An amazing vaccine saving so many lives. This simply has to be extended to all infants without any questioning. How can you put a price on the lives of babies."

Others felt that any cost associated with RSV immunisation was worthwhile given the benefits associated with preventing RSV-related illness in newborns and infants, as well as benefits to families and the healthcare system (n=308/1,247, 25%).

"The cost of this vaccine is worth every penny to ensure all children have an extra level of protection heading into each winter."

Some respondents were critical of the findings of the economic evaluation, feeling that it does not sufficiently capture indirect costs associated with RSV. The indirect costs highlighted ranged from productivity losses and emotional and financial strain on families to the impact of RSV-associated disruption to the healthcare system such as the cancellation of scheduled procedures, surge in hospital capacity and the difficult work demands placed on healthcare workers (n=246/1,247, 20%).

"*My primary concern relates to the cost-effectiveness analysis. While the use of a healthcare payer perspective aligns with standard Irish HTA methodology, this approach excludes caregiver burden and wider societal costs*"

"Although ethical, equity, and patient and caregiver considerations are discussed elsewhere in the report, these factors do not meaningfully inform the interpretation of cost-effectiveness results. Greater contextualisation of these limitations would strengthen the final conclusions."

Other comments relating to the cost of RSV immunisation included a willingness to pay privately for immunisation (n=21/1,247, 2%), and suggestions that the HSE should try to lower the cost of RSV immunisation (such as through price negotiation) (n=22/1,247, 2%).

Comments on overall readability

Through Qualtrics, there were a number (54/1,247; 4%) of responses that commented on accessibility issues with the draft report. The majority of these commented that the report was overly long and therefore difficult for laypersons to read through (n=36/54, 67%). Almost one in five comments related to readability suggested that the language of the report was too technical or lacked clarity (n=10/54, 19%).

Other issues raised included criticism of the accessibility of the report (n=3/54, 6%), a request for improved use of signposting and summary tables throughout (n=2/54, 4%), and that the plain language section was overly complicated or unclear and therefore exclusionary (n=2/54, 4%). Five respondents criticised the public consultation process, with three stating there was insufficient awareness of the consultation itself and two noting that the process and or form was not very accessible.

Positive feedback in relation to the overall readability was provided by some organisations (see section 3.1.4).

Specific comments/queries on report content

While the majority of respondents (n=1,155/1,247; 93%) concerned general views and feedback as summarised in Section 3.1.1, a limited number of respondents provided additional comments that related to specific chapters or sections of the HTA. Of those that did specify a chapter or section, the majority related to the economic evaluation (n=107). A small number of comments referred to the organisational chapter (n=13) or the overall conclusions of the HTA outlined in the discussion chapter (n=13). There was considerable overlap in the feedback provided by individuals and organisations in relation to the burden of RSV and benefits of RSV immunisation.

Feedback submitted by stakeholder organisations or institutions

A total of 43 unique submissions were received from organisations or institutions; multiple responses were received from the HSE (n=14) and Children's Health Ireland (CHI) (n=12). Of the 43 submissions, 18 related exclusively to the infant population. The feedback from some organisations was extensive and has been summarised in this document. Feedback pertinent to this HTA is outlined in Table 2.

Table 2 Feedback submitted by organisations and institutions

Number	Feedback	Response
	Age Friendly Ireland Shared Service and the National Network of Older People's Councils	
1	Age Friendly Ireland organised a focus group with members of the National Network of Older People's Councils on 12th January 2026 for the purposes of gathering the views of older people on HIQA's Health Technology Assessment on the RSV Vaccination. Members of Older People's Councils had a general awareness of the RSV virus. Two people had personal experience of the virus through a family member or friend. In one case the person (a woman in her 60s) found it hard to recover from the virus; and the other known case was also a serious infection. In relation to a potential RSV vaccination programme, members of the National Network of Older People's Councils emphasised the scale of population ageing that is facing Ireland. The CSO projections indicate that there will be 1.8 million people over the age of 65 in Ireland by 2057. The population aged 85 years and over is projected to increase from an estimated 104,300 in 2027 to 389,400 in 2057. Without a vaccination programme, the figure cited in the Plain English summary of 7,000 people diagnosed with RSV each year is likely to increase dramatically in line with the expansion of the ageing population. The Health Technology Assessment should project costs into the longer term, rather than just over the next five years. The cost benefit of a vaccination programme should be considered in the longer term. The Future Forty report published by the	We greatly appreciate the efforts of Age Friendly Ireland in organising a focus group to gather feedback from older adults. The size of the target population in Ireland including older adults is described in Chapter 3 which indicated that the size will increase based on projections from the Central Statistics Offices (CSO). As the size of the eligible population increases, the financial implications of implementing the programme will also rise. Given the finite healthcare budget, any decision to fund a technology may require stopping or reducing funding for another technology or service. In an economic evaluation, costs and outcomes are measured for the duration that is sufficiently long to capture any meaningful differences between the competing technologies (which is RSV vaccination and no vaccination in this context). As described in Chapter 4, available evidence on long-term vaccine effectiveness is limited to a maximum of three years follow-up. As such, a five-year time horizon would sufficiently capture the costs incurred and outcomes accrued from an RSV vaccination programme. Therefore, using a longer time horizon is unnecessary. The pros and cons of administering multiple vaccines in one visit are described in Chapter 7. It is important to note the

Number	Feedback	Response
	Department of Finance should be considered in relation to a long term fiscal outlook and the impact of ageing communities on health services. Members of Older People's Councils who took part in the focus group with Age Friendly Ireland would welcome this vaccination being available to older people. They would like to have an option of receiving the vaccination separately to the regular Flu and Covid vaccinations and they voiced a general concern about potential risks of getting all three at the same time. They do not agree that the vaccination should be made available only to those over the age of 80. They would prefer if the vaccination programme prioritised people with medical needs/chronic conditions, rather than defining eligibility just by age. Targeting 'at risk' groups, such as residents of nursing homes, is a good idea. Eventually, they would like the RSV vaccination to be available to all people over the age of 65, commenting that there are many people in the 60-80 age group who have respiratory problems. Members proposed that the HSE or HIQA should run an information campaign to raise awareness of the RSV virus and remind the public about tips to protect the spread of viruses. There should be information about RSV publicly available online, on social media, and in leaflets in doctors' surgeries, libraries and community facilities. The awareness campaign should advise people about what to do if they become unwell. In relation to the high costs associated with a vaccination programme, Older People's Council members consider that health is a top priority and savings could be made in other areas of government spending. They discussed measures to address the high costs outlined in the technology assessment. Some older people may be able to pay privately for an RSV vaccination, but many could not afford it. Perhaps the vaccination could be subsidised for people	service design or implementation plan is out of scope of this HTA. The cost of public campaigns is included in the economic analysis. While the HTA acknowledges the higher risk of RSV disease among those with chronic conditions, the economic evaluation was conducted for adults aged 65 years and older in the general population. Limited comorbidity data are available in Irish context to support a robust assessment of introducing vaccination in older adults with chronic conditions. The economic analysis conducted as part of the HTA suggested that a considerable reduction in the current list price of the vaccine (€165 ex VAT per dose, excluding cost of administration) would be required for vaccination of adults aged 65 years and older to be considered cost-effective. In Chapter 8 (Ethical issues), the potential inequity issue if vaccines are made available for private purchase in the absence of a funded programme are discussed.

Number	Feedback	Response
	who have some ability to pay, and made available for free to those on low incomes/medical cards. They noted that medicines and vaccination programmes are generally expensive when they are set up, but become cheaper over time. Changing costs should be reflected in long term budget estimates.	
2	Members of the National Network of Older People's Councils had queries about the following points: • Would the RSV vaccination be given on its own or at the same time as Covid and Flu vaccinations? • Would the vaccination be offered every year? • Does the RSV virus mutate and therefore require a different type of vaccination every season (similar to the flu virus)?	While the service design and implementation plan is out of scope for this HTA, in Chapter 7, which examines organisational considerations, the pros and cons of vaccine co-administration are discussed. Additionally in Chapter 4, which examines clinical efficacy, effectiveness and safety, details are provided on the duration of protection for different RSV vaccine products. In Chapter 2, it is noted that the need for a booster has not been confirmed. The strategies assessed in the HTA, as agreed with the Department of Health, included once-off immunisation for different age groups. Details of these strategies are provided in Chapter 6.
	All Island Congenital Heart Disease Network (AICHDN)	
3	Strongly support the provision of RSV vaccination for all children under 2 years of age. In relation to infants and children with congenital heart disease (simple or complex), under the terms of the All Island Congenital Heart Disease Network, the same healthcare provisions must be available to all children with heart disease, north and south of the border. At the moment, RSV vaccination is only available to children under 2 years with complex heart disease, who are felt to be particularly vulnerable.	Thank you for your feedback. As noted in Table 2.1, Chapter 2, the therapeutic indication for medicinal products authorised or recommended for authorisation by the EMA for the immunisation of infants is limited to neonates and infants during their first RSV season. Indications for the immunisation of infants up to 24 months of age is limited to those who remain vulnerable to severe RSV disease through their second RSV season. Per this table, as of

Number	Feedback	Response
		February 2026, there is no intervention authorised for the protection of those in the general population during their second RSV season. The groups at high risk of severe disease, including those vulnerable to severe RSV disease through their second RSV season have been identified by the National Immunisation Advisory Committee (NIAC) and are specified in the Chapter 18a of the Immunisation Guidelines for Ireland and in updated recommendations to the Department of Health published in March 2025. These recommendations are outlined in Chapter 2, Section 2.4.3.
	ALONE	
4	ALONE provided feedback based on their experience of working with older adults. We welcome the draft health technology assessment. RSV is a significant cause of respiratory illness in older adults, with severity increasing sharply with age. Indeed, Irish data from the 2024/25 season shows adults aged 80+ accounted for nearly half of RSV-related hospital admissions and deaths among those aged 65+. Hospitalisation rates rise steeply with age, with the highest burden in those over 80. The Health Technology Assessment states that the burden of RSV in primary care, and the number of deaths among those aged 65+ as a result of RSV, are likely underestimated. It is also stated that immunisation would result in reductions in the numbers of medically attended RSV cases, and hospitalisations. Research carried out in Italy and the Netherlands states that "the primary care burden of RSV infections among older adults is substantial and comparable with influenza" (Hak et al, 2025).	Thank you for your feedback. The burden of disease associated with RSV in older adults is described in Chapter 3 while evidence of the clinical effectiveness and safety of the RSV vaccines for older adults are presented in Chapter 4. Section 6.4.2 of the HTA describes the need for additional care that may arise among some older adults following hospitalisation due to acute respiratory illness. Within the limitations, it is highlighted that the cost of providing this care has not been incorporated into the model due to the data unavailability.

Number	Feedback	Response
	Although the Health Technology Assessment states that the benefits are at a "high financial cost", consideration should also be given to the indirect costs potentially associated with not introducing an immunisation programme. These include loss of functional independence, increased social isolation following illness, heightened demand for home support and social care services, additional strain on family carers, and higher post-hospitalisation healthcare costs. For socially isolated older people, hospitalisation can have lasting medical and social consequences, including reduced confidence, withdrawal from community life, and increased reliance on formal supports. In addition, although significant financial cost is associated with the programme, it would still result in cost savings to the HSE overall. Of note, this programme is also already funded and recommended in the UK. Failure to offer a publicly funded vaccination programme could also result in significant health inequities and financial burden. Boots currently offer this vaccine in pharmacies nationwide, at a cost of €245. For older people with fewer financial resources, this cost presents a significant barrier. Without vaccination, an ageing population will continue to experience significant negative health and social impacts following RSV infection, leading to increased care needs and reduced quality of life. On this basis, we support the roll-out of RSV vaccination for the cohorts listed above.	Additional text has been added to Chapter 8, Section 8.4.2 to highlight that older adults who are hospitalised with RSV may experience functional decline as compared with their pre-admission status, potentially requiring step-down care or increased home support at time of discharge. Text has also been added to highlight that loss of functional independence may lead to a loss of confidence, increased social isolation and additional strain on family carers. The analysis found that the implementation of a vaccination programme for older adults would have substantial financial implications. At the modelled prices, the five-year incremental budget impact for the adult-based immunisation strategies ranged from €70.6 million (vaccinating those aged 80 years and older in year one and 80 years only thereafter) to €73.7 million (vaccinating those aged 65 to 69 years in year one and 65 years only thereafter). This incremental analysis takes account of cost offsets arising from the programme. As stated in comment 1 above, a substantial reduction in the modelled vaccine price would be required for an RSV vaccination programme to be considered cost-effective in Ireland. It is important to note that the healthcare budget is finite. Decisions regarding funding in one area could impact the provision of other health technologies within the healthcare system.
	AMRIC	
5	RSV infection and hospital admissions with pressure on in-patient services Proactive infection prevention and control measures are key to supporting the response and safe delivery of care, transmission of infection and outbreak mitigation.	Thank you for your feedback. We have incorporated the suggested changes in the report as follows:

Number	Feedback	Response
	Regarding IPC the greatest impact is overcrowding and impacts of this in terms of increased disease spread, requirement to prioritise (and therefore deprioritise) certain infections over others limiting our ability to practice ideal IPC. With this is the greater risk of infection transmission between patients, staff and visitors not only of RSV itself but of all types of infections as the capacity of the hospital is stretched. Du et al demonstrate that hospitalisation of older adults was reduced by between 35–64% with vaccination. Ricco et al demonstrate a reduction of 88% in hospital admissions of babies given Nirsevimab. (Du, Ricco) Page 4: Foreword: suggest add in a statement regarding outbreaks and pressures on healthcare facilities during peak periods with co-circulation of a range of respiratory viruses. Page 20: Background: suggest add in statement regarding increased pressures on the health service provision due to increased hospitalisations/presentations and outbreaks occurring during peak periods of co-circulating respiratory viruses. Page 53: 2.4 Prevention: suggest add in departments as well as wards and avoid overcrowding (such as EDs, where possible). Suggest add consideration for managing co-circulation of other respiratory viruses during peak periods and their management, such as isolation and cohorting of different respiratory viruses as these may be managed in the same ward but in different rooms/cohorts. In a hospital/residential care setting additional infection preventative measures (transmission-based precautions) may be implemented, for example risk assessing patient placement, ensuring visiting guidelines are in place, avoiding overcrowding in wards/waiting rooms. The DOH (2023) National Clinical Guideline no. 30, IPC provides additional advice on managing respiratory tract infections through standard and transmission based precautions.	• Additional text added to the Foreword to note that periods of high circulation of RSV and co-circulating respiratory viruses can lead to overcrowding in secondary care facilities which may impact the safe delivery of care. • Additional text added to Chapters 3, 7, 8 and 9 to describe the increased pressures on safe health service provision during the periods of high circulation of RSV coinciding with those of other seasonal respiratory viruses. • Amendments made to Chapter 2, Section 2.3 Prevention.
6	RSV infections and antibiotic use	Thank you for sharing the studies that highlight the considerable rates of antibiotic prescribing associated with RSV

Number	Feedback	Response
	1. RSV infection has a considerable impact on antibiotic use. One recent study found that RSV accounts for 22.9% of antibiotic prescriptions for acute respiratory illness during RSV seasons (Hak). This study also found that RSV may contribute to antibiotic use even beyond the acute infection phase, with infants hospitalised for RSV nearly twice as likely to receive antibiotics for ARI in their first year, excluding antibiotics during hospitalisation itself. 2. Antibiotics are prescribed, often unnecessarily, in patients with RSV infection. There can be multiple reasons for this, including diagnostic uncertainty. Antibiotic use can cause harm to patients (side effects such as stomach upset, rash and collateral damage e.g. C. difficile infection and thrush) and has wider implications for society in terms of increased selective pressure for AMR. Post-RSV bacterial superinfection also increases likelihood of antibiotic use. Antibiotic prescribing rates in hospitalised adults and children with RSV are reported to range between 14-82% (Celante, Hak) 3. A significant proportion of antibiotics in Ireland are prescribed in children (PCRS data in-house). In a UK study (Miller), infants <2 years with RSV had the highest rate of antibiotic prescriptions compared to other age groups. RSV immunisation offers an opportunity to reduce antibiotic use in this cohort, where there is likely to be a significant proportion of unnecessary antibiotics being prescribed for viral RTIs. 4. In this study, older adults accounted for the highest volume of antibiotics prescribed for RSV, and they were more likely to be prescribed broader spectrum antibiotics than young children (Miller). Older adults are also more susceptible to harmful effects of antibiotics. Reducing RSV infection in older adults is likely to lead to less antibiotic use, and associated harms.	and among both infants and older adults. Additional text has been added to Section 8.4.3 to highlight this issue and noting that immunisation-related reductions in RSV infection may lead to less antibiotic use, and a reduction in antibiotic associated harms. While the importance of immunisation for tackling antimicrobial resistance is noted, it is noteworthy that an RCT by Simoes et al. and an observational study by Pérez Narc et al. identified as part of the clinical effectiveness systematic review, found no difference in antibiotic use among immunised and non-immunised infants (Chapter 4).

Number	Feedback	Response
7.	RSV in the community HIQA has appropriately identified data limitations relating to RSV burden in the community. However, the absence of evidence has resulted in a lack of narrative assessment of the likely impact on general practice, even though model inputs clearly assume GP attendances for RSV. International evidence shows that most RSV episodes are managed in primary and emergency care, and only a minority are admitted to hospitals. (Heemskerk). Including a narrative description of expected GP workload effects – reduced acute visits, improved winter capacity, fewer follow-up contacts – would provide a more complete assessment of the health-system impact of immunisation. Specific opportunities for inclusion are the Executive Summary, Burden of Disease (Ch. 3), Economic Evaluation discussion (Ch. 6), Organisational Issues (Ch. 7), and Ethical/Social considerations (Ch. 8). This would ensure the HTA fully reflects the experience of the primary-care sector, which manages the majority of RSV-related workload. RSV immunisation offers broader system-wide, operational and societal advantages that are not fully captured in the current assessment We acknowledge that some of these benefits are difficult, impractical or impossible to quantify. These could be considered for inclusion in Chapter 8 and in the executive summary. Suggested text to address the items identified above: Executive Summary – suggested addition for inclusion immediately after the description of the hospital burden reductions e.g. page 32 and also in the conclusion section Emphasise that immunisation is expected to reduce acute winter GP attendances, improve access for other patients, and support overall system resilience.	Based on this feedback, a number of amendments have been made to report to highlight the burden of RSV on primary care. These include: ○ a new Section 3.5.1 (primary care burden) detailing also the international data on GP visits ○ added text in Section 7.3.1 to note the additional organisational considerations for primary care based catch-up RSV immunisation in infancy and vaccination during pregnancy ○ additional text in Chapter 7 on the contribution of RSV to winter overcrowding including - challenges due to co-circulation of other seasonal respiratory viruses and the potential for RSV immunisation to alleviate some of this burden - added text in Section 8.4.3 to describe wider health system and societal benefits of RSV immunisation. - amendment of text in executive summary and other summary sections to highlight that given established testing practice and policies, data relating to primary care presentations are an underestimate.

Number	Feedback	Response
	Executive Summary – suggested addition for inclusion immediately after the description of the hospital burden reductions e.g. page 31, before the "Organisation Issues" section and also in the conclusion section "Beyond the clinical and economic benefits, RSV immunisation is likely to deliver wider system-level advantages by reducing pressure on the health service. A smoother winter season supports service continuity, eases staffing pressures, and reduces the recurrent media, public and political concern associated with overcrowding". Chapter 3. Burden of disease – suggested addition for section 3.5 A paragraph noting that even without precise Irish estimates, RSV is known to generate substantial GP attendances for cough, bronchiolitis, feeding concerns and parental reassurance. Immunisation would therefore be expected to reduce acute winter pressures in general practice. Chapter 6. Economic Evaluation – suggested addition for section 6.4 A short subsection within the discussion (Section 6.4) outlining that reductions in community RSV incidence would be expected to reduce acute GP consultations, follow-up visits, and calls/triage contacts, thereby freeing GP capacity during winter respiratory surges. Chapter 7. Organisational Issues – suggested addition for section 7.3 Include a short paragraph noting that primary care based catch up RSV immunisation in infancy and vaccination in pregnancy is expected to: • generate some additional scheduled vaccine appointments,	

Number	Feedback	Response
	• reduce unscheduled acute RSV attendances, • improve winter appointment availability, and that these offsetting effects should be considered explicitly. Chapter 8. Ethical/Social considerations – suggested addition for section 8.3 A short description of these non-economic but meaningful burdens, highlighting that immunisation reduces the need for medical attendance and therefore improves family wellbeing. Chapter 8. System-wide, operational, societal and political benefits of RSV vaccination – suggested addition for section 8.4 In addition to the clinical and economic benefits outlined in the draft HTA, RSV immunisation offers broader system-wide, operational and societal advantages that are not fully captured in the current assessment. Reductions in RSV incidence not only decrease hospitalisations but also alleviate pressure across the entire health system, particularly in general practice and paediatrics, where the majority of RSV related workload is managed. A smoother winter season reduces unplanned attendances, mitigates pressure on out-of-hours and emergency services, and helps stabilise staffing and service continuity. Benefits to staff morale are likely to accrue. Reducing unscheduled care would be expected to diminish the recurrent political and media pressure associated with winter overcrowding, thus strengthening public confidence in the health service. Including these wider system-level benefits would provide a more complete and realistic understanding of the value of RSV immunisation in supporting healthcare resilience.	
	Asthma Society	

Number	Feedback	Response
8	The Asthma Society of Ireland advocated for the inclusion of RSV immunisation for older adults, infants and people with asthma within the National Immunisation Programme.	Thank you for your feedback.
9	The Asthma Society noted that the Pathfinder Programme evaluation report was not referenced within this draft HTA, as it was published a week after the consultation opened. Figures and insights within are significant and should be taken into consideration. The submission outlined the findings from the evaluation report such as reductions in the total number of cases, ED presentations, hospitalisations and ICU admissions among infants born during the RSV season in 2024/25 compared with 2023/2024. There was also a marked reduction in critical care transfers with an 86% reduction in neonatal transfers, and a 74% reduction in paediatric transfers. Transfers are complex procedures requiring meticulous planning and skilled staff and utilise significant resources. It must be noted that this cost is not considered in costing models for immunisation of both infants and older people by HIQA. There was also a knock-on effect observed in primary care, with healthcare professionals noting a significant reduction in bronchiolitis among the infant cohort eligible for nirsevimab. Another secondary benefit is the reduced trauma on the family that comes with a sick children hospital.	Although the Pathfinder Evaluation report was not available prior to the public consultation, the HSE reported percentage reductions in notified cases, RSV-associated ED presentations, RSV-associated hospitalisations and ICU admissions based on comparison of outcomes for the 2023/24 and 2024/25 RSV seasons were discussed in Chapters 3, 6 and 7. Following its publication, the evaluation report in addition to other related academic publications are now formally cited in the HTA. Text in relation to other outcomes (reduction in paediatric transfers) has been added to Chapter 3, and Chapter 7. While the HTA acknowledges that RSV immunisation for infants may contribute to a reduction in critical care transfers and associated costs, these costs have not been incorporated into the models due to an absence of robust data. This is identified as a limitation of the economic evaluation (Section 6.4.2 Limitations). Similarly, the analysis did not incorporate broader knock-on effects within the health system and this is also acknowledged as a limitation. The burden of RSV on families and the healthcare system are described in Chapter 3 and Chapter 7. However, in the absence of robust data, it was not possible to quantify and include these aspects in the economic evaluation. The burden that RSV can place on families is described in Chapter 8.

Number	Feedback	Response
10	There is an increased likelihood of long-term health implications for young children who become unwell with RSV. The Asthma Society acknowledge as the authors did that more research is needed to show how causal or not the well-described associations between RSV infection in early life and subsequent wheezing/asthma are. However, in keeping with a preventative public health approach, the Asthma Society supports measures such as RSV immunisation that has potential to reduce the burden of asthma in Ireland and promote healthy lungs. A child developing asthma means a lifelong condition requiring ongoing management, including regular use of medications, repeated GP and hospital appointments, and periodic exacerbations that disrupt education, work, and family life. Beyond the clinical impact, the emotional and financial stress placed on parents and caregivers is substantial and often overlooked. A 2025 survey conducted by the Asthma Society of 623 asthma patients (or their parents) found that nearly 1 in 4 people (24%) with asthma had to go without medication in the previous three months due to cost pressures. From a health system perspective, this represents a largely avoidable long-term burden, with sustained costs related to primary care, specialist services, emergency attendances, and medication use extending far beyond the initial RSV infection. Preventing RSV in infancy through vaccination has the potential not only to reduce acute illness, but to lessen the long-term prevalence and impact of chronic respiratory disease, benefiting families and contributing to a more sustainable healthcare system.	The potential association between RSV and long-term complications, such as recurring or persistent wheezing and the development of asthma, is highlighted in Chapter 3. However as noted in the limitations of the economic evaluation (Section 6.4.2), given that causal links are not yet established, it was not possible to include these long-term sequelae in the economic evaluation. Chapter 3.5.6 describes international evidence of the risk of severe RSV-related disease in adults with asthma or COPD. Development of asthma (child) was included as an outcome in the review of the effectiveness and safety of RSV immunisation (Table 4.1); however, effectiveness was not demonstrated in the included studies. Notwithstanding this, given the biological plausibility and the additional burden of RSV in those with asthma, Section 8.4. notes that benefits of RSV immunisation in infants may also include reducing long-term consequences such as wheezing and asthma.
11	The draft HTA highlights that adults at highest risk of severe RSV include those aged 65 years and older, particularly individuals who are immunocompromised and those living with chronic underlying medical conditions, such as asthma and COPD. The report also acknowledges that, particularly in older adults, the true impact of RSV on the healthcare system is likely substantially greater than currently captured in available data.	While the HTA acknowledges the higher burden of RSV disease among adults with underlying medical conditions, it was not possible to assess the cost effectiveness of strategies specifically targeted at these groups due to a lack of relevant data. Such economic analyses require a range of epidemiological and clinical data disaggregated by risk group,

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	In this context, it is disappointing that none of the four adult-based RSV immunisation strategies assessed included a targeted approach for those most at risk of severe disease. Furthermore, no adjustment was made to account for cases likely missed due to limitations in testing and coding, and no cost modelling was presented for this key population group. This omission is significant, as older adults with chronic respiratory conditions are likely to represent the highest healthcare utilisation and associated costs during the winter months. Prioritising measures that support the health and stability of this population would therefore be both clinically appropriate and economically prudent, and should be explicitly considered within the scope of this HTA. A targeted RSV immunisation pathfinder programme for older adults with chronic lung disease, including asthma and COPD, would address this evidence gap while allowing for the collection of real-world data on uptake, effectiveness, healthcare utilisation, and cost. Such an approach would align with the HTA's acknowledgement of data limitations, support more accurate modelling of RSV burden, and provide a prevention-focused pathway to protect those at greatest risk while informing future decisions on wider programme rollout.	rather than aggregate data for the general population, to produce reliable results. However, such disaggregated data are not available. There are no national level data for Ireland that captures incidence of RSV infection among adults at higher risk of disease. Further, as outlined in Chapter 4, available data suggests no clear differences in vaccine efficacy and effectiveness between subgroups based on age, immunocompromised status, frailty, or the presence or absence of certain co-morbidities. However, by highlighting the burden of disease among individuals with comorbidity (including those with chronic lung disease) and estimating the budget impact for implementing the programme in these populations, the HTA can be used to inform a decision by the Minister for Health and HSE regarding the funding RSV vaccination for specific populations.
12	Health and quality of life for older adults with asthma are a significant concern for the Asthma Society. According to CSO data, people aged 65 years and over are the most likely to die from an asthma-related exacerbation, accounting for approximately 90% of all asthma deaths registered in 2024 . While RSV is not the cause of all asthma-related deaths in this age group, respiratory infections such as RSV are a well-recognised trigger for severe exacerbations and deterioration in asthma control. Proactively protecting older people with asthma from preventable respiratory infections represents a sound preventative health measure that can reduce avoidable morbidity and may indirectly reduce the risk of asthma-related mortality.	In Chapter 2, the increased risk of severe RSV disease among adults aged 65 years and older, particularly those with significant comorbidities including lung disease is described.
13	Beyond the direct cost impacts and potential savings of RSV immunisation for older people on the healthcare system, the report rightly highlights that wider social	In accordance with national guidelines, the base case analysis is undertaken from the healthcare (payer) perspective. A

Number	Feedback	Response
	impacts should be taken into consideration for both a cost benefit analysis and in relation to a benefit-harm balance. This can be difficult to quantify given the potential effect of illness from RSV on lost productivity and need for care. Along with this, the physical, mental, emotional, and social functioning of both vaccinated individuals and their caregivers needs to be taken into consideration. Recommendation: The Asthma Society supports the introduction of an RSV Immunisation Pathfinder Programme for older adults prioritising those with additional risk factors for severe RSV disease, such as asthma. This will generate real-world efficacy, uptake, and cost data valuable to in an Irish context.	societal perspective (which incorporates productivity loss for caregivers due to RSV infection) is presented in Chapter 6 as a secondary analysis. The HTA acknowledges the wider societal impact of vaccinating older adults, including the effects on wellbeing and social productivity of carers, as discussed in Section 8.4. However, as noted by both the Asthma Society and in Chapter 6, it is difficult to quantify the impact of RSV on productivity and quality of life in caregivers, particularly in caregivers of adults. In the absence of relevant data, the economic analysis did not include the productivity loss associated with absence from paid work for those adults caring for adults sick with RSV.
14	The Asthma society expressed concern about the low awareness of RSV and the availability of immunisation among key groups. Findings from the HSE's evaluation of the infant RSV pathfinder programme indicate that only 62% of parents recall being informed about the programme prior to delivery. This is concerning given that the perinatal period is already an intensive and often overwhelming time for families, with multiple clinical, emotional, and practical decisions to navigate. Expecting new parents to make an informed decision about RSV immunisation without adequate advance notice, clear information, or sufficient time to understand the risks and benefits places an unfair burden on families. According to the HSE report, this lack of awareness was the result of a deliberate decision by the RSV Pathfinder Programme Steering Group. Awareness of RSV and available immunisation options is similarly low among older adults. Industry research on RSV awareness in Ireland suggests low levels of awareness of RSV among older adults and their carers. Low levels of awareness among older adults and their carers risk undermining informed decision-making and	Chapter 7, which covers organisational issues, outlines that information and awareness campaigns should be considered by the HSE, if a decision was made to fund an RSV immunisation programme. Additionally, the economic analysis also incorporated the cost of public health information campaigns for both infant-based and older adult-based strategies.

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	may contribute to delayed presentation and poorer health outcomes among vulnerable groups. Improving communication, public awareness, and early engagement around RSV and the availability of vaccines is therefore essential to support informed consent, equitable uptake, and the long-term success of any RSV immunisation programme for both infants and older adults. Recommendation: The Asthma Society of Ireland supports investment in RSV public awareness campaigns to maximise uptake within eligible high-risk cohorts and thereby improve programme efficiency.	
15	Regarding the clarity or presentation of the draft assessment, Asthma Society provided the following feedback: We are happy with the clarity and presentation format utilised in this draft HTA.	Thank you for your feedback.
	Cavan General Hospital	
16	The hospital shared that they observed a 90% reduction in RSV-related admissions among neonates when comparing the year of RSV immunisation implementation with the previous year. In the submission, they listed the following areas of concern: Financial Global health Family impact Employment impact Societal deficits	Thank you for sharing your observation. As highlighted in the HTA report, the positive impact of the Pathfinder Programme was observed nationally. The report discusses the direct and indirect benefits of an RSV immunisation programme, including the avoidance of productivity loss, well-being of the family members etc. in various chapters.

Number	Feedback	Response
	Céile Care	
17	1. Plain Language Summary The summary is longer than necessary and repeats information from later sections. A more concise version that clearly separates key findings from background content would improve accessibility. 2. Burden of Disease Section The impact on infants is well described, but the burden in older adults—particularly those aged 80+ and in long-term care—is less detailed. A clearer comparison between both groups (severity, hospital stay, mortality) would add clarity. 3. Economic Evaluation Key modelling assumptions (e.g., waning immunity, uptake rates) are not always clearly referenced in the main text. A single table summarising core inputs would improve transparency. 4. Equity Considerations While conceptually strong, the section would benefit from brief, concrete examples showing how different immunisation options might affect vulnerable groups (e.g., premature infants, long-term care residents). 5. International Comparison The narrative description of European programmes is text-heavy. A simple comparative table or graphic would improve clarity. 6. Presentation of Findings	Thank you for your feedback. 1.As per response 1 above, separate Plain Language Summaries have been provided for the infant and older adult populations with additional wording changes to improve clarity and accessibility. 2. Chapter 3 of the report describes the epidemiology and burden of RSV in terms of notified cases, ED visits, hospitalisations, ICU admissions and mortality for infants and older adults. The chapter highlights that, among those aged 65 years and older, the RSV disease burden increases with age, with those aged 80 years and older accounting for a substantial proportion of this burden. The lack of Irish data (other than age-based data) specific to groups at higher risk of severe disease (including residents of long- term care facilities) is highlighted. The RSV burden among this cohort is described in terms of the number of outbreaks per season (Table 3.4). 3. The uptake rates for all modelled immunisation strategies are provided in Table 6.4. Model input parameters not provided in the main text are listed in Appendix A6.1. Model inputs regarding efficacy/effectiveness rates and the duration of effectiveness are described in Section 6.2.8.1. The relative risk rates used in the model are provided in Appendix A6.1. 4. All of the strategies evaluated in the assessment included infants or older adults in the general population. As noted above, with the exception of the age-based data, there are

Number	Feedback	Response
	Key messages on effectiveness, safety, cost, and overall conclusions are dispersed across the section. A short "Key Findings Overview" would aid comprehension. 7. Formatting and Figures Some graphs lack clear axis labels or units. Consistent labelling would support interpretation. 8. Terminology Terms such as "immunisation", "vaccination", and "antibody injection" are used interchangeably. A short definitions box early in the report would prevent confusion.	limited Irish data to support the identification of groups that might be at high risk of severe disease and or to estimate the additional burden in these groups relative to the general population. 5. Tables 2.2 and 2.3 provide a summary of nationally funded practices with respect to immunisation against RSV in infants and older adults in EU/EEA countries and the UK, respectively. 6. In line with standard processes, subsequent to the public consultation, a section detailing the Key Findings and Advice to the Minister for Health and the HSE has been drafted, which also takes consideration of the feedback received through this process. As such, separate sets of advice were prepared with respect to the infant and older adult cohorts. 7. All the tables and figures are amended as required for the formatting consistency. 8. Thank you for the suggestion. A glossary of terms is added to the report.
18	Regarding the clarity or presentation of the draft assessment, Céile Care provided the following feedback: The draft HTA is comprehensive, clear, and grounded in robust evidence. HIQA's evaluation presents a balanced analysis of safety, clinical effectiveness, cost-effectiveness, and broader system considerations.	Thank you for your feedback.

Number	Feedback	Response
	The plain-language summary is accessible and helpful for non-technical audiences. The overall structure allows stakeholders to understand both the scientific data and the practical implications for the Irish healthcare system. The finding that RSV immunisation is clinically beneficial but not currently cost-effective at expected prices is clearly articulated and logically supported by the modelling.	
	Children Health Ireland (CHI), Ireland	
19	Children's Health Ireland (CHI) advocated for the retention of the immunisation, especially and critically, for the winter 2026/2027 period, while acknowledging the economic assessment of the HTA. The submissions provided four reasons for the retention of the immunisation programme.	
20	1. Protect the opening of the new National Children's Hospital Ireland High vaccination rates in the paediatric population will be critical to enabling a safe and sustained reduction in activity across our sites ahead of the move to the new hospital. Reducing clinical activity is essential to give staff the capacity to train, prepare, and physically relocate without compromising patient care. If we experience a winter surge similar to those seen prior to the introduction of the RSV immunisation, when paediatric admissions placed significant pressure on services, this planned ramp-down would not be achievable. Strong uptake of routine and seasonal vaccinations, including RSV and influenza, will help minimise preventable illness, stabilise demand, and create the operational headroom required to support our workforce through this transition period. Data from CHI admissions before and after the introduction of the Nirsevimab program indicates a reduction in non-PICU bed days associated with a reduced RSV surge at 2,428 – equating to a cumulative cost reduction in the study period of 3.3	Thank you for your feedback. The HTA has highlighted the substantial and predictable seasonal impact that RSV has on the healthcare system in Ireland, especially in secondary paediatric healthcare services. The report also acknowledges the increased pressure on staff during seasonal RSV surges. In Chapter 3 (Epidemiology and burden of disease), the positive impact of the RSV immunisation programme observed in Children's Health Ireland (CHI) at Crumlin and CHI at Temple Street is described. Additional text has been added to the report (Chapter 7, Chapter 8, Summary Sections) to highlight that RSV immunisation would help strengthen the resilience of the healthcare services and support staff to provide safe and

Number	Feedback	Response
	million euro. Extending the RSV immunisation program to the winter 2026/7 is critical to CHI's activity ramp down plans for opening the NCHI campus on the St James site. As it currently stands within the information that is known, CHI expects to move to the new hospital in mid to late Q4 2026. If this move has to be deferred to the start of February 2027 due to an RSV surge, the cost would approximately be €3.3 Million for every month that the hospital opening has to be deferred. This would not only put an increased economic burden on CHI and the health service in general but also would place an increased general clinical and operational risk across CHI due to the age and condition of the current buildings.	effective care particularly during periods of high circulation of RSV and other seasonal respiratory viruses.
21	2. The significant impact the immunisation has had on Paediatric ICU (PICU) occupancy There has been a 70% reduction in acute PICU bed days in winter 2024/5 - with an estimated 2 million euro saving; and enabling winter spinal surgery cases to proceed due to PICU recovery option. The non IPATs/NNTP transfer of critically unwell children is a high-risk process. Critically unwell infants are required to be stabilised by adult anaesthetic teams in preparation for transfer to CHI PICUs. The journey time for these transfers can exceed 3 hours from the furthest general hospitals. Due to the changing nature of adult anaesthesiology training programmes and the increasing centralisation of neonatal surgery, the clinical experience of the accompanying anaesthesiologist is less than historical situations. There is an additional economic cost of when PICU capacity is exceeded (surge) and number of days in the year by which this is reduced.	The CHI team previously shared with us their study evaluating the impact of RSV immunisation on RSV related PICU admissions in Ireland. We have reported the findings of this study in 'Burden on tertiary hospitals' part of section 3.5.2 in Chapter 3 of the report, including the data highlighted in this submission. In accordance with national guidelines, the base case analysis is undertaken from the healthcare (payer) perspective. A societal perspective (which incorporates productivity loss for caregivers due to RSV infection) is presented in Chapter 6 as a secondary analysis. Additional text has been added to Chapter 6 to recognise that families may incur additional out-of-pocket expenses associated with healthcare attendances and hospitalisations (for example, transportation costs, subsistence). In the absence of relevant data, these costs are difficult to quantify and are noted as a limitation. Chapter 7 (organisational considerations) also discusses the burden that RSV places on the healthcare system (section

Number	Feedback	Response
	- Cost to the family unit in terms of earnings lost and accommodation/food etc. during a PICU stay. - The quantity of patients with RSV infection admitted to PICU whereby the immunisation was not given. (Parental refusal or otherwise) The data on this is incomplete but we know that this patient group make up a significant proportion of PICU admissions to CHI at Temple Street in Winter 2025. - The psychological impact of a PICU admission on the parents and family of a young child is immeasurable.	7.2.3), noting that RSV immunisation may represent a means of achieving resilience in the healthcare system during periods of traditionally high health service utilisation within the RSV season. Chapter 8 (Ethical, patient and social considerations) qualitatively describes the worry and distress among families when infants experience severe RSV illness.
22	3. Improved management of paediatric chronic diseases Reduced number of ICU admissions and intubations leads to less infants (especially males <1 year of age) with long term chronic respiratory illness/morbidity and symptoms secondary to RSV, less patients requiring follow up in Respiratory clinic, resulting in shorter respiratory OPD waiting times and lists which are already very long. Less acute admissions with RSV resulting in less patients with long term respiratory symptoms requiring follow up in Respiratory clinic, therefore reducing waiting time and waiting lists for Respiratory OPD clinics, which are already very long.	See responses to row numbers 9 and 10 above. In Chapter 8 of the HTA, we have described the benefits of RSV immunisation at the individual and population level.
23	4. Improved access to elective lists in Q4 and Q1 of the calendar year Number of children cancelled due to intercurrent RSV infection is reduced. Number of elective surgeries cancelled due to reduced bed availability caused by a surge in acute admissions with RSV is reduced. Only one MRI list under General Anaesthesia has been cancelled so far during the Winter 2025/26 season – this is significant when compared with previous years and	Thank you for highlighting the study conducted by CHI staff examining the burden of RSV at CHI at Crumlin and Temple Street during the 2023-2024 season and which is cited in the report. The findings of this study are included in the discussion section (section 3.10) of the epidemiology chapter, in the context of the positive impact of RSV immunisation in the 2024/25 season as identified also in the Pathfinder evaluation report.

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	has a huge impact when the current waiting list has over 900 children pending imaging under anaesthesia. Clinical colleagues in 2024 published a paper in the Irish Medical Journal which quantified the impact of the immunization of the hospital we are attaching the citing reference below and a link to the paper. https://imj.ie/wp-content/uploads/2025/02/RSV-Burden-on-Irelands-Tertiary-Childrens-Hospitals-1.pdf	Chapter 7 (organisational considerations) also discusses the burden that RSV places on the healthcare system (section 7.2.3).
24	Additionally, nine submissions were received from individual CHI staff members, which are summarised below. Most of these submissions described staff experiences during RSV seasons before and after the implementation of the immunisation programme. Overall, CHI staff reported that the RSV immunisation programme had a substantially positive impact on service delivery and supported the continuation of the programme. It was perceived as a 'gamechanger', associated with reductions in RSV-associated ED presentations, hospital admissions, ICU admissions, as well as reduced disease severity and shortened ICU stay. Staff observed fewer requirements for non-invasive therapies and high flow oxygen compared with previous RSV seasons. Staff also noted reduced burn out and improved patient management at the ward level. Additionally, staff reported that the immunisation helped reduce cancellations of day procedures and cardiac surgeries, easing pressure on hospital services during peak RSV season. One submission noted that prolonged ICU stays reduce overall bed availability and potentially put other children at risk due to the lack of available beds. One submission highlighted the need to raise awareness about RSV and its potential to cause severe disease, particularly among first time parents. It noted that the acceptance of RSV immunisation may be low in this group due to limited awareness of RSV and being in a stressful environment within the maternity hospital. The submission emphasised the importance of educating these parents about the disease	Thank you for sharing your experience. The benefit that RSV immunisation has for the healthcare system, along with other accounts of personal experiences of both RSV and RSV immunisation, have been identified as part of the considerable feedback received through the public consultation and described in section 3.1.1 of this summary of outcomes report. The substantial and predictable seasonal impact that RSV has on the healthcare system in Ireland is outlined in Chapters 3 and 7 of the HTA which incorporate national data from various sources, including CHI. The potential clinical role of RSV immunisation in reducing this burden is highlighted in Chapters 4, 6, 7 and 8. Cost effectiveness is one of the domains that is evaluated in a HTA to support informed decision-making. The model included cost offsets arising from health outcomes that are averted through immunisation (for example, reduction in GP visits and hospitalisations). The cost associated with ICU admissions is incorporated as part of the weighted average cost of a hospitalisation which reflect also differences in length of stay.

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	severity (for example. by sharing families experience, showing pictures) and highlighting the protective role of immunisation. The submission also described instances where parents reported difficult experiences when their children were not eligible for immunisation and subsequently became seriously unwell with RSV. Another submission reported communication gaps, noting that some parents did not receive HSE invitations and that some GPs were unaware of the programme. These issues were perceived to have contributed to missed immunisations and preventable hospitalisations. Further, the submission noted that these real-world clinical outcomes are not fully reflected in the draft, and their inclusion would strengthen the report and better inform future RSV immunisation planning. One submission disagreed with the conclusions of the HTA, while another noted that cost alone should not be the sole factor in decisions regarding continuation of the RSV immunisation programme, highlighting the associated improvements in patient outcomes and the potential to reduce pressures on the healthcare system as sufficient justification for its continuation. The importance of continuing to provide immunisation for infants and children at highest risk of severe disease was emphasised. One submission stated that a 70% reduction of RSV admissions to PICU in the 2024/25 season, compared with the previous season, represents a substantial cost saving given the daily PCIU cost of €7000.	These weighted average costs were included in the model disaggregated by age band (as per Table 6.9); the highest estimated costs were for those aged 0-2 months followed by those aged 3-5 months, likely reflecting the higher proportion of PICU admissions in these age bands. At the modelled unit prices of €301 for the extended half-life monoclonal antibody (EHL-mAb) and €165 for the maternal vaccine, the incremental cost-effectiveness ratios per QALY gained exceeded the commonly accepted willing to pay threshold required for health technologies to be considered cost-effective. However, it is important to note that cost effectiveness is not the sole consideration when deciding whether to fund an intervention. Factors such as the burden of disease, clinical effectiveness and safety, the impact on patients and families, organisational and ethical issues, which are described in detail in this HTA, are also considered. Moreover, the substantial uncertainty in relation to the likely cost and relative cost of RSV interventions to the HSE is highlighted given the absence of list prices for all the interventions considered, and the potential for price reductions through competitive tender. In Chapter 8, when considering public health ethics, it is necessary to acknowledge that the funding of interventions that are not cost effective raises ethical concerns due to the finite nature of the healthcare budget and the need for fairness in the allocation of resources.
	Child Health Public Health, HSE and Faculty of Public Health Medicine	
25	The submission from the Child Health Public Health focused exclusively on RSV immunisation for infants, and noted a disproportionate burden of severe RSV-	Thank you for your feedback.

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	associated disease, hospitalisation and intensive care use among infants. The submission highlighted that the enormous clinical impact and benefit provided to infants through RSV immunisation needs to be front and centre, so readers can be in no doubt that this has been a 'game changer' for infants, at individual and population level, from a clinical perspective. The provided feedback largely related to methodological choices within the epidemiological, economic and ethical analyses of the HTA.	
26	Omission of the targeted immunisation strategy • The model treats "no immunisation" as the main comparator, but does not consider continuation of a targeted immunisation strategy for high-risk infants (Figure 6.9, page 363). A targeted immunisation programme for high-risk infants against RSV has been in place in Ireland using palivizumab since 2005. It is highly unlikely that Ireland will revert fully to no immunisation programme against RSV due to this precedent and clinical need. Nirsevimab is best placed to replace palivizumab for this cohort due to similar clinical efficacy but longer duration of protection (avoiding the need for monthly injections during the RSV season that are required with palivizumab). • The use of no immunisation as the base model, therefore, makes the economic model presented challenging to interpret. Firstly, the epidemiology of RSV prior to the RSV Immunisation Pathfinder Programme does not represent a no-immunisation scenario – it is the epidemiology of RSV in the infant cohort when the most vulnerable have been immunised with palivizumab. This masks the most severe impacts of RSV that would be present in a true no immunisation scenario, where you would expect to see more hospitalisations, intensive care unit (ICU) admissions and deaths. • Including the targeted immunisation strategy as a comparator will likely significantly affect the Incremental Cost-Effectiveness Ratio (ICER) between that and	The HTA focuses on infants and adults aged 65 years and older in the general population. Additional text has been added to the report to highlight that publicly-funded immunisation of specified cohorts of infants and children at the highest risk of severe RSV-related disease has been available in Ireland for over 20 years. While the choice of immunisation agent may change over time (for example, from palivizumab to nirsevimab in 2024/25 in line with NIAC recommendations, and considering previous advice from HIQA that such a change would be cost saving), the advice from HIQA which relates to infants in the general population assumes the ongoing immunisation of infants and children up to two years of age at high risk of severe disease (that is, those previously identified as eligible for palivizumab in line with NIAC recommendations). Text has been added to Chapters 2, 6, 7 and 8 as well as to summary sections and the Advice document to highlight this assumption. The epidemiological inputs used in the economic model are in the context of this existing policy of providing RSV immunisation to infants and children up to two years of age at high risk of severe disease. The model used notified case data

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	the universal immunisation approach. The two approaches will retain some of the fixed costs required for both strategies, such as information technology (IT) system upgrades and programme management (Table 6.5, page 349), and some quantity of immunisation products will need to be purchased anyway.	for infants and children under two years of age from the most recent three RSV seasons (2021/22, 2022/23 and 2023/24) before the introduction of the HSE Pathfinder pilot RSV immunisation programme. As noted in Chapter 3, apart from the age-based data, there are limited Irish data to support the identification of groups that might be at high risk of severe disease and or to estimate the additional burden in these groups relative to the general population. As such, the epidemiological model did not specifically account for this cohort. However, due to the small number of high-risk infants (on average, 600 unique patients in receipt of palivizumab annually from 2019 to 2023, compared with an average of 54,000 births per year, that is, less than 1% of the total infant population), this limitation would not alter the results of the economic model. Additional text has been added to Section 6.4.2 to clarify this issue. It is considered best practice in economic evaluation of health technologies to include potential costs associated with the initial launch of any new immunisation strategy. As highlighted in Chapter 6 and in the Rapid HTA published in 2025, there are no centralised data source relating to palivizumab immunisation; the size of the high-risk cohort was estimated based on palivizumab claims data and the uptake captured in the Pathfinder pilot. As noted in Section 7.5, the National Immunisation Information System (NISS) was operationalised on 1 October 2025. Updates to this system would be required to capture RSV immunisation of infants, with additional and complexity if a maternal vaccine is adopted given the need for data linkage between the mother's and infant's record. It is also

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		important to note that the total annual costs (as shown in Table 6.5) are driven almost entirely by operational costs, including procurement and administration of immunisation products; therefore, variations in capital costs are unlikely to materially affect the results of this economic evaluation.
27	Underestimation of quality adjusted life years (QALYs) and overestimation of costs • The QALYs considered in the economic model for infants appear to only include primary care attendance, emergency department attendance and hospital admission (Table 6.2, page 346). The QALYs presented here are also very low (e.g. 2-3 days for a medically attended RSV case, and the same values are used for a 1-month-old as an 11-month-old). Intuitively, this would seem to underrepresent the burden of RSV in this population group. The extreme concern and stress for parents with sick babies having difficulty breathing, feeding and sleeping for a prolonged period (2+ weeks) but not sick enough to require hospitalisation is also not represented. It does not appear to consider the impact of intensive care unit admission and infant death (part of which is also hidden from previous epidemiological data because the palivizumab programme was in place). The calculations also do not consider post-discharge morbidity and longer-term sequelae (for example, recurrent wheeze or asthma), thereby underestimating QALY loss per infection in infancy. These QALY loss values are presented in Table 5.7, page 290. However, death is also omitted from Table 5.7. • In Table 6.9 on page 352, the cost for an average hospitalisation appears to include cost of ICU admission in the calculation. This creates an imbalance in the calculations if ICU QALYs are not considered. • The calculations used to estimate the number of hospitalisations among infants due to RSV do not align with observed experience. In Table 6.12 on page 358, the S1 model estimates 649 hospitalised RSV cases among infants aged 0-5	The following are noted in relation to the QALY data in Chapter 6 of the report: - QALY loss for hospitalised cases represents an average QALY loss for all hospitalised cases including those admitted to the ICU. - QALY losses used in the model are based on data from published studies designed specifically to measure the impact of RSV on quality of life. - QALY loss among those who do not receive an intervention is typically not considered when conducting an economic evaluation. Additionally, reliable data on the impact on the quality of life of a carer for an individual with a particular disease, and for use in economic evaluation, are lacking. - Costs and QALY losses associated with long-term consequences of RSV, such as asthma and or wheezing, were not included in the model as the causal links are not yet established. - QALY loss due to RSV-related mortality was estimated over the life course using published life tables for Ireland (section 6.2.8.3). See also response to comment 24.

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	months. However, in 2024/25, there were just 296 hospitalised cases with confirmed RSV among infants aged 0-5 months (Table 3.6, page 104). In 2024/25, there was the RSV Immunisation Pathfinder Programme, similar to model S1. This inflation in estimated hospitalisations will overestimate hospital-related costs. The no immunisation model in Table 6.12 does not appear to inflate estimated RSV-associated hospitalisations as much as the estimates are closer to those observed before the Pathfinder programme. Therefore, this underestimates the impact of an RSV immunisation programme and would likely make it appear less favourable in economic calculations.	In line with the National Guidelines for the Economic Evaluation of Health Technologies in Ireland, efficacy estimates for the immunisation products used in the economic modelling were informed by synthesised evidence from randomised controlled trials (RCTs) (Chapter 4). For nirsevimab, synthesised observational data from published studies substantiated the RCT findings (Chapter 4). While the modelling outputs for the seasonal EHL-mAb based strategy and the findings reported by the HSE for the 2024/25 Pathfinder Programme are not directly comparable, the results broadly align. Further, the infant-based model outputs broadly align with those reported by the HSE for the 2024/25 Pathfinder RSV immunisation programme. The Pathfinder Programme data provides important contextual information for the Irish setting. However, it is important to note that these data are not linked with individual immunisation status and introduces uncertainty in directly attributing observed outcomes to immunisation.
28	Wider perspective • The infant model uses a primarily static structure focused on direct protection, with no explicit allowance for indirect benefits (for example, reduced transmission to high risk older adults, less nosocomial RSV spread, and fewer hospital acquired cases in neonatal/paediatric wards); this systematically undervalues population level impact. • In the setting of universal immunisation, it is likely that antibiotic use in infancy is also reduced both through reduced superimposed bacterial infection and reduced broad-spectrum cover for an unwell baby (Antibiotic use attributable to RSV infections during infancy - an international prospective birth cohort study). Given the emerging evidence of the importance of the microbiome and how disrupting it early	As highlighted in Chapter 5, almost all economic modelling studies identified in HIQA's rapid review employed a static modelling approach; two of 16 studies used dynamic transmission models, likely reflecting a lack of available data, parameter uncertainty and insufficient evidence indicating that the target groups for immunisation are epidemiologically influential for onward transmission. One study presented a model comparison of three static models and two dynamic transmission models and reported similar outcomes for medically attended RSV cases between the static and dynamic models. The static cohort model used in HIQA's economic analysis does not capture the indirect benefits of immunisation,

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	in life can lead to increased risk of lifelong conditions such as asthma, obesity and atopy, we should consider including that as an indirect potential benefit of immunisation also (Antibiotic exposure and adverse long-term health outcomes in children: A systematic review and meta-analysis). • Another potential impact not presented is the impact on breastfeeding that RSV has. Hospitalised babies who are being fed by nasogastric (NG) tubes or parenterally can pose a huge challenge to breastfeeding, potentially leading to supplementation or early discontinuation of breastfeeding, which may not have otherwise occurred. This is compounded by the many undiagnosed community cases of RSV, for whom care at home is a very challenging time for parents, and with the challenge for a baby feeding who has RSV, and the stress placed on parents of an unwell poorly sleeping infant, is likely to lead to milk supplementation and decreased or cessation of breastfeeding. • The budget impact analysis emphasises gross programme costs over net system savings, despite documented high bed day consumption and ICU use for infant RSV; by not fully valuing released capacity in over stretched winter services (for example, postponed elective lists, diversions), the model underestimates economic and organisational benefits and the issues of higher acuity patients outside paediatric ICU who can't get in to full PICUs and they staff impact and stress potentially leading to mistakes errors. • The experience of paediatricians and general practitioners (GPs) documented in the RSV Immunisation Pathfinder Programme 2024-2025 Evaluation Report describes the RSV immunisation programme as being really important, given the drastic reduction in RSV admissions, freeing up capacity, and those patients who were admitted turned around quicker and needed less support. GPs said that they saw almost no cases of respiratory infections in the eligible cohort, and if they did see some, they were less severe.	notably the reduced transmission. This limitation is noted in section 6.4.2 and the potential impact on the results of the economic evaluation are discussed. The wider societal benefits of RSV immunisation are qualitatively described in chapters 7 and 8. However, as most of these benefits are not readily quantifiable, they are not incorporated into the economic modelling conducted from the societal perspective. See responses to row number 5 with respect to the impact of RSV immunisation on antibiotic prescribing. Section 8.3.1 of the ethics chapter notes that hospitalisation among infants may create barriers to breast feeding, thereby highlighting the benefit of immunisation in this cohort. The ethics chapter also describes the increased pressure on GPs that may result from the sharp rise in unplanned attendances during peak periods.

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29	Ethical considerations • Although the HTA has a dedicated ethics chapter, the economic decision rule effectively treats severe RSV in very young infants as equivalent to less severe morbidity in other age groups, without explicit weighting for catastrophic early life events (for example, ventilated PICU admissions or infant deaths), which many would regard as carrying higher priority. Paediatricians have called the RSV immunisation programme "a game changer" due to the dramatic reduction in severe cases of RSV and need for intensive care [RSV Immunisation Pathfinder Programme Evaluation]. This enormous clinical impact to the most vulnerable cohort in society needs to be clear, unambiguous and transparent to allow for this to inform policy decisions around RSV Immunisation. • Justice and equity considerations recognise socioeconomic gradients and the concentration of RSV burden in more disadvantaged populations, but these are not incorporated quantitatively (for example, no equity-weighted QALYs or distributional analysis), meaning that the ICERs do not reflect the programme's potential to reduce health inequalities. Additionally, should RSV immunisation no longer be offered publicly and given that it is now widely recognised by parents and clinicians as hugely effective, some parents will pay privately, which would increase baseline health inequalities. • Finally, the de facto policy shift created by the RSV Immunisation Pathfinder Programme in 2024/25 and 2025/26, already acknowledges RSV as a priority and demonstrates feasibility. The HTA makes a permanent programme look like a "new" cost rather than consolidation of existing spend.	- As outlined in the national guidelines for the economic evaluation of health technologies in Ireland, no quantitative modifiers are currently accepted for use in economic evaluations in Ireland, although factors such as disease severity and rarity can be accounted for narratively in the assessment. -The model was informed by Irish data and reflects the disproportionate burden among infants. -The enormous clinical impact is highlighted in the summary sections as well as relevant chapters of the HTA. - While local level data for individual NICUs have reported the immunisation status of individuals admitted with RSV-related complications, it is noted that the Pathfinder programme outcome data are not linked to the immunisation status of the infant. - As outlined in the national guidelines, there are significant methodological issues concerning the derivation of equity weights and the circumstances and mechanisms by which these would apply to QALY calculations. Moreover, it is noted that there is a lack of robust data to inform such analyses. Equity issues are qualitatively discussed in the ethics chapter. -The ethics chapter considers the issue of injustice if the programme is discontinued or if immunisation is made available only through private purchase.

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		- The HTA was conducted at the request of the Department of Health to inform a long-term policy decision on RSV immunisation in Ireland.
30	Feedback on the clarity or presentation of the draft HTA: Limitation transparency • The executive and plain language summaries convey strong confidence that while an RSV immunisation programme would be beneficial, it would also come at "high financial cost". While there is a paragraph noting limitations (page 30) of the economic modelling, these seem to be dismissed by the statement: "the findings of the economic evaluations presented are largely robust to data and structural assumptions with the exception of the uncertainty over the price of EHL-mAbs and vaccines" (page 31). We disagree that the only uncertainty is over the price of the immunisation products. Readers should be informed clearly of what benefits were measurable, and therefore included in calculations, and which potential benefits were unmeasurable (and therefore not included) or where there was uncertainty in measurements (e.g. QALY quantification) so they can reach their own conclusion as to whether or not an RSV immunisation programme would be worth the cost. Combination of Infant and Older Adults in a single HTA • Infants and older adults are assessed together in a single HTA, yet the epidemiology, transmission dynamics and value judgements differ markedly between these groups; this can dilute the infant case by forcing shared assumptions (for example, on discounting and opportunity cost) that are more aligned with older adult programmes than early life prevention. • This HTA is a very large document, and most of it is presented such that infants and older adults are discussed separately. It would be better if the HTA was	In line with the Guidelines for the Economic Evaluation of Health Technologies in Ireland, the base-case analysis for economic evaluation for HTA is conducted from the payer perspective. As such, indirect societal benefits are not included in the primary analysis. Probabilistic and deterministic sensitivity analyses were conducted to test the robustness of the economic model outputs which demonstrated that the findings of the economic evaluations are largely robust to data and structural assumptions, with the exception of the uncertainty over the price of EHL-mAbs and vaccines, as described in sections 6.2.10 and 6.3. Although both infant and adult cohorts are included within the HTA, the report presents distinct sections within each chapter to ensure clarity and to reflect the differing epidemiology, clinical efficacy and effectiveness of immunisation products for infants and older adults, organisational considerations, ethical issues etc. It should also be noted that separate cost-utility analyses were conducted for infants and older adults. Additionally, the summary of key findings and advice and the plain language sections have been separated into two separate sections for infants and for older adults. These documents highlight the substantial clinical benefits of immunisation programmes.

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	split into two documents. Much of the information would be duplicated but it would be easier to digest as a reader. • The Plain language summary presented is not clear or explicit on the hugely successful clinical impact that RSV immunisation has had for babies, partly because it is shared as a summary for all age groups. We might reasonably expect this summary to be the most widely read, and therefore to not appropriately represent the enormous clinical impact of the vaccine, which is challenging and may directly affect future success for RSV immunisation or be used adversely by anti-vaccine groups. RSV Immunisation Pathfinder Programme Evaluation Report now available The RSV Immunisation Pathfinder Programme 2024-2025 Evaluation Executive Summary and Technical Report have now been published by the Health Protection Surveillance Centre and are in the public domain. https://www.hpsc.ie/a-z/respiratory/respiratorysyncytialvirus/immunisation/evaluation/ These documents have previously been shared with HIQA and can now be cited in the HTA where appropriate. The evaluation report highlights the substantial beneficial impact of the RSV immunisation programme for infants, and these benefits should be reflected in the HTA document. Duplication of references Please recheck the reference list. This reference appears twice as [189] and [331]: Dahly DL, O'Brien K, Domegan L, O'Leary M, Kelly E, Hanrahan M, et al. Surveillance-based estimation of the impact of introducing a pathfinder programme for	Evidence in relation to the Pathfinder programme were highlighted in the report; however, the evaluation report is now formally cited in various sections of the report. Thank you for flagging the duplication of references, which is now corrected.

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	nirsevimab immunisation in Ireland on infant hospitalisations due to respiratory syncytial virus in 2024/2025. medRxiv. 2025:2025.04.23.25326289- to be corrected.	
	Department of Paediatric Emergency Medicine, Children's Health Ireland	
31	Department of Paediatric Emergency Medicine strongly supported the continuation of a national RSV immunisation programme, as outlined in the HTA and recommended by NIAC, based on its demonstrated clinical effectiveness and its substantial effect in reducing pressure on an already overstretched healthcare system. The submission provided feedback for the following sections of the HTA:	
32	Clinical Effectiveness (Clinical Effectiveness Sections) The assessment clearly demonstrates the proven effectiveness of RSV immunisation in reducing severe RSV disease, emergency department (ED) attendances, hospitalisations, and paediatric intensive care unit (PICU) admissions. These findings align with our experience on the ground and with international evidence from countries where RSV immunisation has been introduced. CHI experienced a 30% reduction in all cause bronchiolitis in the first full season of RSV vaccination, and a 40% reduction in admissions. Unmitigated, RSV remains one of the most significant drivers of winter paediatric ED activity, particularly among infants, and the reductions experienced in the pathfinder programme represented a major advance in paediatric population health. The submission included a graph showing a large reduction in all cause seasonal bronchiolitis emergency department attendances in the 2025/26 season compared with the previous two seasons.	Thank you for these data. As per the responses to rows 9, 10, 19, 20 and 22 above, the positive impact of RSV immunisation in the 2024/25 RSV season is documented in the report. These data have now also been added to Section 3.5.2 (Burden in Tertiary Care). The relative numbers of RSV-related and bronchiolitis- related (not otherwise specified) ED attendances and hospitalisations was analysed in the Rapid HTA published in 2025. As noted, the apparent increase in incidence of RSV-related attendances has been accompanied by a decline in seasonal bronchiolitis attendances, likely reflecting improved RSV case ascertainment due to changes in testing practices and policy. Chapter 3 highlights that RSV-related ED attendance data, particularly paediatric ED data, are likely significantly underestimated as not all those who present are tested.
33	Impact on Emergency Departments and Health System Capacity (Burden of RSV, System Impact and Modelling Sections)	Additional text has been added to the executive summary, the key findings and advice, as well as the plain language summary

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	The report recognises of the impact of RSV on healthcare capacity. Seasonal RSV surges are a key contributor to ED overcrowding, prolonged waiting times, and delayed admissions in paediatric hospitals. Reducing RSV-related attendances have demonstrated direct positive effect on patient flow, ED crowding, and overall patient safety. Respiratory viral testing is not routinely performed in children presenting to ED with bronchiolitis. The report states that the modelling used to capture ED attendance data is likely significantly underestimated in the economic modelling however it is not clear by what factor this is underestimated, nor is it clear why this doesn't impact the cost of medically attended RSV in the ED setting. ED overcrowding in Ireland has been consistently identified as a patient safety risk, with national reports linking overcrowding to poorer outcomes, including increased mortality. While much of the published mortality data focuses on adult EDs, the same systemic risks—delayed assessment, care delivered in non-clinical spaces, and reduced staff-to-patient ratios—apply to paediatric emergency settings. Additionally, there have been several serious clinical incidents in children where ED overcrowding has found to be a contributory factor on review. The draft assessment recognises these pressures. CHI data demonstrates reduction in emergency department overcrowding in the last 2 seasons associated with the introduction of RSV immunisation as part of the Pathfinder Programme. The effect on ED overcrowding deserves greater prominence in describing the benefits of RSV vaccination.	to highlight that the available data for ED presentations is an underestimate. As highlighted in Chapter 3, the impact of the RSV immunisation aside, there has been apparent trend of increasing incidence over time across all age groups. For example, the rate of ED visits in those aged 0-2 years increased from 287 to 991 per 100,000 between 2018/19 and 2023/24 (Table 3.5), with approximately a six-fold increase in notification rates in those aged 6 months and over when considering the period 2018/19 to 2024/25. It is noted that this is likely due to improved ascertainment due to changes in testing practices and policy. Therefore, while expert clinical feedback highlights that testing is not undertaken in all those who present to paediatric EDs with symptoms of RSV, the degree of under ascertainment appears to have reduced over time. Moreover, testing policies and practices differ internationally. The difference between the available data and the current true burden in the ED setting could not therefore be reliably estimated. In Chapter 6, it is highlighted that given the estimated cost of an ED visit (€474), higher rates of attendance than those used in the sensitivity analysis would not materially alter the overall results of the economic evaluation. As per responses to row numbers 5 to 7 above, text has been added throughout the report to reflect that a reduction in winter overcrowding due to RSV immunisation would provide a means of strengthening resilience in the healthcare system.

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34	PICU Capacity (Clinical and System Impact Sections) The demonstrated reduction in RSV-related PICU admissions is of particular importance. PICU capacity in Ireland is highly constrained, and winter RSV surges have significant knock-on effects across the wider healthcare system, including ED boarding and delayed admissions. Reducing PICU demand would benefit critically ill children while improving patient flow and safety throughout the emergency and planned care system.	Thank you, this has been already highlighted in the report. The burden of RSV on the healthcare system is discussed in Chapter 3 section 3.5.2 and Chapter 7 section 7.2.3.
35	Patient Experience and Quality of Care (Discussion Sections) RSV-related surges have a significant negative impact on patient and family experience. Infants often endure long waits in overcrowded ED environments while acutely unwell. By preventing RSV disease, immunisation would allow EDs to deliver more timely, family-centred, and high-quality care to all patients, not solely those with respiratory illness	As per responses to row numbers 5 to 7 above, text has been added throughout the report to reflect that a reduction in winter overcrowding due to RSV immunisation would provide a means of strengthening resilience in the healthcare system, and likely improve patient experience, quality of care and public confidence in healthcare services. Such text has been added to the Executive Summary, Chapter 7 section 7.2.3, and Chapter 8 section 8.4.3.
36	Infection Prevention and Control (Clinical Impact Sections) RSV immunisation would also reduce nosocomial transmission within hospitals. High RSV prevalence during winter increases the risk of in-hospital spread, particularly in EDs and paediatric wards where isolation capacity is limited. Lower community incidence would reduce this risk to vulnerable children in hospital, improving patient safety and operational efficiency.	As per responses to rows 5 to 7 above, additional text has been added in relation to infection protection and control issues, and the impact of RSV on the capacity and resilience of the healthcare system.
37	Workforce Impact and Sustainability (System and Organisational Impact Sections) The draft assessment rightly acknowledges system capacity constraints. From a PEM perspective, the implications for staff wellbeing and workforce sustainability are particularly important. Seasonal surges driven by RSV contribute significantly to staff burnout, sickness absence, and challenges with recruitment and retention in	As per responses to rows 5 to 7 above, text discussing the burden of seasonal surges of RSV on staff has been added to Chapter 7 section 7.2.3 and Chapter 8 section 8.4.3

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	emergency departments. Irish data consistently demonstrate high levels of burnout among ED staff. Reducing predictable seasonal pressures such as RSV would improve working conditions, support staff retention and wellbeing, and enhance the sustainability of emergency care services.	
38	Broader Societal and Economic Benefits We support the inclusion of wider societal benefits in the economic analysis, including reduced parental absenteeism, fewer missed workdays, and reduced productivity loss. From a health system perspective, reduced staff absenteeism due to illness or exposure is an additional important benefit during winter surge periods.	As per response to row number 20 above, in line with the Guidelines for the Economic Evaluation of Health Technologies in Ireland, the base-case analysis for economic evaluation for HTA is conducted from the payer perspective. It is acknowledged that an RSV immunisation programme may reduce staff absenteeism due to RSV illness within the health service and therefore represent an additional benefit from the health system perspective. However, in the absence of data that enables us to quantify this absence nationally, it cannot be incorporated into the economic modelling.
39	Additionally, the submission highlighted the following areas where clarity and presentation could be enhanced to better reflect frontline emergency care realities: Executive Summary and Conclusions While the Executive Summary reflects the clinical and economic findings, the health system benefits—particularly reductions in ED overcrowding, PICU pressure, and winter surge mitigation— could be more prominently highlighted. Greater emphasis here would strengthen the report's impact. Emergency Department Impacts (Multiple Sections and Plain Language Summary) Given that ED overcrowding represents a major patient safety issue, clearer and more prominent presentation of the reduction in ED presentations and the subsequent overcrowding would provide more clarity and relevance. While we	Text describing the burden of RSV on the healthcare system (including on risk of infection, staffing and patient safety) has been added to Chapter 3 section 3.5.2, Chapter 7 section 7.2.3 and Chapter 8 section 8.4.3. Updates have been made to the chapter key points, executive summary, as well as the additional summary of key findings and advice section. The specific limitations associated with the economic evaluation are acknowledged in Chapter 6 section 6.4.2. The summary sections have been updated to add clarity. The summary of key findings and advice and the plain language

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	understand the challenges in incorporating indirect effects into the QALYs calculations, we are of the opinion that this is a weakness of the assessment. Workforce and Staff Wellbeing The implications for healthcare staff—particularly burnout, retention, and sickness absence—are acknowledged but could be more emphasised. Explicitly linking RSV-related surges to workforce sustainability challenges in ED would strengthen the report. Infection Prevention and Control The benefits of reduced nosocomial transmission are referenced but could be more clearly presented, particularly in relation to operational challenges in EDs and paediatric wards during peak RSV periods. CHI have observed significantly fewer cancellations in scheduled activity including surgery and diagnostic imaging. Summary In summary, the draft assessment provides a strong evidence base for RSV immunisation. Improvements in emphasis and presentation—particularly around emergency department flow and overcrowding, workforce wellbeing, and system resilience—would further strengthen the report's clarity and policy relevance from a paediatric emergency medicine perspective.	sections have been separated into two separate sections for infants and for older adults.
	Department of Public Health, HSE Mid-west	
40	In their submission, the Department of Public Health, HSE Mid-west noted that there has been a marked reduction in RSV notifications in children aged 0-6 months and aged 0-4 years since the introduction of the RSV immunisation Pathfinder programme. The Department of Public Health, HSE Mid-west expressed concern about the detrimental effect that it would have on the healthcare system if this programme	Thank you for your feedback. While cost effectiveness is one the domains evaluated as part of a HTA, it is not the sole consideration when deciding whether to fund an intervention.

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	were stopped. Trust has been built in this effective intervention, and they did not believe it is beneficial to now remove that intervention because of cost alone. The cost of an immunisation programme is wider than just the cost of the vaccine/immunisation. Because the implementation of the programme has already occurred there is now a skilled workforce, an effective programme and a body of expertise, materials and communications that can be built on for future campaigns. While the catch-up campaign has been a huge success integrating it within the current childhood immunisation schedule would likely improve it further. While cost effectiveness was noted to be important, the respondents wanted to advocate as public health professionals that young babies born in future seasons in Ireland be offered this very effective and safe immunisation that will significantly reduce their likelihood of requiring admission to hospital with RSV. While the HTA has attempted to quantify costs, Department of Public Health, HSE Mid-West feel that hospitalisations at this important time in a family and babies life, are difficult to measure and the reduction seen, even at this early stage, in notifications of RSV in babies is certainly leading to improved outcomes for babies, which may be apparent in future studies. E.g., breastfeeding rates. Immunisation is a public good and we have a collective responsibility to prevent avoidable harm. The RSV immunisation programme for babies, in their opinion does this and should be continued.	The clinical effectiveness and safety of the RSV immunisation products included within this HTA, (including for nirsevimab which was used in the HSE RSV Pathfinder immunisation programme), is described in Chapter 4 and subsequently in summary sections of the report. The benefits observed from the Pathfinder programme are discussed in Chapter 3 and Chapter 7 and are noted to be consistent with those observed in the international literature (Chapter 4). The acceptability and feasibility of RSV immunisation for the infant cohort as demonstrated by the Pathfinder Programme and which achieved a cumulative uptake rate of 83% in the 2024/25 RSV season is noted in Chapter 7 of the report. The cost of developing a training module along with other once-off programme implementation costs were incorporated into the economic analysis to ensure that the full resource implications of introducing a long-term immunisation programme are appropriately captured. This also considers potential changes arising in relation to the setting in which immunisation would be provided (primary care vs. dedicated clinics for the catch-up cohort), the type of immunisation that might be provided (for example, maternal vaccine vs. EHL-mAb).
	GlaxoSmithKline (Ireland) Ltd	
41	GSK, the manufacturer of the Arexvy RSV vaccine provided comprehensive feedback. In their submission, GSK highlighted the following eight reasons in support of an RSV immunisation programme for vulnerable at-risk older adults (OAs) from season 2026-27 onwards: - Demonstrated Disease Burden of RSV in OAs	

Number	Feedback	Response
	- RSV Vaccine Clinical Efficacy, Effectiveness and Safety in OAs - Targeting High-Risk Groups of OAs maximises Impact of RSV Immunisation - Healthcare System Benefits of RSV Immunisation in OAs - Economic Analyses of RSV Immunisation in OAs - Organisational Readiness for RSV Immunisation in OAs - Equity & Ethical Imperatives for RSV Immunisation in OAs - International Precedence and Best Practice for RSV Immunisation in OAs Additionally, they provided detailed comments on the executive summary and various chapters of the report. Since the comments on the executive summary overlapped with the issues raised within the individual chapters, these are not documented separately in this report.	
42	Chapter 2 Description of technology Refer to Arexvy SmPC section 4.5: "Arexvy may be administered concomitantly with a COVID-19 mRNA vaccine, pneumococcal conjugate vaccine, herpes zoster vaccine (recombinant, adjuvanted), or inactivated seasonal influenza vaccine (standard dose unadjuvanted, high dose unadjuvanted, or standard dose adjuvanted). If Arexvy is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites." Please update the text.	Text has been amended in Section 2.4.2 in line with these details.
43	Chapter 3 Epidemiology and burden of disease and chapter 4 clinical efficacy, effectiveness and safety GSK suggested conducting a scenario analysis using the RSV- related hospitalisation data among older adults aged 75 to 79 from England and Scotland reported in Chapter 3.	The preference is generally to use RCT evidence where available, with cognisance to the quantity, quality and applicability of data available. The data that were identified via systematic review in Chapter 4 were used to inform Chapter 6, as is standard practice in our HTAs and in accordance with the national HTA guidelines.

Number	Feedback	Response
44	Chapter 6 Economic Evaluation Model structure GSK commented that the HIQA's model structure focuses on medically attended RSV only. Further, they noted that the HIQA's model does not account for the indirect effects of immunisation including herd immunity and therefore underestimates the benefits of an RSV immunisation programme in infants and children. They highlighted that RSV transmissibility is also relevant within older adults and requested that this limitation also be attributed to the modelled analyses of immunisation strategies for older adults. GSK noted that the HIQA's CEA is structured on the occurrence of medically attended RSV, but efficacy is modelled more broadly according to the general occurrence of LRTD. ED and hospitalisation rates GSK stated that the rates for ED attendance and hospitalisation in older adults seem low, are not adjusted for underdiagnosis/reporting, and ICU admissions are not modelled at all. Cost of hospitalisation GSK noted that the cost of hospitalisation used in the HIQA model is lowest in those aged 80 years and older, and that it does not incorporate costs or outcomes relating to ICU stay. Cost of GP visit GSK noted that the modelled cost for a GP visit is conservative and only attributed to a proportion of patients in the HSE perspective model.	Model structure The methodological limitations of the model are acknowledged in section 6.4.2 and discussed in the report. See response also to comment 28. As Irish surveillance data are based on notified cases, it is appropriate to use medically attended RSV data to inform the analyses. ED and hospitalisation rates As stated in the report, and recognising that not all medically attended cases of RSV are tested, a multiplier of four was applied to the notified case data observed in Ireland to estimate the incidence of medically attended RSV. Using Irish data on the number of notified RSV cases that presented at the ED and the number of notified RSV cases hospitalised (as provided by the HPSC); the proportions of medically attended cases that attend the ED and are hospitalised were estimated. As such, the multiplier was not applied to notified cases that attend the ED or are hospitalised. As not all the cases presenting to ED are tested, the incidence of RSV-associated ED attendance is likely somewhat underestimated in the model. However, it is noted that given the cost of ED attendance, higher rates of attendance than those used in the sensitivity analysis would not materially alter the overall results of the economic evaluation. There is less uncertainty regarding the hospitalisation rates. This is due to increased testing and the use of a highly sensitive diagnostic test in hospital settings, as discussed in the epidemiology chapter. ICU admissions are incorporated in the model as the Irish hospitalisation data include ICU stays.

Number	Feedback	Response
	QALY loss data GSK remarked that the data underpinning QALY losses is not reported clearly and appear to be underestimated due to selective inclusion of QoL inputs (e.g., exclusion of disutility relating to nonmedically attended RSV and ICU admission). Vaccine efficacy data The point estimates and confidence intervals for vaccine efficacy in OAs, reported by HIQA on page 344, do not align with any of the pooled analyses in Chapter 4. Additionally, HIQA present alternative input data for the relative risk of RSV in vaccinated adults for seasons 1-3 on page 610 which match neither chapter 4 nor page 344. Evidence to confirm efficacy against hospitalisation GSK referred to one study reporting patient-reported outcomes, along with several observational studies, as evidence supporting the efficacy of RSVPreF3 in reducing hospitalisation. Modelling waning immunity Despite acknowledging that immunity will likely persist for longer, HIQA's approach assumes no efficacy in years 4-5. This is not in line with standard modelling practice and results in a substantial underestimation of vaccine effectiveness. Indirect effects GSK highlighted that RSV transmissibility is relevant within OA population and across other populations. This is a clear limitation which underestimates the potential benefits from indirect effects of immunisation. However, HIQA does not attribute this limitation to evaluation of immunisation strategies targeting older adults. Please	Cost of hospitalisation The cost data provided in the appendix were used in the model. Table 6.9 has been updated to correspond with the cost data in the appendix. As described in the report, the average cost of an RSV-related hospitalisation by age group was estimated based on cost data from HIPE (provided by the HPO for the period from 2018 to 2024) and were adjusted for each age group based on the proportion of hospitalisations within each group that included an ICU stay (supplied by the HPSC). Cost of GP visit The average cost of a GP consultation for a public patient was sourced from a study that estimated unit costs for non-acute medical care in Ireland and was adjusted using the Consumer Price Index for health and relevant sub-indices. The cost was attributed only to a proportion of people with a GP visit and or medical card / GP visit card to account for the cost borne by the HSE. QALY loss data Data sources in Table 6.3 are updated. The utility data used in the modelling are conservative due to poorly reported data and sources of those data, lack of clarity around derivation of QALY loss estimates and a lack of consistent data across studies. As noted above in response to comment 24, the cost associated with ICU admissions is incorporated as part of the weighted average cost of a hospitalisation which reflect also differences

Number	Feedback	Response
	ensure that this limitation is also attributed to the modelled analyses of immunisation strategies within the older adult population. Threshold analysis GSK remarked that HIQA should acknowledge the strength of threshold analysis depends on the acceptability of model assumptions and the selected mean values used in HIQA's base case analysis and does not account for structural or parameter uncertainty.	in length of stay. As such, costs and QALYs associated with hospitalisation account for ICU admission. Vaccine efficacy As reported in Chapter 4, the vaccine efficacy estimates were based on pooled data from the RCTs. The reported efficacy against hospitalisation represented the risk ratio across all trial participants. For the purposes of modelling, the risk ratio for hospitalisation was expressed conditional on having RSV as it is only applied to medically attended RSV cases. The efficacy estimates reported on page 344 and page 610 are consistent, except for a minor typo which has now been corrected. Evidence to confirm efficacy against hospitalisation As noted above, RCT evidence were used to inform vaccine efficacy estimates. The RCTs were underpowered to detect differences in RSV-related hospitalisation between the vaccine and control groups, as outlined in Chapter 4. Waning There were no robust data to model waning efficacy beyond the third season. Threshold analysis Methodological limitations are noted in section 6.4.2.

Number	Feedback	Response
45	**Budget Impact Analysis** GSK suggested presenting the breakdown of the BIA according to subgroup (those aged 60-74 with additional risk factors for severe disease due to comorbidity, those aged 75+, those aged 60+ and living in LTCF) and year of time horizon. GSK identified a typo in the Strategy 6 description. GSK suggested the vaccine administration cost should not be applied to the LTHCF strategy as the vaccination would be undertaken by the HSE staff.	The BIA was conducted and reported as agreed with the Department of Health. It is not feasible to report findings for every possible permutation. The identified typo has been amended. RSV vaccination for adults would be a new programme and therefore it cannot be assumed that existing staff could absorb this additional workload. As outlined in Chapter 7, RSV vaccination would represent a third seasonal vaccine for this cohort and may necessitate a second visit to the LTCF, given a potential preference not to co-administer three vaccines. The conservative approach is to assume that additional staff would be required and therefore an additional cost would be incurred in administering a new vaccine.
46	**Chapter 7 Organisational considerations** GSK suggested a stepwise implementation of the older adult programme targeting those aged 80 years and older, followed by those aged 75-79 years and those living in the LTHCFs as an alternative to manage the demands. GSK commented on the timing of the vaccine administration and the co-administration with other vaccines.	The BIA has estimated the budget impact for different age groups and those living in the LTCFs to support the Minister for Health in assessing the financial implications. As described in the organisational issues chapter, vaccination will have most impact if administered just before the RSV season due to evidence of the waning immunity. The chapter also outlines the potential benefits and limitations associated with co-administration of the vaccine.
47	**Chapter 9 Discussion** GSK requested an appropriate balance in the wording to highlight the benefits versus disease burden in older adults as was presented for infants and not to focus	The HTA described the benefit-risk balance of immunisation among infants and older adults based on the burden of the disease and the available data on clinical efficacy, effectiveness and safety of different immunisation products. As noted in Chapter 4, the potential harms that are associated with

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	observations on the risk of rare GBS side effects. Further, GSK indicated that they are working to generate long-term efficacy data beyond three years.	immunisation must be considered in the context of the potential clinical benefit within the given population. Post-marketing surveillance studies evaluating the safety of adult RSV vaccines suggest a small potential increase in GBS cases with vaccination, although these events remain rare. The relative potential for benefit and harm in different subgroups of older adults are also reflected in the updated NIAC recommendations for older adults, which recommended moving from an age-based to a risk-based recommendation for those aged 54 to 74 years.
	HSE representative	
48	In terms of providing RSV Vaccination to older adults the Mobile Vaccination Team could support the roll out of this programme in long term care residential facilities. While the RSV vaccine can be co-administered with Covid 19 and the flu vaccine I would be of the view that administering three vaccines during one residential care setting visit would present a barrier to take up. In my view the RSV vaccine would need to be delivered in the RCF's in the weeks prior to the Winter Vaccination Programme commencing in early October. Consideration should be given to a 4 to 6 programme to deliver RSV commencing the last week in August and finishing at the end of September. Mop up RSV vaccinations can be offered when the Mobile Vaccination Teams are back on these sites for the Covid/Flu Vaccinations commencing early October. Consideration needs to be given to ensure that that all vaccinators employed under the new vaccinator grade code regardless of their original qualifications are authorised to deliver RSV. A proportion of staff currently employed as vaccinators are from an EMT background.	Thank you for your feedback. We agree that organisational points noted here would need to be considered in the event of implementing a programme of RSV immunisation. These points broadly align with the considerations discussed in Chapter 7 of the report. Should a decision be taken to implement RSV immunisation for a particular cohort, a detailed implementation plan would need to be developed by the HSE, who are responsible for the operational delivery of immunisation programmes. Such implementation plans are typically developed in consultation with the stakeholders who are responsible for delivering this care.

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	NIAC currently recommended adults aged 60 years and older living in long term care facilities should be vaccinated. Therefore the cohort of RCF residents in both North Dublin IHA's in (private and public) would be in the region of 4,000. The Pathfinder Programme to offer hospital based RSV administration to infants after birth in the maternity unit has achieved high coverage rates. However the RSV catch up programme delivered by the Mobile Vaccination teams within community settings did not achieve the same strong demand for vaccination. The proposal to administer a catch up programme in GP practice setting in line with the approach to the Primary Childhood Immunisation Schedule is welcome. Extending this proposal to include Community Pharmacies is also welcome. To mitigate against the large number of infants involved and the requirement to immunise as close to the start of the RSV season as possible the Mobile Vaccination Team can offer in parallel to the GP/Community Pharmacies approach a two to three week burst of bookable local clinics in Primary Care Centres using the same approach as this year's RSV catch up but reducing the time span of the programme from 6 weeks. This would need to be heavily advertised and the shorter time programme period be leveraged ed to create a sense of urgency about the need for vaccination. Consideration should be given to promoting the RSV catch up by giving to parents of all infants born from the 1st March onwards (Pathfinder finishes in February) a leaflet on discharge promoting the RSV catch up campaign. Any Mobile Vaccination Team activity should again be scheduled for the September to avoid overlap with the Winter Vaccination Programme.	
	HSE Clinical Programme for Paediatrics	

Number	Feedback	Response
49	The National Clinical Programme for Paediatrics and Neonatology (NCPP&N) strongly supports the continuation and full implementation of a nationally funded RSV immunisation programme for infants in Ireland. The RSV Immunisation Pathfinder Programme has already demonstrated that RSV immunisation is not merely clinically effective in trials, but that it is transformative in practice. The programme has delivered measurable reductions in severe disease in the youngest infants, reductions in hospital admissions, improved patient flow, and significant relief of winter pressures across paediatric acute services. These are high-value health system gains which must be protected and sustained. Discontinuation or downgrading of the programme would represent a major reversal in child health protection, and would predictably lead to avoidable hospitalisations, avoidable ICU admissions, and avoidable morbidity in infancy. RSV is consistently one of the leading causes of acute respiratory illness requiring hospitalisation in infants. The HTA rightly recognises that the burden is greatest in early life, particularly in infants aged under 6 months. The early signals from the Pathfinder Programme have provided real-world confirmation that protection in this age group translates into meaningful clinical benefit at population level. From a paediatric service perspective, RSV immunisation has delivered system-wide benefits: ▪ fewer infants requiring hospital admission for bronchiolitis/pneumonia ▪ shorter lengths of stay and lower acuity of admitted cases ▪ reduced demand for escalation, high-flow oxygen, and critical care pathways ▪ reduced requirement for transfer of children from across Ireland to Intensive Care in Children's Health Ireland ▪ reduced "spill over" winter capacity risks for children with other acute illness	Thank you for highlighting these points. In Chapter 3 section 3.5.2 the reductions in RSV-related outcomes in 2024/25 compared with 2023/24 are described, reflecting the impact of the RSV Immunisation Pathfinder Programme. The discussion section of Chapter 3 also refers to the HSE's reporting on the impact of the RSV Immunisation Pathfinder Programme, with an estimated reduction in notified cases, ED presentations, RSV-related hospitalisations and RSV-related ICU admissions in 2024/25 compared with the same period in 2023/24. The clinical efficacy, effectiveness and safety of RSV immunisation products are described in Chapter 4. In addition, Chapter 7 section 7.2.3, notes the potential for RSV immunisation to provide a means of achieving resilience in the healthcare system by preventing the worst of seasonal surges of RSV-related cases requiring access to primary and secondary healthcare services during the RSV season. Chapter 8 describes also the impact RSV can have on patients, families and caregivers.

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	▪ protection of safe flow through emergency departments and paediatric assessment units These benefits extend far beyond individual episodes of care and include the prevention of crowding-related harm and the prevention of care delays for other children during winter surges.	
50	Methodological Concerns While we acknowledge the rigour and breadth of HIQA's work, NCPP&N shares concerns raised in the Public Health consultation response that certain modelling decisions appear to systematically underestimate programme benefits and overestimate programme costs. Comparator scenario: "no immunisation" is not a realistic policy baseline The economic model heavily relies on "no immunisation" as the principal comparator. This is not a credible policy option for Ireland. A targeted immunisation programme for high-risk infants has existed for two decades (palivizumab). Even if the universal programme was altered, Ireland will almost certainly continue with immunisation of high-risk infants. The absence of a realistic comparator (for example, "targeted immunisation only") limits interpretability and may distort conclusions. QALY valuation likely underestimates true burden in infancy The QALY losses applied for infant RSV appear low and limited to short episodes (primary care / ED / hospitalisation), without reflecting: • parent distress and disruption when infants are unwell for prolonged periods at home • post-discharge morbidity • longer-term respiratory sequelae in early childhood • ICU-associated morbidity and family impact	Thank you for your comment. As per response 26 above, additional text has been added to the report to highlight that the Advice from HIQA which relates to infants in the general population assumes the ongoing immunisation of infants and children up to two years of age at high risk of severe disease (that is, those previously identified as eligible for palivizumab in line with NIAC recommendations). With respect to the QALY valuations: - QALY losses used in the infant model are based on data from published studies designed specifically to measure the impact of RSV on quality of life. - QALY loss associated with long-term consequences of RSV, such as asthma and or wheezing were not included in the model as the causal links are not yet established. - QALY loss among those who do not receive an intervention is typically not considered when conducting an economic evaluation. Additionally, reliable data on the impact on the quality of life of a carer for an individual with a particular disease, and for use in economic evaluation, are lacking.

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	• mortality impacts in infants (rare, but critical in valuation) This approach risks systematically undervaluing what RSV prevention actually delivers for infants and families. Organisational and system-value benefits are likely underestimated The organisational domain is essential for RSV because winter RSV surges create acute, high-risk capacity shocks in paediatric services. Reduced RSV admissions: • releases inpatient and ED capacity during winter peaks • reduces cancellation of elective lists • reduces boarding and cohorting risks • reduces staffing strain and associated patient safety risk • reduces "near miss" escalation events caused by system overload These are not marginal benefits — they are central determinants of safe paediatric care delivery during winter. Real-world evidence: Pathfinder Programme outcomes must be weighted heavily The HTA notes substantial reductions in RSV burden in the youngest infants after implementation of the Pathfinder Programme in 2024/25. From a frontline paediatric clinical perspective, these findings align strongly with operational experience across Irish hospitals: • lower bronchiolitis volumes in eligible cohorts • lower acuity cases presenting • improved flow and fewer admissions • reduced burden on paediatric wards and escalation pathways	- QALY loss for hospitalised cases represents an average QALY loss for all hospitalised cases including those admitted to the ICU. - QALY loss due to RSV-related mortality was included in the model estimated over the life course using published life tables for Ireland (section 6.2.8.3). In terms of organisational aspects and evidence from the RSV Immunisation Pathfinder Programme - Chapter 3 describes the burden of RSV in Ireland and highlights the disproportionate burden in infants and young children. Section 3.5.2 describes the reductions in RSV-related outcomes in 2024/25 compared with 2023/24, reflecting the impact of the RSV Immunisation Pathfinder Programme. The discussion section of Chapter 3 also refers to the HSE's reporting on the impact of the RSV Immunisation Pathfinder Programme, with an estimated reduction in notified cases, ED presentations, RSV-related hospitalisations and RSV-related ICU admissions in 2024/25 compared with the same period in 2023/24. These positive impacts are noted to be consistent with the national and international evidence, including the clinical efficacy, effectiveness and safety of RSV immunisation products as described in Chapter 4. In addition, Chapter 7 section 7.2.3 notes the potential for RSV immunisation to provide a means of achieving resilience in the healthcare system by preventing the worst of seasonal surges of RSV-related cases requiring access to primary and secondary healthcare services during the RSV season. Chapter 8 also describes the impact RSV can have on patients, families and caregivers.

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	The real-world impact provides compelling justification to continue the programme pending longer-term strategy decisions. A successful seasonal national intervention should not be destabilised after demonstrating early, meaningful benefit. Equity and child-centred care A universal infant RSV immunisation programme is consistent with principles of: • child-centred care • prevention of avoidable hospitalisation • reducing inequities related to access to timely paediatric services • protecting infants at highest baseline vulnerability (youngest age groups) • reducing disruption and burden on families during a critical developmental period Stopping the programme would disproportionately harm those already most impacted: • young infants • families facing barriers to accessing care rapidly • infants with vulnerability not captured by "high-risk" eligibility criteria Cost assumptions / market evolution (Chapter 6 – Economic Evaluation): The unit cost used for immunisation should be interpreted cautiously as the initial Pathfinder Programme procurement was linked to a single supplier with constrained availability; future procurement is likely to occur in a more competitive and stable market, with potential for improved availability and more favourable pricing.	
51	Conclusion and recommendation The National Clinical Programme for Paediatrics and Neonatology strongly recommends:	Thank you for your feedback. We have responded to these individually above.

Number	Feedback	Response
	1. Continuation of the national RSV infant immunisation programme without interruption. 2. Formal adoption of a long-term RSV infant prevention strategy, aligned with NIAC recommendations and evolving international practice. 3. Revision of the economic modelling approach to include: o a realistic targeted-immunisation comparator o improved valuation of infant/family burden (QALYs) o fuller inclusion of system-capacity and organisational benefits From both a clinical and service delivery perspective, infant RSV immunisation is a high-value intervention with demonstrated real-world impact in Ireland. Disinvestment would be clinically regressive, operationally high-risk, and contrary to our objectives for safe winter care.	
52	Feedback on clarity/presentation of the report Overall, the draft HTA is comprehensive and clearly structured. However, we highlight the following issues relating to clarity/presentation: • Comparator clarity / policy baseline (Economic Evaluation – Chapter 6): The use of "no immunisation" as the principal comparator requires clearer signposting as it is not reflective of current Irish practice (targeted prophylaxis exists for high-risk infants). This framing risks misinterpretation of economic findings and should be clarified in the model description and conclusions (Chapter 6: Sections 6.2 Methods and 6.5 Conclusion). • Pathfinder Programme should be more prominent in summary/conclusions (Epidemiology Chapter 3; Organisational Chapter 7; Executive Summary): Preliminary Irish real-world evidence from the HSE RSV Immunisation Pathfinder Programme is highly policy-relevant but is not sufficiently foregrounded in the Executive Summary and overall conclusions (Executive Summary; Chapter 3; Chapter 7). The report itself notes Pathfinder findings (including reductions in RSV burden) (e.g. Chapter 3: Section 3.2 and relevant burden sections including Section 3.5).	Thank you for this feedback. As per responses 26 and 50 above, text has been added within the report including Chapters 2, 6 and the summary of findings and advice at the beginning of the report to clarify that the Advice from HIQA assumes the ongoing immunisation of infants and children up to two years of age at high risk of severe disease (that is, those previously identified as eligible for palivizumab in line with NIAC recommendations). As per response 50, there is reference to the findings from the RSV Immunisation Pathfinder Programme throughout the report. This includes in the executive summary where the substantial reductions in the RSV burden in those aged less than six months in the 2024/25 season compared with previous seasons are highlighted.

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	• Modelled vs non-modelled outcomes (Chapters 6 and 7): The report would benefit from more explicit differentiation between outcomes captured quantitatively in the economic model versus wider health service impacts described qualitatively only (e.g. winter capacity/ED crowding). A brief summary table would improve transparency (Chapter 6; Chapter 7: Section 7.2 Organisational implications).	Chapter 6 discussion details the limitations of the economic model and the challenges in modelling a number of outcomes due to a lack of robust data.
	HSE Department Public Health Dublin and South East	
53	This feedback has been collated by Department of Public Health HSE Dublin and South East. It has also been reviewed by Martina Queally, Regional Executive Officer HSE DSE, and she is in agreement with the below. As a regional Department of Public Health we strongly support the continuation of the infant RSV immunisation programme. We would like to share some general feedback on the HTA from the perspective of a regional Public Health department. At the outset we consider that the infant and older adult programmes are significantly different and these assessments should be presented separately. Initial signal from data collected over the past 2 years shows a significant reduction in hospitalisation for infants with RSV and a substantial reduction in ICU admissions in the cohorts that received immunisation. Overall, in our region, there was a 56% reduction in infant cases of RSV from 2023/24 to 2024/25 and a 72% reduction in 2025/26 compared to the 2023/24 RSV season. 47% of inpatient cases locally were in infants less than 12 months of age in the 2023/24 season. Following the pathfinder campaign this fell to 34% in 2024/25 season and 24% for the 2025/26 season. Similar trends were seen for Emergency Department cases, in the 2023/24 season 40% of ED attendances due to RSV were in the <12 months age group. This proportion dropped to 29% and 20% for the 2024/25 and 2025/26 seasons respectively. This HTA refers to data from Pathfinder 1 which was akin to the S1 scenario from 2024-2025 season; we now are seeing the significant real world effectiveness in Ireland of Pathfinder 2, akin to S2, although we are still in the winter	Thank you for sharing the regional data. Chapter 3 section 3.5.2 details national level data on reductions in RSV-related outcomes in Ireland for 2024/25 compared with previous seasons, indicating the impact of the RSV Immunisation Pathfinder Programme. In Chapter 6 section 6.4.2, the incidence of RSV in Ireland is acknowledged to be highly uncertain and it is noted that the notified case data are likely an underestimate of the total burden. While the notified case data was used as a starting point to estimate the incidence of medically attended RSV, a multiplier of four was applied, which was based on relevant international data. Thank you for highlighting additional factors to be considered. While the quantifiable direct impacts of RSV on the healthcare system have been described in Chapter 3, in Chapter 7 section 7.2.3 a qualitative discussion is provided of the impact of seasonal surges on the healthcare system, and which notes the potential for RSV immunisation to support resilience in the healthcare system by preventing surge-related burden.

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	season it would be important to refer to these impacts also in this report as a brief update. Regarding immunisation for older adults, RSV contributes to respiratory outbreaks in residential care facilities(RCFs) in our area. These outbreaks not only cause morbidity and mortality in residents but also lead to upstream effects in clinical care due to delayed hospital discharges secondary to a reduction in RCF bed availability. These data are likely an underestimate of the total burden of RSV particularly in primary care, as not all RSV cases are laboratory confirmed and some discharges may not be coded. Increased use of PCR multi-pathogen testing will provide further clarity on RSV rates in older persons and will increase case ascertainment. Particularly in congregate residential settings for older persons where outbreaks of acute respiratory infection occur in which the underlying pathogen is not always identified. We may be currently underestimating RSV impact in older persons. In addition to these findings, we also consider that the following additional factors should be taken into account, particularly regarding the assessment of the infant immunisation programme. This programme was highly acceptable to parents, in an environment of stalling or falling childhood vaccinations due to increased vaccine disinformation and misinformation there was a very high uptake rate for eligible infants. This reinforces the importance society places on infant health and shows that parents widely recognise how effective this programme is. The reduction in infant RSV cases also has wider benefits to the health system. Prior to the introduction of the immunisation programme winter surges of RSV led to >100% paediatric ICU bed occupancy in tertiary hospitals as well as significant strain on regional hospital paediatric departments. The knock-on implications for	In line with the Guidelines for the Economic Evaluation of Health Technologies in Ireland, the base-case analysis for economic evaluation for HTA is conducted from the payer perspective. As such, indirect societal benefits are not included in the primary analysis. The guidelines highlight that a societal perspective may also be adopted as a secondary analysis, if warranted. This was done within this HTA. However, it is noted that the inclusion of any outcome is subject to the availability of robust evidence and relevant and reliable data needed to estimate effects, QALYs and costs. Chapter 8 provides a qualitative description of the impact RSV can have on patients, caregivers and families. In this chapter ethical considerations, including justice and equity are also discussed.

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	patient safety and impact on the provision of other necessary care is unable to be accurately quantified in financial terms. Indirect societal benefits of reducing primary infant cases are not accounted for in this model. Hospital stays are known to impact negatively on infant development as well as exposing families to additional financial burden through missed work and added expenses. RSV's impact on breastfeeding is another overlooked concern. Hospitalized infants requiring NG tubes or parenteral feeding face significant breastfeeding challenges, often resulting in supplementation or early weaning. This extends to the many undiagnosed community cases, where the combination of infant feeding difficulties, disrupted sleep, and parental stress frequently leads to formula supplementation or breastfeeding cessation. This is on a background of Ireland having the lowest breastfeeding rates in Europe and one of the lowest globally1. This programme also reduces health inequities, which again we appreciate is difficult to capture in financial analysis but essential to include in this assessment. Our mobile vaccination teams were able to specifically target and perform outreach clinics to communities that we know are at increased risk of respiratory illness and all-cause morbidity such as international protection applicants and members of the travelling communities. Uptake of maternal vaccinations (such as pertussis and influenza) is suboptimal in Ireland limiting the effectiveness of such a programme and introduction of a programme based on maternal vaccination is likely to increase inequity. Finally the pathfinder programme has been running for 2 years and has received widespread publicity. As such an ongoing RSV immunisation programme does not truly represent a new cost and the HTA should reflect same, it also needs to be acknowledged that it may be seen as unjust if future infants are now not offered the same level as protection as those who have been eligible for the pathfinder programme over the last 2 seasons.	

Number	Feedback	Response
	1. Gillian Paul, Niamh Vickers, Regina Kincaid, Denise McGuinness, 'It's far from the norm': breastfeeding beyond 1 year in the Republic of Ireland, Health Promotion International, Volume 39, Issue 4, August 2024, daae088, https://doi.org/10.1093/heapro/daae088	
	Irish Gerontological Society	
54	The Irish Gerontological Society (henceforth referred to as 'the IGS' or 'the society') welcomes both the publication of the Draft health technology assessment (HTA) of immunisation against respiratory syncytial virus (RSV) in Ireland, and the opportunity to provide feedback as part of the current public consultation process. Founded in 1951, the IGS is one of the oldest multidisciplinary societies in the world concerned with Gerontology. The society is an all-Ireland interdisciplinary professional organisation which enables research and education that translate into age-attuned practices and policies. The Society's mission comprises improving the experience of ageing through advocating and promoting excellence in issues and practices that are important to the well-being, health, support, and care of older adults. As such, our submission relates to RSV immunisation in older adults as opposed to infants. The HTA appropriately recognises the significant disease burden that RSV infection imposes on older adults. Epidemiological data highlight that this burden increases with age, particularly impacting those aged 80 years and older, as well as high-risk individuals aged over 65. The authors of the HTA state that morbidity and mortality related to RSV in this country are likely to be underestimated, dependent as they are on laboratory confirmation, hospital coding, and data gleaned from death certificates. We further emphasise this point, and highlight that the true burden of disease imposed by RSV in older adults may be far higher. RSV-related illness may precipitate functional decline, prolonged deconditioning, and delirium among frail older adults and those with multi-morbidity. These outcomes are often not captured	Thank you for your feedback. The HTA acknowledges that the identified data for adults aged 65 years and older are likely an underestimate of the total burden in this age group, particularly at primary care level. As highlighted in response 33 above, Chapter 3 highlights the apparent trend of increasing incidence over time across all age groups, likely reflected improved ascertainment due to changes in testing policy and practices, with this most notably the case for adults presenting to secondary healthcare services in the last few years. The underestimate of the burden in primary care is highlighted within the document (Chapter 3, Chapter 6) and in the key findings and advice to the Minister for Health that has been added to the report. To account for the possible underestimation of the burden, a multiplier of four was applied to the notified cases to derive the incidence rates used in the economic model. The HTA also notes the potential requirement for post-discharge rehabilitation, particularly among frail older adults. However, in the absence of robust data, these costs are not incorporated in the economic model and is acknowledged as a limitation of the economic model. Chapter 7 section 7.2.3 notes the potential for RSV immunisation to provide a means of achieving resilience in the

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	in routine data, hospital coding, or economic models, yet they are highly relevant to patients, families, and health and social care services. From a health systems perspective, RSV-related admissions in older adults significantly add to winter bed pressures, prolonged lengths of stay, and delayed discharges. Even modest reductions in RSV-associated hospitalisation may yield disproportionate benefits for health system resilience during peak winter periods. Whilst vaccine uptake varies internationally, vaccination appears generally acceptable to older adults in Ireland. As highlighted in Section 9.1.2 of the HTA, Irish uptake data for other respiratory viruses demonstrate increasing uptake with age, reaching, for example, 89.6% in those aged 80 years and older in the 2024/25 influenza season. Influenza vaccination uptake appears even higher in high-risk cohorts, reaching 98% among those enrolled in the HSE's Chronic Disease Management Treatment Programme. These figures arguably augur well for the success of any potential immunisation programme in older adults in Ireland. This hypothesis is further supported by real-world data from Scotland where the first year of an RSV vaccination programme in older adults saw uptake in 70.7% of the total eligible population. The society is cognisant of healthcare budgetary constraints and the necessity for an RSV vaccination programme to represent an efficient use of healthcare resources in Ireland. In this context, we advocate for the provision of vaccination in line with NIAC guidelines. NIAC recommends RSV vaccination for those: (a) aged 75 years and older, (b) aged 60-74 years with any additional risk factors for severe RSV disease, (c) aged 60 years and older living in long-term care facilities for older adults. As highlighted above, and in the HTA, severe disease and associated adverse outcomes are more prevalent with increasing age, and in high-risk individuals. The inclusion of adults in long term care settings is also, we believe, essential. Frailty is highly prevalent in long term care settings and, as highlighted by the authors of the HTA, residents in these settings may not have the ability to control their exposure to	healthcare system by preventing the worst of seasonal surges of RSV-related cases requiring access to primary and secondary healthcare services during the RSV season. Chapter 8 also describes the impact RSV can have on patients, families and caregivers. Although these benefits were not included in the economic model, they are noted to be important considerations for the decision-maker in the context of an RSV vaccination programme for older adults. As noted in Chapter 3, achieving a high uptake rate is important for an immunisation programme to achieve the best outcomes. The uptake rates used in the economic evaluation were informed by the uptake of other seasonal respiratory virus vaccines (influenza) in Ireland and evidence from RSV programmes implemented internationally. These data indicate that comparable high uptake may be possible for RSV immunisation, if supported by proactive health information campaigns, which would contribute to the overall success of the programme. While the HTA acknowledges the higher risk of RSV disease among those with comorbidity and those living in long-term care facilities, the economic evaluation was conducted for adults aged 65 years and older in the general population. However, the HTA estimates the budget impact for implementing the programme in these populations and can be used to inform a decision by the Minister for Health and HSE regarding the funding of the RSV vaccination for specific populations.

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	infection. Provision of vaccination in keeping with NIAC guidelines represents a judicious use of resource, and would, we believe, significantly reduce the burden of disease imposed by RSV on older adults, as well as the broader healthcare system.	
	Irish Heart Foundation	
55	The Irish Heart Foundation conveyed their strong concern for the vulnerability to infectious diseases among their patient network and the need for protective interventions to minimise their risk.	
56	<u>Section 3: Description of the Health Problem (Burden of Disease)</u> The Irish Heart Foundation supports the findings in Section 3.5.5 regarding the disproportionate risk faced by vulnerable populations. The report states hospitalisation rates are 11.1 times higher among high-risk individuals aged 65-74 compared with their low-risk peers (p,129). It also identifies the highest RSV incidence among individuals with a history of transplantation and those with severe underlying cardiopulmonary conditions (Section 3.4.5, p.97). As cardiovascular disease is identified as a key determinant of high-risk status, these findings highlight the need for a prioritised, risk-based immunisation strategy. Age alone is an insufficient marker for vulnerability. Prioritising clinical vulnerability would more effectively reduce severe outcomes and relieve pressure on acute hospital services. <u>Community protection</u> Infant immunisation should be recognised as an important secondary protective measure for vulnerable older adults. Recent Irish analysis shows a clear pattern of RSV transmission, with peaks in infants and young children preceding peaks in older	The HTA has highlighted the elevated risk of disease among individuals with comorbidity (including those with cardiopulmonary conditions) and estimated the budget impact for implementing the programme in these populations. As such, the HTA can be used to inform a decision by the Minister for Health and HSE regarding the funding of the RSV vaccine for specific populations. There is not sufficient evidence to determine the extent to which infants contribute to RSV transmission to older adults. Two modelling studies included in Chapter 5 assumed that infants play a limited role in transmission given that they have few contacts with others outside the household. Additional text has been added to section 8.4.2 to describe the psychological burden among adults with comorbidity.

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	adults by approximately 3-5 weeks. This pattern suggests household transmission plays a significant role. By reducing RSV infection in infants, vaccination can lower the likelihood of virus introduction into households where older adults with chronic cardiovascular disease are at risk. We support a life-course approach to immunisation that reflects the interconnected risk faced by those two vulnerable groups. Psychological Burden While the draft report acknowledges the anxiety of parents with young children, it does not sufficiently consider the psychological burden experienced by older adults living with chronic disease. For individuals with heart failure, respiratory infection represents not a routine seasonal illness, but a direct threat to survival and independence. The persistent fear of infection drives health-seeking behaviour and places sustained emotion strain on patients, their carers and families. Access to RSV vaccination would provide significant reassurance, helping reduce the chronic stress associate with winter viral surges. We urge HIQA to recognise this psychological impact as an important component of patient-centred value. EU Comparison Table 2.3 (pg. 72) indicated that in 6 out of the 9 EU countries listed, chronic heart disease is used as a key eligibility criterion for RSV vaccination in adults aged 60 and older. This reflects a broader World Health Organisation consensus that individuals with chronic conditions, including cardiovascular disease, are at increased risk of severe RSV and infection can exacerbate these conditions. Public health policies in these regions prioritise immunisation for cardiac patients to prevent hospitalisation and exacerbation of existing cardiac conditions. We urge HIQA to align Ireland's national approach with these established practices across the EU.	

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57	Section 5: Economic Evaluation The economic analysis should account for the secondary financial impact of RSV on cardiovascular care. Citing the data from the World Health Organisation from 2025, the submission suggested that cardiovascular disease costs the Irish state approximately €1.7 billion annually. RSV infection can trigger acute cardiac events requiring hospitalisation, intensive care, or prolonged rehabilitation, further increasing healthcare costs. Preventing RSV-related cardiac decompensation would help preserve capacity within an already overstretched HSE system and reduce avoidable downstream expenditure.	The HTA recognises that RSV infection may exacerbate chronic health conditions, including circulatory conditions. However, there is insufficient evidence to quantify RSV-specific cardiac arrest incidence; therefore, this cost was not incorporated in the economic model.
58	Section 6: Organisational Issues and Patient Preferences The report highlights the success of the HSE Chronic Disease Management Programme, including influenza vaccine uptake of 98% among people with chronic disease (p.138). This programme presents an established and effective delivery mechanism for RSV vaccination. High uptake within the programme indicates strong risk awareness and receptiveness to preventive interventions among patients with chronic diseases. Leveraging this existing infrastructure could achieve high coverage in the most vulnerable populations and improve cost-effectiveness compared with a purely age-based approach.	As noted, Chapter 7 suggests that the HSE Chronic Disease Management Programme could serve as an effective delivery mechanism for RSV vaccination among older adults aged 60 years and older with comorbidity. Although there is international evidence suggesting higher risk of RSV disease in this population, Ireland-specific data are not available. Therefore, the cost-effectiveness of the targeted strategy was not evaluated in the economic analysis.
59	Executive Summary: Clarity of Risk Communication The presentation of disease burden in the Executive Summary should integrate a clearer differentiation between healthy older adults and those with significant comorbidities. While the report accurately states that RSV burden in older adults is much lower than in children at population level, this narrative ignores the	Text added to the executive summary to highlight the elevated risk among people with underlying conditions. Additionally, this fact is highlighted in the key finding and advice to the Minister for Health and the HSE section, which has been added to the report.

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	substantially elevated risk faced by people with underlying conditions. Clarifying this distinction would improve understanding of the specific value of vaccination for clinically vulnerable subgroups and support more informed decision making. Clarity of Social Impact The discussion of social implications is currently limited and should include a more explicit assessment of the long-term loss of independence following hospitalisation. For patients with cardiovascular disease, an RSV episode can trigger lasting functional decline, increasing reliance on home support or residential care. These indirect and social care costs are essential to a holistic assessment of vaccine value. In addition, the report does not adequately reflect the lived experience of older adults with chronic disease. Evidence indicated that older people with comorbidities experience severe RSV illness, sustained functional decline and high healthcare utilisation. The report notes that older adults have a higher RSV related mortality rate than infants. NIAC further acknowledges that individuals with risk factors for severe disease, including cardiovascular, pulmonary, renal and endocrine conditions, as well as immunosuppressive treatments, are likely to derive greater benefit from RSV vaccination. This reinforces the importance of prioritising immunisation for these high-risk populations.	The potential requirement for post-discharge rehabilitation is noted in the key findings and advice to the Minister for Health and HSE, and is further discussed in Chapters 3, 7 and 8. The HTA report acknowledges the increased risk of severe disease among individuals with comorbidity. Limited data on the lived experience of older adults are available and are presented in Chapter 8.
	Irish Pharmacy Union (IPU)	
60	The IPU supported a long-term policy which ensures equitable access to RSV vaccination to those identified as being at highest risk. The IPU highlighted the statement included in the HTA about a significant role of community pharmacies in the national vaccination programmes, particularly the national influenza and COVID-19 vaccination programmes. They stated that work is currently underway to include community pharmacists within the national pneumococcal programme, allowing community pharmacists to provide vaccination to those aged 65 years and older.	Thank you for your feedback.

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	They noted that a smaller, but not insignificant number of community pharmacies, offer further vaccination services such as RSV, Shingles, travel vaccines to private patients who can pay for the service. They also commented with respect to pharmacists' experience of the negative impact of RSV and RSV-related complications on the patients and carer's quality of lives. The submission stated that anecdotal evidence would support that the disease prevalence is higher than the surveillance data suggests. The implementation of the Pathfinder programme for infants has been a very effective initiative. Further, they noted that the older cohorts recommended for RSV vaccination by the National Immunisation Advisory Committee (NIAC) already receive COVID-19 and influenza vaccination in community pharmacies. Pharmacists also engage with these older patients and those who are immunocompromised routinely when supplying medication and offering counselling and professional advice.	
61	Vaccines such as influenza, COVID-19 and pneumococcal fall within Schedule 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) meaning that pharmacists can supply and administer these vaccines without the need to obtain a prescription. At the moment pharmacists can administer RSV vaccines but only where they have been prescribed by a medical practitioner. Legislation would be welcomed to include RSV vaccines within Schedule 8 of the Medicinal Products Regulation 2002 (as amended).	Section 7.3.3 discusses the need for the legislation to be amended so that RSV vaccines can be provided by pharmacists as part of a nationally-funded programme.
62	As noted within section 7.3.3 Training of the HTA there is a large proportion of community pharmacists who have already completed the core training required for the administration of any vaccine. Accredited training programmes for pharmacists are readily accessible. Should RSV vaccination be added to the national vaccination programme upskilling the pharmacist population to administer the vaccine would be straight forward and would ensure a considerable trained workforce is readily available.	Thank you for your feedback. This is discussed in section 7.3.3.

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63	Many of the resources required to facilitate the expansion of the national vaccination programme are already in place. Operational supports such as the HSE Vaccination Primary Care Contractor Team, National Cold Chain for vaccine supply are in place and work extremely well. The HSE Communication teams now routinely communicate with the public around vaccination and ensure the necessary and correct information is easily accessible.	Thank you, immunisation programme costs relevant for Ireland were derived from Irish sources and supplemented by input provided by experts where necessary, as outlined in section 6.2.8.
64	The IPU would strongly recommend that RSV vaccinations are included in a national vaccination recording system, National Immunisation Information System (NIIS), to enable all healthcare professionals to have visibility of a patient's vaccination history.	Thank you, this is noted in the organisational chapter.
65	The IPU supported a reimbursement policy that covers both the vaccine and service cost. This policy ensures accessibility for all in society including the most vulnerable and removes a significant barrier.	Thank you, this is noted in the ethical, patient and social considerations chapter.
	Luke's General Hospital Kilkenny	
66	I really hope this immunisation continues every year for these vulnerable newborn babies. Having seen very sick babies with RSV I would not wish any parent to go through that.	Thank you for your feedback.
	Midlands Regional Hospital Portlaoise	
67	We have seen a huge reduction in the acute presentations that RSV brings every winter. The number of critical transfers to Dublin hospitals has declined. Reducing the impact on IPATS retrieval and also on the ICU departments in Dublin. Not only does RSV impact small babies, we see a link to older children that have had RSV infections in the past, where it predisposes them to severe wheezy episodes. To prevent RSV will have a massive positive impact for children and their families, not only in infancy but throughout their childhood. It also alleviates burden on the healthcare system.	Thank you for your feedback.

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	To take away this vaccine is going backwards in healthcare.	
	Mobile Vaccination Team, Dublin and Midlands	
68	The mobile vaccination team supported the conclusions of the draft HTA and recommended that the final report more explicitly reflect the role of community and mobile vaccination delivery models in enabling timely, equitable, and scalable implementation of infant RSV immunisation strategies. The submission noted the various organisational considerations recognised in the HTA. The submission suggested that the national SMS communications targeting the eligible cohort would yield increased engagement and participation in the programme. Further, the submission highlighted that the community and outreach-based delivery capacity are important to ensure timely coverage of infants who are discharged early, not immunised in hospital, or whose families face barriers accessing primary care as well as to avoid differential uptake among eligible population by reducing reliance on a single delivery setting and facilitating engagement with harder-to-reach families. The submission noted that the MVT routinely delivers immunisation across diverse settings and contributes to national data reporting systems, supporting real-time monitoring and post-implementation evaluation. The submission noted that the MVT has demonstrated the ability to provide surge capacity during peak respiratory seasons through time-limited clinics, outreach activity, and flexible deployment across community settings.	The HTA acknowledges the demonstrated role of mobile vaccination teams within immunisation programmes in Ireland. In addition, the HTA recognises the potential role of mobile vaccination teams within RSV immunisation programmes in supporting higher uptake, improving access for hard-to-reach population groups, and alleviating capacity pressures in primary and secondary care settings, as discussed in Chapters 7 and 8. As highlighted in response 48, should a decision be taken to implement RSV immunisation, a detailed implementation plan will be required that is informed by consultation with the key stakeholders that would be involved with the delivery of this care.
69	The submission included the following feedback for chapter 7. 1. Clear linkage between strategy and delivery setting Chapter 7 would benefit from a concise table summarising, for each infant RSV immunisation strategy, the anticipated delivery settings (maternity units, primary care, community/outreach) and the implications for workforce and logistics.	The items identified are noted in Chapter 7 to be important considerations for programme planning. However, the purpose of the organisational issues chapter is to highlight key aspects for consideration rather than to set out a detailed implementation plan. The development of such a plan would be the responsibility of the HSE, should a policy decision be taken to implement the programme.

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	2. Explicit treatment of catch-up delivery requirements Given the significantly larger eligible cohort under seasonal-plus-catch-up strategies, clearer articulation of the operational implications of catch-up delivery would support service planning (Chapter 7.2.1). 3. Earlier visibility of monitoring requirements Bringing forward a short summary of minimum programme monitoring and data capture requirements would assist planners in ensuring that implementation aligns with the evaluation expectations described in Chapter 7.5.	
	MSD, Ireland	
70	Clinical Efficacy, Effectiveness and Safety: The CLEVER trial has been included in this analysis. We believe the SMART trial also meets the eligibility criteria as defined on pg 156, table 4.1 (PICOS table). We request that the SMART trial also be included in the analysis of clinical efficacy, effectiveness and safety of EHL-mAbs. If it will not be included in the final HTA please could you provide rationale for this decision? Pg 215: States "The GRADE certainty of evidence of Nirsevimab for this outcome was assessed to be high". We request that Clesrovimab also be included in this statement. Pg 215: Analysis of RSV associated medically attended LRTI. MALRI with one indicator of severity from the CLEVER was used as the endpoint, in this analysis. However, we believe that MALRI with two indicators of severity would be a more appropriate endpoint, as it aligns more closely with other endpoints used. We have included our definition of endpoints, in the attached materials.	The SMART trial is noted as an ongoing trial in Section 4.7.2 of the report. As per the inclusion and exclusion criteria outlined in Table 4.2, study results were excluded if only presented in abstract form, editorials, letters, results, trial registries, or non-peer reviewed articles. In relation to pages 215, 219, 222 and 226, thank you for noting this typo. The text has been updated from nirsevimab to EHL-mAbs in each instance. Regarding outcome definition – the inclusion of an updated outcome definition to more closely align with that used in clinical trials of nirsevimab was assessed post-hoc in the CLEVER trial. As standard practice, the prospectively defined outcome definitions were used in our analysis. While the inclusion of additional indicators of disease severity would reduce variance in the definitions and increase efficacy estimates, it is not clear that this is reflective of the spectrum of

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	Pg 218 & 219: There is post-hoc ICU admission data for Clesrovimab. We have included this data in the attached materials. Pg 219: All cause medically attended LRTI. Statement "The GRADE certainty of evidence of Nirsevimab for this outcome was assessed to be high for this outcome". We request that Clesrovimab be included in this statement. Pg 222: "Safety outcomes of Nirsevimab against RSV in infants". We request that Clesrovimab be added to this statement. Pg 226; Serious adverse events "Griffin 2020 reported a lower incidence of SAEs in the Nirsevimab group compared to with placebo, while MELODY, HARMONIE, CLEVER and the pooled result found no statistical difference in SAEs between the Nirsevimab and control groups". We request that Clesrovimab be included in this statement.	medically attended RSV-related LRI cases seen in practice in Ireland. Thank you for providing post-hoc ICU data. As these were not published as part of the included CLEVER RCT, it was not possible for them to be included in this assessment.
71	Review of methodology for economic modelling studies of RSV immunisation strategies: Pg 263, Table 5.3 General study characteristics of included studies in infants MSD feels that another study met the criteria for inclusion: JC Lang, K Kura, SM Garba, EH Elbasha, YH Chen. Comparison of a static cohort model and dynamic transmission model for respiratory syncytial virus intervention programs for infants in England and Wales. Vaccine, 2024. This study compares a static model with a dynamic transmission model selected in the HTA document and it provides insight on the drivers of the primary differences between the static and the dynamic transmission models.	The study was excluded based on the eligibility criteria defined in Section 5.3.2. The study did not report the costs used in the analysis or the ratio of incremental costs to incremental benefits.

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	If this study is added, it will need to be fully incorporated into section 5.4. If it is not to be included, could a clear rationale be provided?	
	National Immunisation Advisory Committee (NIAC)	
72	Firstly, NIAC commends the immunisation HTA team in HIQA for completing this extensive and robust evidence synthesis against the immensely challenging background of a rapidly changing environment for RSV immunisation, with new products coming to market, and new data constantly emerging on existing products. Illustrative of the rapidly growing body of data, NIAC has issued four recommendations since RSV immunisation products for adults and infants were first licenced in Europe in 2022 and 2023. NIAC's recommendations, including the most recent update to recommendations in older adults are accurately described in this HTA. NIAC will continue to review and update recommendations should new data emerge. The HTA finds that that RSV immunisation products, currently authorised and recommended by NIAC are safe and effective for the prevention of RSV and associated complications in the relevant eligible populations. The HTA details the epidemiology of RSV in infants, children and older adults in Ireland highlighting, as NIAC has previously noted, that the RSV burden is highest in infants and young children.	Thank you for your feedback.
73	While the burden is clearly highest in infants and young children, NIAC agrees with the assessment included in the HTA report that RSV burden in older adults is likely underestimated due to lack of standardised routine testing in this population. Moreover, it has been highlighted by clinical members of NIAC, that the downstream impact of a hospitalisation due to RSV infection on frailty is difficult to quantify and thus the contribution of RSV to morbidity and mortality in older adults is likely underestimated.	As noted by NIAC and within this HTA, the impact of RSV-associated hospitalisation on frailty is not readily quantifiable. The potential need for rehabilitation services after discharge, particularly among frail adults is highlighted within the report (Chapters 3 and 7). However, in the absence of robust data, the cost of rehabilitation services following RSV-associated

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		hospitalisation is not incorporated in the economic model. This is reported as a limitation of the model (Section 6.4.2).
74	The findings of the economic evaluation contained within the HTA were that at current estimated prices none of the infant or adult immunisation strategies examined met the thresholds commonly applied to determine cost effectiveness. This finding, particularly as it relates to infant immunisation is driven primarily by the estimated high cost of the products.	As detailed in Chapter 4, there is consistent evidence that all RSV immunisation products included within this HTA are safe and effective for the prevention of RSV and associated complications. It is the assumed price of the products that are the key driver of the cost-effectiveness results in Chapter 6. This is highlighted within the Chapter and in the summary sections of the report, including in the newly added section detailing the key findings and advice to the Minister for Health and the HSE.
75	NIAC advocated for more explicit detail on the broader impact on paediatric services, patients and their families to be included in the report. NIAC noted that the significant wider impact on paediatric services and in particular on the delivery of safe patient care can be more difficult to quantify and was not accounted for in the economic evaluation of the HTA, however it is critical that this broader impact of RSV on paediatric services is also considered by decision-makers when weighing up the benefits of RSV immunisation in infants. In the submission, NIAC described the wider impact of RSV on paediatric services. The impact of RSV on paediatric services, includes but is not limited to the following issues which can significantly impact patient safety: • Paediatrics emergency department overcrowding • Paediatric Acute Transport Service at capacity • Paediatric ICU beds at capacity • Paediatric inpatient beds at capacity In addition to impacting the ability to deliver safe care to paediatric patients with and without RSV, this substantial burden also results in delays and cancellations of	Additional text describing the wider impact of the paediatric RSV burden has been added to the summary sections and the relevant chapters of the report.

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	surgery and other procedures in paediatric hospitals. Moreover, maternity units are also impacted as transfers from NICUs to paediatric hospitals can be impeded by decreased PICU and inpatient capacity in paediatric referral centres.	
78	Feedback on the clarity or presentation of the draft HTA: The report would benefit from greater separation of the evaluation of adult and infant immunisation strategies where feasible. Consideration should particularly be given to this in the executive summary, plain language summary and final advice to the minister. This would provide more clarity for readers on the different clinical benefits, considerations and data limitation for the two populations.	Although both cohorts are included within the economic chapter, separate cost-utility analyses were conducted for infants and older adults, and the results are presented in distinct sections. As per response 1, to improve clarity, the plain language summaries (PLS) have been separated for the infant and older adult populations. Additionally, a decision was taken to present separate sections for the two populations that outline the key findings and advice to the Minister for Health and HSE.
	National Neonatal Transport Programme	
79	All of my feedback on the draft HTA of RSV immunisation is based on the immunisation of neonates with nirsevimab, given my lived experience of taking care of babies pre and post the pathfinder programme. I have no recent experience of caring for older adults and no experience of maternal immunisation for RSV. The feedback does not assess any of the impact of the pathfinder programme on the transport of babies with RSV bronchiolitis to or between hospitals. Our service provides 24/7 critical care transport for babies less than 28 days corrected age. The babies with bronchiolitis that are transferred by our service are transferred to CHI at Crumlin and Temple Street Paediatric Intensive Care Units, from all units nationally and CHI at Tallaght in Dublin We reviewed our records for the 2023-2024 and 2024-2025 RSV seasons and found that there was a 75% reduction in the total number of neonates with bronchiolitis	Thank you for sharing the data. They have been included in Chapter 3, Burden in Tertiary Care section and in Chapter 7. The cost of these transfers is not included in the economic analysis due to the lack of robust cost data and is acknowledged as a limitation of the economic model. While acknowledging the positive impact observed of the RSV Pathfinder programme on the national neonatal transport programme given the relatively small number of cases involved, its inclusion would not be expected to alter the overall result of the economic analysis given the size of the ICER. There is substantial uncertainty in quantifying the impact of these transfers on the rest of the neonatal transport workload.

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	who were transferred by our transport service, and an 83% reduction in the number of babies with RSV positive bronchiolitis transferred. Of essential note, and also not explored in detail in the HTA, 80% of the neonates who were transferred with RSV positive bronchiolitis had not received Nirsevimab at parental request. Pre nirsevimab, in Epoch 1, we transferred 35 babies with bronchiolitis, 30 of whom tested positive for RSV. Post Pathfinder introduction, in Epoch 2, we transferred 9 babies with bronchiolitis, 5 of whom tested positive for RSV, and as above, 4 of those babies' parents had refused consent for their baby to receive nirsevimab. 40% (n=14) babies in Epoch 1 were transferred on invasive ventilation, while 33% (n=3) were transferred ventilated in Epoch 2. We approached IPATS, the paediatric critical care transport service, who provide a daytime service, to combine our data, and our combined results showed that in Epoch 1 61 babies were transferred with bronchiolitis compared to 16 in Epoch 2. Again 80% of the babies with RSV bronchiolitis who required transfer had not received nirsevimab due to parental refusal of same. As IPATS does not run 24/7 and NNTP has only one critical care team available at any time, this data has not captured any of the babies who required transfer by their own hospital teams, using frontline ambulance assets. This means that we have not been able to capture the highest risk transfers - performed by a non-specialist team - and the transfers with the greatest impact on the general public - because they are using a frontline HSE NAS ambulance that has been diverted from frontline cover locally to this urgent interhospital transfer. The impact of these transfers on the rest of our neonatal transport workload has also not been quantified. We know that planned essential cardiac and other surgeries get deferred when PICU capacity is overwhelmed, and this also does not appear to have been addressed in the HTA.	However, the knock effects of capacity surge are described in Sections 7.2.3 and 8.4.

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	We strongly support the continuation of the nirsevimab programme for the people who are at most risk of poor outcomes from RSV, the babies who are less than a year old, and nirsevimab appears anecdotally to have been well received and certainly appreciated by teams across our service, the babies we look after and their families.	
	Our Lady of Lourdes Hospital Drogheda	
80	Over the last 2 years with RSV vaccine, there was a big change not only in patient numbers but there have also been fewer sick babies that need a CPAP and high flow and transfer to ICU. I think this would cost more money than giving the vaccine to the newborns. Providing the vaccine would mean that we are less short-staffed because of too much work load, and would not have room shortages for other cases that need care.	Thank you for sharing your observation. Chapter 3 details the reductions in RSV case numbers and RSV-related complications in the 2024/25 RSV season following the introduction of the HSE RSV Immunisation Pathfinder Programme.
	Pfizer, Ireland	
81	Pfizer, the manufacturer of Abrysvo vaccine considered in the HTA, provided comprehensive feedback. In their submission, Pfizer highlighted concerns in relation to the following four main issues:	
82	<u>The Draft HTA Underestimates the Healthcare Burden of RSV infections in Older Adults</u> The incidence of RSV and RSV-attributable hospitalisations among older adults in Ireland is substantially underestimated in the draft HTA analysis. HIQA's model relies on notified cases adjusted by a multiplier of four, yet multiple studies (including those with Irish specific estimates) indicate that the true RSV hospitalisation incidence is considerably higher. A systematic review and meta-analysis reports that standard surveillance captures less than 10% of RSV hospitalisations in older adults. Additionally, the German HTA, referenced by NIAC in their updated recommendation,	The HTA acknowledges the uncertainty around the incidence of medically attended cases. As stated in the HTA report, the multiplier was estimated based on the difference between the incidence of medically attended RSV reported in the international literature and incidence based on the notified case data for Ireland. The best available evidence at the time of the assessment was used. None of the studies included in the literature review submitted by Pfizer provided estimates for the incidence of medically attended cases. It should be noted that RSV has been a notifiable disease in Ireland since 2012,

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	used a factor of eight (rather than the four multiplier used by HIQA) to account for under ascertainment of RSV incidence in older adults.	whereas in many European countries including Germany, it only became notifiable more recently. Moreover, Chapter 3 highlights a general trend of increasing notification rates in Ireland, most notably in older adults. It is noted that this is possibly being driven by changes in testing capacity and testing practices leading to improved ascertainment. As a result, a relatively lower level of under ascertainment of RSV cases would be expected in Ireland.
83	<u>Vaccine Effectiveness Following Adult and Maternal Vaccination is Higher than Assumed in the Draft HTA</u> For adult vaccination, the draft HTA assumes vaccine effectiveness (VE) of 78% in the first season and considerable waning thereafter based on pooled early clinical trial data. However, recent real-world evidence and the DAN-RSV randomised trial suggest higher and more sustained VE against RSV hospitalisation compared to the conservative estimates used in the draft HTA. This should be reflected in the HTA analyses to more accurately assess the vaccine's impact. For maternal vaccination, the draft HTA relies on data from the MATISSE Phase III trial, conducted during an anomalous COVID-19–affected period (Section 4.3.4). The base estimates used for vaccine efficacy against medically attended RSV-associated lower respiratory tract disease (LRTD) and RSV-associated hospitalisation at 180 days' follow-up after birth were 49% and 55%, respectively. However, the primary endpoint that led to stoppage of the trial for efficacy was medically attended severe lower respiratory tract infection (LRTI) with a VE of 70% up to 180 days. Furthermore, real-world data from Argentina, the UK and the USA consistently show high effectiveness in preventing RSV-related infant hospitalisations, consistent with this primary endpoint from the clinical trial. These findings suggest that the draft	The HTA recognises that the evidence base for RSV immunisation products will continue to evolve. However, an assessment is necessarily based on the available information at a point in time, synthesised using systematic review and meta-analysis. The DAN-RSV randomised trial was published on 30 August 2025, which was beyond the search cut-off date of our systematic review. Although it was not possible to include the trial in the pooled analysis, it is now discussed in section 4.7.1. In addition, while the point estimates differ, the confidence intervals overlap for the reported VE estimates for RSV-associated hospitalisation across the two studies included in section 4.3 and the two additional studies noted in section 4.7.1. The VE estimates for the three outcomes, medically attended RSV-associated LRTD, RSV-associated hospitalisation, and severe medically attended RSV-associated LRTI are reported in section 4.3.4 of Chapter 4. For the different interventions and populations modelled in Chapter 6, the modelled outcome VE was medically attended RSV-associated LRTD.

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	HTA significantly underestimates the benefits of maternal immunisation and should be revised to reflect current evidence.	As outlined above, the report highlights that this is a rapidly changing area of research, given that immunisation interventions to protect infants and adults in the general population against RSV have only been authorised since 2022. Summary sections within the report clarify the potential that additional effectiveness and safety data are likely to become available in the near future, which may influence the cost effectiveness of the strategies under consideration.
84	Discrepancies in Economic Evaluations Compared to Other Studies for a Vaccination Programme in Older Adults HIQA's draft analysis concludes that no older adult vaccination strategy meets the €45,000/QALY threshold. HIQA's cost-effectiveness conclusions diverge significantly from those of other health agencies and published literature, mainly due to the underestimated disease burden. These other assessments have found the bivalent RSV vaccine to be cost-effective at a higher price and for a broader population than the HIQA evaluation. Specifically, the UK's Joint Committee on Vaccination and Immunisation (JCVI), found RSV vaccination to be cost-effective for adults aged 75 and older. This positive assessment led to the funding of an RSV vaccination programme with RSVpreF vaccine (Abrysvo) for both maternal immunisation and adults aged 75+ years. With high uptake of the vaccine, the data has shown a significant reduction in RSV hospitalisations. An example of a clear discrepancy between UK and HIQA results are in the deaths adverted. HIQA estimates only 2.5 deaths prevented per 100,000, whereas UK modelling suggests deaths averted may be as high as 34 per 100,000. Given the epidemiological similarities between Ireland and the UK, this discrepancy highlights the need to revisit input assumptions, particularly RSV incidence and RSV-attributable hospitalisations.	As described in Section 6.2.8, the model was built using Irish demographic data and epidemiological data of notified RSV cases sourced from the HPSC. In line with the national guidelines, the clinical effectiveness data were gathered from a systematic review. Further, sensitivity analyses demonstrated that the findings of the economic evaluation are largely robust to data and structural assumptions with the exception of the uncertainty over the price of immunisation products. The epidemiological and cost-effectiveness results may not be comparable to those from other jurisdictions, largely due to differences in modelling inputs and structural assumptions. However, as highlighted in the review of published economic modelling studies (Chapter 5), while included studies found immunisation of infants to be cost effective or cost saving, this was typically highly sensitive to the assumed unit price (or price per dose [PPD] delivered) of these interventions and frequently at a significant reduction relative to their list price. Moreover, the optimal strategy (maternal vaccination or EHL-mAb) was influenced by their relative prices. Similarly, the cost effectiveness of offering vaccination to older adults was found

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		to be largely dependent on the PPD of the vaccines, and was cost effective typically only at a significant reduction relative to the vaccine list price.
85	HIQA Budget Impact Estimates are Uncertain Additionally, the budget impact results reported by HIQA were not reproducible by Pfizer. Based on a vaccination strategy for all adults 75+, the cost incurred of the vaccine inclusive of administration costs and excluding cost offsets has been estimated to be €80 million (excl. VAT) to €93 million (incl. VAT). HIQA have reported this cost incurred as €148.9 million (costs incurred in S8 – vaccination in 75-79 years old, + S9 – vaccination in 80+ years old). The analysis includes VAT in vaccine acquisition costs. VAT is revenue paid to the government and therefore should not be considered in a budget impact assessment. VAT is paid to the government	The budget impact analysis (BIA) was undertaken in accordance with the Guidelines for conducting BIA in Ireland. These state that VAT should be included in BIA estimates. Strategy 9 involves vaccinating those aged 80 years and older in year one of the programme and those aged 80 years only in subsequent years. Therefore, those aged 79 years old in Year 1 of the programme would become eligible for vaccination in Year 2, those aged 78 years old in Year 1 of the programme would become eligible for vaccination in Year 3, and so on. The required data therefore are the projected number of 80-year-olds in Years 2 – 5. CSO estimates of the number of 80-year-olds in 2027 and beyond are 30,000+ and increasing. The eligible numbers provided by Pfizer, Ireland, ranging from 14,739 in Year 2 to 10; 119 in Year 5; therefore, do not reflect CSO projections for the number of 80 year olds in Ireland.
	Pharmaceutical Society Ireland	
86	Pharmaceutical Society of Ireland, an independent statutory regulator of pharmacists and pharmacies in Ireland, welcomed the opportunity to respond to the consultation. PSI expressed their support for the immunisation of infants and older adults against RSV, in accordance with the WHO and the NIAC recommendations. The society also recognised the positive impact that the Pathfinder Programme has had in significantly reducing the burden of RSV among the infant cohort and noted the potential challenges that may arise should this programme be discontinued. The society also acknowledged the issue of cost effectiveness and expressed their	Thank you for your feedback.

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	agreement that the positive impact of providing RSV immunisation for infants and older adults should be balanced with the most efficient and equitable use of healthcare resources in Ireland where possible.	
87	In the event that an RSV immunisation programme is introduced for infants and older adults in Ireland on a more permanent basis, PSI would strongly support the inclusion of pharmacists as key participants in the programme. PSI would be happy to support the involvement of pharmacists in any national RSV programme, as relevant to its role and remit.	Thank you for your feedback.
88	We note that Section 7.3.3 of the report 'Training' states that for pharmacists to provide RSV vaccination as part of a nationally-funded programme, the vaccines would need to be included within Schedule 8 of the legislation in a similar manner to the other vaccines currently administered by pharmacists. We consider that this section should be updated to reflect the introduction of the Medicinal Products (Prescription and Control of Supply)(Amendment) Regulations 2025 (S.I. 353 of 2025), which added Nirsevimab to the Twelfth Schedule to these Regulations. Regulation 4F of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. 540 of 2003)(as amended) enables registered pharmacists, as well as other health professionals, to administer vaccines listed in the Twelfth schedule, in accordance with a national vaccination programme, coordinated, overseen and implemented by the HSE. In addition, we would suggest that the wording of this paragraph is updated to 'Appropriately trained pharmacists are authorised through Regulation 4B and 4F of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), to supply and administer vaccines listed in Schedule 8 and Schedule 12 of the regulations'.	Thank you for your feedback. Additional text has been added to Section 7.3.3 of the organisational chapter to reflect the introduction of the Medicinal Products (Prescription and Control of Supply)(Amendment) Regulations 2025 (S.I. 353 of 2025), which added Nirsevimab to the Twelfth Schedule to these Regulations. The paragraph has been amended to include the following text: "Appropriately trained pharmacists are authorised through Regulation 4B and 4F of The Medicines Products (Prescription and Control of Supply) regulations 2003 to 2024, to supply and administer vaccines listed in Schedule 8 and Schedule 12 of the regulations."

Number	Feedback	Response
89	Regarding the clarity or presentation of the draft assessment, Pharmaceutical Society of Ireland provided the following feedback: We found the information in the draft report to be very comprehensive and presented clearly throughout.	Thank you for your feedback.
	The National Maternity Hospital (NMH) and the Rotunda Hospital	
90	The NMH and the Rotunda hospital commended HIQA and the advisory group on their work on this HTA. They noted that the HTA will play a vital role in ensuring cost-effective pricing models for procurement processes. They advised that the HTA should be updated to reflect the following issues any underestimation of the true overall societal benefits should be addressed. **1. Parallel Assessment of Infant and Older Adult Immunisation** The draft HTA presents neonatal and older-adult cohorts within a shared report. These groups differ significantly in disease burden, contribution to system pressure, and overall cost impact. This approach risks obscuring the relative value of neonatal immunisation (Chapters 3 and 6). HTAs dedicated to each group would strengthen clarity. Infants under six months have historically comprised the majority of notified RSV cases, emergency department presentations and hospitalisations prior to intervention. Adults aged 65 and older represent a comparatively low proportion of RSV-related hospital demand and ICU utilisation, even at seasonal peaks. Aggregating these populations dilutes the economic signal of neonatal immunisation. Recommendation: neonates require a standalone HTA. Adult RSV immunisation should be assessed separately. They require clearly segregated modelling within individual HTAs.	Thank you for your feedback. In accordance with the terms of reference and deliverables agreed with the Department of Health, the HTA includes both the infant and older adult populations. Although both cohorts are included within the HTA, the report presents distinct sections within each chapter to ensure clarity and to reflect the differing epidemiology, clinical efficacy and effectiveness of immunisation products for infants and older adults, organisational considerations, ethical issues etc. It should also be noted that separate cost-utility analyses were conducted for infants and older adults. To improve clarity, the plain language summaries (PLS) have been separated for the infant and older adult populations. Additionally, a decision was taken to present separate sections for the two populations that outline the key findings and advice to the Minister for Health and HSE.

Number	Feedback	Response
91	**2.** Comparator Selection and Product Availability The HTA's economic modelling chapter does not mention palivizumab. Nirsevimab is not an incremental expansion, but rather a displacement of an obsolete standard. The direct and indirect costs of delivering palivizumab were substantial. The discontinuation of Synagis (Palivizumab) in the USA has been announced as has the home administration support service SynSupport in Ireland. Palivizumab was the only legacy intervention for high-risk infants. Costs were €692.67 (50mg) and €1,009.93 (100mg), with 5-dose schedules standard. Effective cost baseline per eligible infant was routinely in the range of €3,500–5,000. Between 2020-2024, 406 doses were administered to NMH patients alone. The national burden extends substantially beyond a single site. The home administration service SynaSupport is being withdrawn in Europe, making palivizumab's continued use unviable. Modelling needs to consider the unavailability of palivizumab on an ongoing basis and the need to continue to provide immunisation cover to high risk infants. Recommendation: Re-examine the comparator strategy to reflect current and future availability, ensuring outputs are grounded in the environment in which policy decisions must operate. Cost savings must account for avoided legacy spend, avoided administration burden, and avoided homecare logistics of administering multiple monoclonal antibody doses in the home setting	As per response 26 above, clarifications have been added to report to confirm that the economic evaluation was undertaken in the context of infants in the general population and assumed an ongoing policy of providing immunisation to infants and children at high-risk of severe disease (that is, the population previously eligible for palivizumab).
92	**3.** Integration of Domestic Evidence: Pathfinder Programme The RSV Immunisation Pathfinder Programme (2024/25) generated Ireland-specific data that is uniquely relevant to the HTA's purpose. Current treatment within the draft positions this dataset as supplementary. The HTA reframes these outcomes as preliminary rather than integrating them into core economic modelling. This diminishes the impact of Ireland's most relevant dataset.	In line with the National Guidelines for the Economic Evaluation of Health Technologies in Ireland, efficacy estimates for immunisation products were informed by synthesis of evidence from randomised controlled trials (RCTs). For nirsevimab, synthesis of observational data substantiated the RCT findings. Further, the infant-based model outputs broadly align with those reported by the HSE for the 2024/25 Pathfinder RSV immunisation programme. The Pathfinder Programme data

Number	Feedback	Response
	Findings from the April 2025 evaluation include: • 78% reduction in hospitalisations, 60% reduction in ED presentations, 71% reduction in ICU admissions. • Estimated 1,861.9 bed days avoided and €4.2 million in hospital-related costs averted. • Number needed to immunise (NNT) to prevent one hospitalisation: 51, which in vaccination economics is exceptional performance These outcomes demonstrate effectiveness within the exact operational structure being considered for long-term adoption. Greater integration of Pathfinder data, potentially as a primary effectiveness input, may lead to more policy-ready modelling outputs. Recommendation: incorporate Pathfinder outcomes as primary Irish-effectiveness inputs. International RCTs and meta-analyses remain supportive but secondary.	provide important contextual information for the Irish setting. However, it is important to note that these data are not linked with individual immunisation status and introduces uncertainty in directly attributing observed outcomes to immunisation.
93	**4.** Scope of Economic Evaluation Current cost domains in the models, while consistent with convention, do not reflect societal or total health system benefits in the Irish context. Areas for consideration: • The HTA acknowledges that RSV surges disrupt elective care and paediatric ICU capacity, which has a knock-on effect on neonatal ICU capacity and workloads for the neonatal transport programme, but these organisational benefits were not captured. Including these could improve cost-effectiveness estimates at the cost of limiting comparability internationally, however international health systems may be better funded and might not exceed 100% capacity during surges.	As per response 53 above. In line with the Guidelines for the Economic Evaluation of Health Technologies in Ireland, the base-case analysis for economic evaluation for HTA is conducted from the payer perspective (that is, the HSE). As such, indirect societal benefits are not included in the primary analysis. The guidelines highlight that a societal perspective may also be adopted as a secondary analysis, if warranted. This was done within this HTA. However, it is noted that the inclusion of any outcome is subject to the availability of robust evidence and relevant and reliable data needed to estimate effects, QALYs and costs.

Number	Feedback	Response
	• Assumed 0% cost/productivity loss during statutory maternity benefit of 26 weeks is cynical. Infections in this time do have an economic impact on the family. Infections may also occur outside of this time and the family unit may suffer significantly as a consequence of medically attended or unattended cases. The models should be stress tested to take a broader benefits perspective. • Potential timing bias where the HTA applied historical HIPE cost data (including 2024) to model hospitalisation costs when nirsevimab was implemented during 2024. • The primary analysis adopts a healthcare payer perspective. A societal perspective (including productivity loss for parents and long-term sequelae) would likely improve cost-effectiveness. The impact of non-medically attended RSV is also not considered, although the impact may be substantial in terms of time lost from work. • Avoided disruption to breastfeeding and resultant clinical implications. • Operational efficiencies arising from predictable immunisation scheduling. • Long term neonatal and infant morbidity following recovery from hospitalisation from RSV Recommendation: expand cost domains to include the above	
94	The submission included the following issue with the clarity or the presentation of the report: The parallel presentation of infant and older-adult models may be interpreted as implying equivalent impact. Structural separation within the document, or a summary of core differences, could support interpretation (Executive Summary; Chapter 6).	As per response 1 above, separate Plain Language Summaries have been provided for the infant and older adult populations with additional wording changes to improve clarity and accessibility.

Number	Feedback	Response
	Comparator descriptions would benefit from clarity on current and projected availability of palivizumab (Section 2.4). The role and weighting of Pathfinder evidence within the model is not fully explicit. A brief methodological note on evidence hierarchy and weighting decisions would improve transparency (Chapters 3 and 6).	
	Royal College of Physicians Ireland (RCPI)	
95	From a child health perspective, we consider the programme clinically hugely impactful and vital for the health and wellbeing of all infants. It helps reduce service pressures for staff. Clinically many paediatric colleagues would also view the impact of the RSV immunisation as profound. The consensus from Paediatricians nationally is that it has been a gamechanger in terms of infant health, reducing admissions and preventing surgery cancellations. There is robust data supporting this from the RSV Immunisation Pathfinder Programme that was implemented in 2024/25.	Thank you for your feedback. The positive impact of the Pathfinder Programme is described in Chapter 3.
	RSV Pathfinder Steering Group - National Health Protection Office (NHPO), Health Service Executive (HSE)	
96	The RSV Pathfinder Steering group submitted comprehensive feedback on behalf of the HSE. While recognising the robust clinical safety/effectiveness synthesis and the transparency of the economic modelling used in the HTA, the submission expressed concern that the HTA does not fully quantify several material benefits to the healthcare system based on evidence from the HSE RSV Immunisation Pathfinder Programme. As a result, the current ICERs and conclusions risk underestimating the cost-effectiveness of universal nirsevimab prophylaxis for infants in Ireland. The submission included the following comments and suggestions.	

Number	Feedback	Response
97	A. Under-quantified system benefits (organisational & operational): 1) Large, observed reductions in severe infant RSV burden (Pathfinder): In 2024/25, among infants born in-season, ED presentations fell by 57%, hospitalisations by 76%, and ICU admissions by 65% versus 2023/24. These are real-world, national figures following programme introduction. While the HTA acknowledges clinical effectiveness, these system-level gains appear not monetised within the ICERs beyond direct episode costs. We recommend explicit valuation of surge relief and knock-on service continuity. 2) Critical care transfers and winter resilience: Paediatric critical care transfers for the target cohort dropped from 19 (2023/24) to 5 (2024/25); neonatal transfers dropped from 35 to 5, with immunised infants experiencing shorter PICU stays and less invasive support. The HTA's organisational chapter describes system pressure qualitatively but does not incorporate the economic value of avoided transfers, reduced bed occupancy, and preserved elective activity into the ICERs. We recommend adding a scenario analysis that prices these avoided operational disruptions. 3) Bed days and hospital cost offsets: Pathfinder estimated ~1,862 to ~2,288 in-patient bed days avoided and €4.2–€5.2 million in direct hospital-related costs avoided (including ICU). These savings are observed impact estimates from 2024-25 season with an in season only programme and should be proactively integrated into the economic model, not only in budget impact but also within ICER sensitivity scenarios that reflect system surge costs. 4) Primary care & caregiver burden:	1) Chapter 3 (Epidemiology and burden of disease) describes the observed impact of the Pathfinder programme in the 2024/25 season. The HTA recognises the wider impacts of the immunisation programme and qualitatively describes them in the summary sections (Executive summary, Plain Language summary, Key findings and Advice), as well as in relevant chapters of the HTA. Quantifying these indirect impacts is challenging and requires Irish specific studies, which were not feasible within the timelines of this project. 2)While we acknowledge these system-wide benefits, precise cost estimates to quantify them are not available. This limitation is noted. While operationally complex and challenging, given the relatively small number of transfers this limitation would not alter the results of the economic model 3) In line with the National Guidelines for the Economic Evaluation of Health Technologies in Ireland, efficacy estimates for immunisation products were informed by synthesis of evidence from randomised controlled trials (RCTs). For nirsevimab, synthesis of observational data substantiated the RCT findings. Further, the infant-based model outputs broadly align with those reported by the HSE for the 2024/25 Pathfinder RSV immunisation programme. The Pathfinder Programme data provides important contextual information for the Irish setting. However, it is important to note that these data are not linked with individual immunisation status and introduces uncertainty in directly attributing observed outcomes to immunisation. 4) In line with the National Guidelines for the Economic Evaluation of Health Technologies in Ireland, the base case

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	Qualitative evidence demonstrates benefits to families (reduced distress/trauma, fewer PICU episodes, fewer sibling disruptions) and primary care (drop in bronchiolitis presentations reported). We recommend adding conservative caregiver time/productivity and GP workload relief modules in sensitivity analyses, given demonstrable reductions in acute RSV load. 5) Long-term sequelae (uncertainty acknowledged in HTA): The HTA notes associations of early RSV with wheezing/asthma later in childhood but (appropriately) highlights causal uncertainty. We recommend scenario analyses that incorporate low-range QALY decrements and downstream costs for wheeze/asthma, recurrent LRTI and lung function impairment, effects that can persist into adulthood as chronic respiratory disease in children - clearly labelled as exploratory - to test robustness of conclusions, rather than omitting this domain entirely.	analysis was conducted from a healthcare perspective (that is, the HSE). In the societal perspective, which was undertaken as a secondary analysis, productivity losses for parents were included. The inclusion of any outcome in economic modelling is subject to the availability of robust evidence and relevant and reliable data needed to estimate effects, QALYs and costs. The burden of RSV in primary care is noted to be an underestimate and reflects existing testing policy and practices. To account for this underestimate, as per response 44 above, a multiplier of four was applied to the notified case data observed in Ireland within the economic model to estimate the incidence of medically attended RSV. The economic model also accounted for the average number of GP visits per medical attended RSV. In the absence of Irish-specific data, the frequency of GP visits related to medically attended cases of RSV was sourced from a number of international studies and expert opinion from Ireland (Chapter 6, Table 6.7). 5) As per response 10, development of asthma (child) was included as an outcome in the review of the effectiveness and safety of RSV immunisation (Table 4.1); however, effectiveness was not demonstrated in the included studies. Notwithstanding this, given the biological plausibility and the additional burden of RSV in those with asthma, Section 8.4. notes that benefits of RSV immunisation in infants may also include reducing long-term consequences such as wheezing and asthma. However, due to substantial data uncertainty, the suggested scenario analysis would not provide reliable estimates. Some of these data include the frequency of recurrent wheezing in a year and

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		associated cost of primary care visits and hospitalisations, cost of treating asthma and health-related quality of life data for children with asthma subsequent to RSV infection.
98	B. Coverage assumptions & real-world feasibility Pathfinder achieved national cumulative uptake of 82.6% in maternity hospitals/CHI; CHI reached 95.7%, and the TCP Homecare high-risk programme 99%. Pathfinder 2.0 achieved close to 90% coverage in newborn cohort. The catch up cohort uptake although lower than expected for pathfinder 2.0, would most likely not reflect future uptake rates as the model of service in future would involve primary care delivery with expectations of higher uptake. HTA coverage inputs could be conservatively low for infant prophylaxis delivered at birth in maternity units—especially with improved antenatal communication/digital consent pathways. We suggest running higher-coverage scenarios and incorporating operational enablers (e.g., MN-CMS expansion, NIIS integration).	Uptake of the EHL-mAb for the seasonal cohort is based on the Pathfinder 2024/25 programme while uptake for the catch-up cohort was based on published rates in the international literature (76.0%). The uptake rate assumed for an EHL-mAb as part of a catch-up programme was acknowledged to be higher than the uptake rate achieved during the initial clinics (September 2025 to first week of October 2025) provided for this cohort under the HSE Pathfinder 2 pilot RSV immunisation programme for 2025/26 in Ireland. While high uptake rates for nirsevimab were achieved within the Pathfinder Programme, uptake of other items listed in the Irish Primary Childhood Immunisation Schedule are noted to vary by vaccine, by region and over time, with a general decline in uptake across vaccines (to well below the 95% WHO target rate) in recent years. The BIA estimates were based on the modelled uptake rates; higher uptake rates would result in a higher budget impact. However, changes in the uptake rate would not impact the cost effectiveness findings.
99	C. Price assumptions & procurement realism HTA base case uses €301 (ex VAT) per dose for EHL-mAb and €165 for maternal vaccine—driving ICERs above typical WTP thresholds. We request scenario bands reflecting real procurement practice (tender outcomes, negotiated rebates) and transparent VAT/distribution assumptions. HSE Contract Approval Request confirms direct negotiation with the sole supplier and documented cost avoidance vs the	The considerable uncertainty in relation to the likely cost and relative costs of the included interventions to the HSE, is acknowledged within the report. This uncertainty exists given the absence of list prices for all products and the potential for price reductions through a competitive tender. Where list prices

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	initially proposed price; moreover in future, multi-annual contracts and market competition are likely to lead to more favourable costs. These factors warrant price bands and sensitivity analysis around plausible net acquisition costs in Ireland for ICERs for the different strategies.	were not available, they were assumed based on published international contract prices. These estimates were subject to sensitivity analysis through the probabilistic analysis and threshold analysis which were conducted to determine the price at which the interventions would be cost effective. The base case value, upper and lower bounds and the statistical distribution for each parameter are detailed in Table A.6. For example, the ranging from €243.92 to €364.26 for an EHL-mAb). (Table A.6) The report notes that the cost-effectiveness results are highly sensitive to the assumed intervention prices and that lower procurement costs would improve the cost effectiveness of the interventions.
100	<u>D. Modelling approach & externalities</u> The HTA's Markov model is appropriate for individual outcomes but does not capture system externalities of winter surges (spillover delays, cancellation rates, queue growth, hospital-acquired infection risk at >100% PICU occupancy). We recommend either adding a resilience module that prices surge avoidance or presenting two-way sensitivity analyses that apply shadow prices to bed days during Q4, reflecting real-world scarcity conditions, alongside organisational metrics measured in Pathfinder (transfers avoided, ICU profiles). Linkage & measurement improvements: Pathfinder highlights the absence of a national immunisation data repository linking RSV immunisation status to surveillance notifications, limiting on-the-ground effectiveness estimation. Development work is ongoing on a National Outbreak Case and Incident Management system (OCIMS) and linkage of immunisation records (including RSV) on NIIS to OCIMS. With NIIS roll-out which may be enhanced by insights from	The limitations of the economic model have been detailed in section 6.4.2. As with any modelling exercise, the inclusion of any outcome is subject to the availability of robust evidence and relevant and reliable data needed to estimate effects, QALYs and costs. The suggested sensitivity analyses are not undertaken due to the lack of required data.

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	MN-CMS analytics, this should be prioritised to strengthen ongoing model inputs and reduce parameter uncertainty.	
101	E. Equity & inclusion benefits The programme invested in translated materials, NGO partnerships (e.g., Pavee Point), and bespoke engagement to address equity gaps. We propose quantifying equity impacts (e.g., expected reductions in disproportionate ICU admissions among younger infants, improved access for home births/community midwifery with clear pathways), and testing ICER sensitivity when high-deprivation quintiles experience larger risk reduction.	The importance of reaching out to different communities to address equity gaps and to improve uptake is outlined in Section 7.3.5. In accordance with the national HTA guidelines, equity weights are not recommended to be applied to the outcome due to significant methodological issues.
102	F. Comparator and epidemiological baseline – high-risk infant programme (since 2005) Ireland has operated a targeted RSV immunisation programme for high-risk infants since 2005, using palivizumab each season. In the current HTA, infant models appear to compare new programmes to a "no immunisation" scenario. Given long-standing use of palivizumab for the highest-risk infants, this comparator risks misrepresenting both effectiveness and costs. Specifically, a comparator of "no immunisation" is misleading when current practice includes a targeted, publicly funded programme. A more appropriate baseline is current practice (i.e., targeted palivizumab for eligible high-risk infants), with ICERs presented as incremental to that baseline. Costing: even a targeted programme entails substantial costs to the State. Palivizumab is an expensive monoclonal antibody that requires monthly administration over approximately five months each RSV season to confer protection in high-risk infants. These existing expenditures should be explicitly reflected in the economic model and budget impact as part of the status-quo comparator.	Please see responses to comments 24 and 50. Additional text has been added to the report to highlight that publicly-funded immunisation of specified cohorts of infants and children at the highest risk of severe RSV-related disease has been available in Ireland for over 20 years. It is recognised that the choice of immunisation agent for this cohort may change over time. For example, as operationalised through the HSE Pathfinder Programme, the choice of immunisation agent changed from palivizumab to nirsevimab for this cohort in 2024/25 in line with NIAC recommendations, and considering previous advice from HIQA that such a change would be cost saving. The Advice from HIQA which relates to infants in the general population assumes the ongoing immunisation of infants and children up to two years of age at high risk of severe disease (that is, those previously identified as eligible for palivizumab in

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	Epidemiology and attribution: it is unclear whether the HTA's epidemiological inputs fully account for the historical presence of the high-risk palivizumab programme. If pre-Pathfinder epidemiology was used as the "no-immunisation" baseline, additional benefits attributed to new programmes (especially for the highest-risk infants) may be under- or mis-estimated. We recommend that the epidemiological baseline be adjusted to reflect the ongoing targeted immunisation since 2005,including coverage and effectiveness parameters for palivizumab. Recommendations: (i) present base-case results versus current practice; (ii) include sensitivity/scenario analyses varying the scale and cost of the high-risk programme; (iii) transparently separate incremental benefits/costs for highest-risk infants to avoid double counting or understatement of benefits; and (iv) clarify in Methods the treatment of pre-existing targeted immunisation in both epidemiologic and economic components.	line with NIAC recommendations). Text has been added to Chapters 2,6,7 and 8 as well as to summary sections and the Advice document to highlight this assumption. The epidemiological inputs used in the economic model were in the context of a programme that offered immunisation to those at highest risk of severe disease (that is, those previously eligible for palivizumab). The model used notified case data for infants and children under two years of age from the most recent three RSV seasons (2021/22, 2022/23 and 2023/24) before the introduction of the HSE Pathfinder pilot RSV immunisation programme. However, due to the small proportion of the high-risk infants, the epidemiological impact is considered to be nominal.
	In conclusion, given the observed national impact – • hundreds of ED attendance, hospitalisations and ICU admissions prevented, • thousands of bed days freed, • critical care transfers sharply reduced, and • high uptake achievable in maternity settings, our view is that the current HTA likely undervalues nirsevimab's system-wide benefits. Incorporating the above adjustments and robust scenario sensitivity analyses would provide a more balanced and realistic assessment of cost-effectiveness for infant RSV monoclonal antibody prophylaxis in Ireland.	Thank you for your feedback.
	Sanofi	
103	Sanofi, the manufacturer of one of the EHL-mAbs (Nirsevimab) considered in the report, provided comprehensive feedback. Sanofi expressed disagreement with	

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	various aspects of the methodology, the assumptions used in the analysis, and the conclusions. The submission included feedback for various chapters of the HTA which are summarised below:	
104	<u>Chapter 4 Clinical efficacy, effectiveness and safety</u> Sanofi disagreed with the following statement from the HTA and highlighted the differences between nirsevimab and other RSV EHL-mAbs and maternal vaccination. "Overall, there is consistent evidence that all currently authorised RSV immunisation products are safe and effective for the prevention of RSV and associated complications, over one season." Sanofi provided references to recently published observational studies from France and Spain indicating protection against RSV into the second RSV season.	The quantity and quality of data to support specific interventions are documented in detail within Chapter 4, including within the key points of this chapter. Specifically, it is noted that the observational data for EHL-mAbs relate exclusively to nirsevimab. The individual findings from each study for the respective RSV immunisation products are presented throughout the results section as forest plots, with overall results discussed in the main text for brevity. The studies provided were published in December 2025 and in January 2026, since the search date of the systematic reviews in this HTA. The HTA acknowledges that this is a rapidly changing area of research and longer-term data are likely to become available in the near future, which may influence the clinical effectiveness and safety of these interventions. It should be noted that the individual product characteristics and licensed indications are described in Chapter 2. While there are noted biological differences between nirsevimab and clesrovimab in how the mechanism of action is achieved, these do not preclude pooling of estimates relating to clinical outcomes for products of a shared type, indication and target population.
105	Chapter 7 Economic Evaluation	<u>Target population</u>

Number	Feedback	Response
	Target population Sanofi expressed concern that the model does not distinguish prematurity-based subgroups (≤29 weeks, 30–35 weeks) or other NIAC-recommended high-risk cohorts prioritised in clinical practice. Strategies assessed Sanofi commented that three of the infant-based strategies assessed leave high-risk infants (e.g., palivizumab-eligible) unprotected. Sanofi recommended updating the model to incorporate scenario analyses that account for timing of immunisation, gestational age, and uptake variability—factors that directly influence the proportion of infants requiring EHL-mAb. Stress-testing coverage shortfall risks and seasonal timing effects on maternal immunisation outcomes is essential to ensure robust and realistic policy conclusions. Modelling input: Efficacy and effectiveness of RSV intervention Sanofi suggested that HIQA's model should also reflect real-world effectiveness to validate the effectiveness assumptions implemented in the model. Immunisation coverage Sanofi highlighted the uptake rates achieved in the Pathfinder programme for nirsevimab and remarked that the uptake rate assumed for the maternal vaccine is optimistic. It was further added that there is no uptake data for clesrovimab. Cost Sanofi queried whether 'once-off immunisation programme implementation costs' have been included.	The higher risk of RSV disease among premature infants and other high-risk cohorts as identified by NIAC is acknowledged in the report. However, due to the lack of sufficient epidemiological and clinical data specific to these groups, it was not possible to incorporate these distinctions within the model. Strategies assessed As per response 26 above, additional text has been added to the report to clarify that the advice from HIQA which relates to infants in the general population assumes the ongoing immunisation of infants and children up to two years of age at high risk of severe disease (that is, those previously identified as eligible for palivizumab in line with NIAC recommendations). The suggested scenario analyses were not undertaken for the following reasons: – the timing of maternal vaccination is considered to be an insignificant source of uncertainty in relation to the model results. – Irish incidence data disaggregated by gestational age are not available. – variability in uptake is not expected to influence cost-effectiveness, as the model is static. Modelling input: Efficacy and effectiveness of RSV intervention In line with the National Guidelines for the Economic Evaluation of Health Technologies in Ireland, efficacy estimates for immunisation products were informed by synthesised evidence from randomised controlled trials (RCTs). For nirsevimab,

Number	Feedback	Response
	Results Sanofi commented that S5 (combination of maternal vaccination and an EHL-mAb offered seasonally) appears more cost effective in the base-case analysis, and this finding relies on simplifying assumptions that understate clinical heterogeneity and implementation complexity. Sanofi highlighted the sensitiveness of indirect protection provided through maternal vaccination to the real world uncertainties and the operational challenges of delivering combined programme. It was also noted that the protection from maternal immunisation appears to be modelled as binarily (fully protected versus not protected), whereas in practice protection exists along a protection gradient driven by timing of vaccination, timing of birth, and variability in antibody transfer.	synthesised observational data substantiated the RCT findings. Further, the infant-based model outputs broadly align with those reported by the HSE for the 2024/25 Pathfinder RSV immunisation programme. Immunisation coverage Uptake of the EHL-mAb for the seasonal cohort is based on the Pathfinder 2024/25 programme while uptake for the catch-up cohort was based on published rates in the international literature (76.0%). For the maternal vaccine, the uptake rate was informed by existing uptake rates for maternal vaccines in Ireland. Cost Once-off immunisation programme implementation costs are included in the analysis (see Table 6.5 - heading "Once-off immunisation programme implementation costs") to ensure that the full resource implications of introducing a new immunisation programme are appropriately captured. Results Operational challenges of delivering different immunisation strategies are discussed in Chapter 7. There are currently insufficient data to support the existence of a protection gradient from maternal vaccination and so it was not factored into the model.

Number	Feedback	Response
105	Organisational issues Sanofi highlighted the organisational challenges of mixed RSV immunisation programmes for infants.	In Chapter 8 (Organisational issues), the organisational considerations with different immunisation strategies, including a combined strategy infant strategy, are described.
106	Ethical, patient and social considerations Sanofi highlighted that the concerns about the safety of an intervention are the primary reason for refusal or hesitation of an RSV immunisation to protect infants. The safety and effectiveness of nirsevimab have been demonstrated in over 50 studies involving more than 400,000 infants.	Data available within the search date regarding the safety of immunisation products are described in Chapter 4. The quantity and quality of evidence underpinning the included outcomes are described in detail in Chapter 4 and within summary sections of the report. Notwithstanding this evidence and the post-marketing surveillance data to date support the overall safety of nirsevimab administration to this cohort, the HTA highlights that nirsevimab along with the other included RSV interventions are subject to additional monitoring requirements by the EMA, owing to the fact that they contain new active substances, and are new biological medicines. Common factors that contribute to vaccine and immunisation hesitancy were identified in Chapters 7 and 8. The need for an information campaign and materials to clearly communicate the benefits, risks and eligibility regarding RSV immunisation and to support informed decision-making are highlighted in Chapters 7 and 8.
107	Sanofi outlined the following issues for the clarity of the report, a need for: ▪ Clear explanation of how 46% efficacy vs RSV-associated hospitalisations were derived from the RCT evidence for use in the model. ▪ Disaggregated results for the strategies showing all outcomes including mortality for each intervention and within strategy.	The vaccine efficacy estimates were based on pooled data from the RCTs. The reported efficacy against hospitalisation represented the risk ratio across all trial participants. For the purposes of modelling, the risk ratio for hospitalisation was expressed conditional on having RSV as it is only applied to medically attended RSV cases.

Number	Feedback	Response
	▪ Expansion on the limitations section regarding the modelling approach, inputs and assumptions and the impact these have on the results.	Given that mortality rates are so low in infants, these data were not reported. The adult mortality data are reported in Table 6.18. The limitations of the modelling approach are as outlined in Section6.4.2.

3.2 Changes to the report from the consultation process

The following changes were made to the draft report in response to comments and feedback received through the consultation process:

- Text has been added throughout the report to emphasise that a reduction in winter overcrowding due to RSV immunisation would likely improve patient experience, quality and safety of care, and public confidence in healthcare services and would provide a means of strengthening resilience in the healthcare system. Such text has been added to the organisational issues, ethical, patient and social considerations and conclusion of the Executive Summary. Chapter 7 sections 7.2.3 and 7.3, and Chapter 8 key points and section 8.4.3 have also been updated.
- Text has been added describing the burden of RSV on the healthcare system (including on risk of infection, staffing and patient safety) to Chapter 3 section 3.5.2, Chapter 7 section 7.2.3 and Chapter 8 section 8.4.3 and the overall HTA Discussion. Updates have been made to chapter key points, the Executive Summary, as well as the additional summary of key findings and advice sections.
- Text has been added to the Executive Summary and within the relevant chapters to better explain that the context of this HTA is to inform a decision with respect to the immunisation of the general infant population, not the cohort of infants and children at high risk of severe disease. For infants and children at high risk of severe disease, a policy decision was made in 2024/25 to switch from palivizumab to nirsevimab (as informed by NIAC guidance and previous advice from HIQA).
- Text has been added to Chapter 2 section 2.3, regarding the use of isolation and cohorting to manage different respiratory viruses in a hospital and residential care settings.
- Text was amended in Chapter 2 section 2.4.2 entitled 'Co-administration with other vaccines' regarding updated vaccine co-administration data for RSVPreF3.
- Text has been added to Chapter 3, (burden on paediatric acute transport service and to Chapter 7 regarding the observed reduction in RSV-related transfers by neonatal and paediatric acute transport services between the 2023/24 and 2024/25 RSV seasons, arising from the positive impact of the HSE Pathfinder Programme.
- Text has been added to the Executive Summary and Chapter 3 key points regarding the likely underestimate of the total RSV burden in the ED and primary care. A new section (Section 3.5.1) has been added to Chapter 3 regarding the burden of RSV specifically in primary care.

- Additional text on the impact of RSV immunisation on GP and out-of-hours services has been added to the Executive Summary, Chapter 8 key points and Section 8.4.3.
- Further detail regarding the implementation and positive impact of the Pathfinder Programme has been added to the Executive Summary and Chapter 7 sections 7.2.1, 7.2.3 and 7.3.1. Text has also been added to section 7.3.1 entitled 'Staff' regarding the role of staff in the Pathfinder programme and organisational issues related to a primary care-based RSV immunisation catch up programme.
- Figure 3.1 in Chapter 3 has been enlarged and text in other figures and graphs enlarged where appropriate to enhance readability.
- Additional detail has been added to Chapter 3 section 3.5.2 entitled 'Burden on tertiary hospitals' regarding a reduction in admissions in CHI.
- One duplicated reference was removed.
- It was highlighted in the Executive Summary and Chapter 3 key points that while international data indicate the burden of RSV is highest in those with certain underlying conditions, there is a lack of data specific to these groups.
- Additional detail was added to the Executive Summary regarding the infant RSV immunisation products for which observational data was identified.
- Additional text was added to Chapter 4 key points and section 4.7.2 regarding second season observational data for nirsevimab published after the systematic reviews were conducted. It was noted in the conclusion that longer-term data are likely to become available in the near future which may influence the clinical effectiveness and safety of included interventions.
- Some instances of "nirsevimab" have been changed to "EHL-mAbs" throughout Chapter 4 as appropriate.
- A typo in the Strategy 6 description has been amended.
- Data sources in Table 6.3 were updated.
- Table 6.9 has been updated to correspond with the cost data in the appendix which corresponds to the data used in the model.
- Text was added to Chapter 7 section 7.3.3 regarding detail of the Medicinal Products (Prescription and Control of Supply) Regulations.
- Text was added to Chapter 8 section 8.4.2 regarding how adults who are hospitalised with RSV may experience functional decline requiring step-down care or increased support.
- Text was added to Chapter 8 section 8.4.3 referencing evidence of RSV infection contributing to antibiotic use.

In line with standard processes, subsequent to the public consultation, a section detailing the Key Findings and Advice to the Minister for Health and the HSE has been drafted, which takes consideration of the feedback received through this

process. In line with feedback received, separate sets of advice were prepared with respect to the infant and older adult cohorts.

Appendix A – copy of submission feedback form

Health Technology Assessment of immunisation against respiratory syncytial virus (RSV) in Ireland

Public Consultation feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

The Health Information and Quality Authority (HIQA) is holding a six-week public consultation to give people an opportunity to provide feedback on the health technology assessment (HTA) of RSV immunisation in Ireland.

Your views are important to us. HIQA will carefully assess all feedback received and incorporate feedback into the report, where appropriate.

The final HTA and a statement of outcomes report (a summary of the consultation responses) will be published on HIQA's website once the HTA has been completed.

The closing date for the public consultation is 5pm on Wednesday 20 January 2026.

How to provide feedback:

- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information.
- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into one submission form. We will request a name and contact number for a designated representative from your organisation in case we need to clarify your feedback.
- If your feedback contains any commercially sensitive or confidential information, please highlight this at the time of submission, so it can be excluded from the summary of feedback that will be published by HIQA.
- Please spell out any abbreviations that you use.

You can **email** the completed form to consultation@hiqa.ie

OR

Print the consultation feedback form and **post** the completed form to:

Health Information and Quality Authority
Public consultation for Alternative Telephone Pathway
Health Technology Assessment
Dublin Regional Office
George's Court, George's Lane
Smithfield, Dublin 7
D07 E98Y

Data protection and Freedom of Information

HIQA will only collect personal information, such as the names of individuals who provided feedback or any other personal details during this consultation, for the purposes of seeking clarification on your feedback, if necessary. No personal information will be included in the stakeholder consultation document that will be published by HIQA.

Any response you provide will be held securely and anonymised. Information provided in your response, for example, an anecdote or statement about an experience may be included in the statement of outcomes that will be published by HIQA at the end of the HTA process. However, information will be provided in a manner which protects the privacy of respondents. All personal information will be deleted once no longer needed, in line with HIQA's record retention policy.

For further information on how HIQA uses personal information, please see our Privacy Notice available here. If you have any concerns regarding your personal information, please contact HIQA's Data Protection Officer on dpo@hiqa.ie.

Please note that HIQA is subject to the Freedom of Information (FOI) Act and the statutory Code of Practice in relation to FOI. We cannot give you an assurance that confidentiality can be maintained in all circumstances due to the requirements of the FOI Act.

☐ **I agree to take part in the public consultation**

1. About you

1.1 Your name:

1.2 Are you providing feedback as:

☐ an individual

☐ on behalf of an organisation

1.3 If answer is 'on behalf of an organisation', please give the name of the organisation:

If applicable, for clarification purposes, please provide your name, your role in the above organisation and your contact details:

You can request that your organisation's name be kept confidential and excluded from the published summary of responses:

☐ Do not publish organisation name

☐ Publish organisation name

This form contains two questions focused on the draft assessment. These relate to (i) general or specific feedback on the draft assessment, and (ii) the clarity or presentation of the draft report.

These questions are presented on the following two pages.

2. Your feedback on the draft health technology assessment

2.1 Please provide any general or specific feedback you have on the draft assessment. Where applicable, please specify the section of the draft assessment to which you are referring.

2.2 Please outline any issues with the clarity or presentation of the draft assessment. In your response, where applicable, please specify the section to which you are referring.

Thank you for taking the time to give us your views

After the closing date, we will carefully access all feedback and incorporate it into the report, where appropriate. The final report and the Statement of Outcomes (a summary of responses) will be published on the HIQA website.

If you have any questions, please contact the evaluation team at consultation@hiqa.ie.

Please ensure that you return your form to us either by email or post, to reach us by 20 January 2026.

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