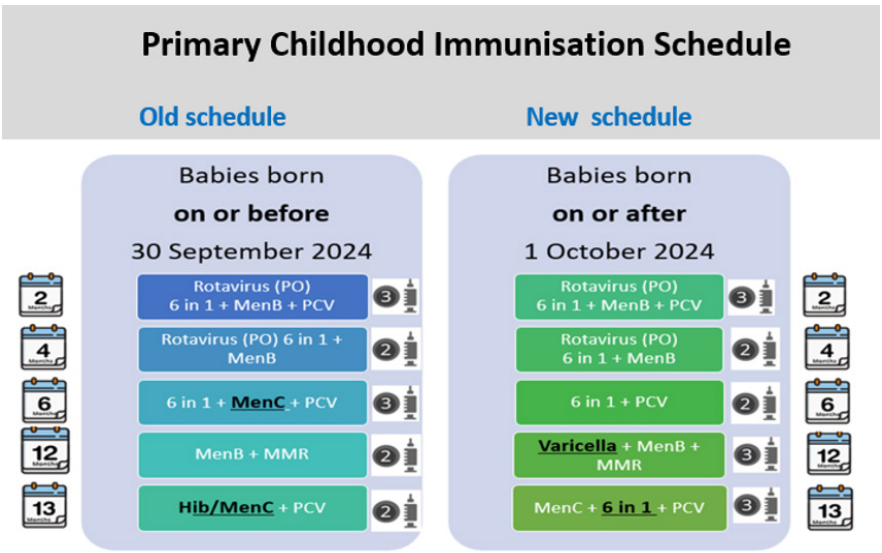
Frequently Asked Questions on the Primary Childhood Immunisation Programme, including Varicella (Chickenpox) Vaccine

Applicable from: 1st October 2024

1. What are the changes to the Primary Childhood Immunisation Programme (PCIP)?

The following are the changes to the PCIP. They apply to children born on or after 1st October 2024:

- The MenC vaccine will no longer be given at the 6-month visit,
- Varicella (Chickenpox) vaccine has been added to the schedule. Varicella (Chickenpox) vaccine will be given with MMR and MenB vaccines at the 12 month- visit[1],
- The Hib/MenC vaccine given at 13 months will be replaced by a Men C and a 6 in 1 vaccine at 13 months. Men C and 6 in 1 vaccines will be given with the PCV vaccine.



2. Why is the MenC vaccine being removed from the 6-month visit?

The National Immunisation Advisory Committee (NIAC) have advised that since the introduction of meningococcal C vaccine, the incidence of meningococcal C disease in Ireland has declined significantly. It is now known that giving one dose of MenC vaccine in the 2nd year of life, with a booster dose of MenC vaccine (in the MenACWY vaccine) in adolescence, provides protection against severe meningococcal C disease and establishes herd immunity, which helps to protect younger children.

3. Why is Varicella (Chickenpox) vaccine being introduced at the 12-month visit?

NIAC recommends the introduction of Varicella (Chickenpox) vaccine, to reduce the significant burden of Varicella (Chickenpox) zoster virus morbidity and its complications.

4. Why is the Hib/Men C vaccine being replaced with a Men C and a 4th dose of 6 in 1 vaccine?

The Hib/MenC vaccine will no longer be available from the manufacturers after 2025. To replace Hib/MenC vaccine given at 13 months, NIAC recommended a MenC vaccine and the introduction of a 4th dose of 6 in 1 vaccine at 13 months.

The 6 in 1 provides protection against Hib (every child is recommended one dose of Hib vaccine from the age of 1 year to 9 years inclusive). The 6 in 1 vaccine also offers enhanced protection in young children from diphtheria, pertussis and paralytic polio.

This will bring the Irish childhood immunisation programme in line with most countries worldwide, which already give a 4th dose of a tetanus, diphtheria, pertussis and polio vaccine to children aged 12 to 18 months to increase protection from these diseases in childhood.

[1] The second dose of Varicella (Chickenpox) vaccine will be given as a combined MMR and Varicella vaccine (MMRV) when children are aged 4-5 years, in junior infants in primary school.

5. What about children born before 1st October 2024, what schedule should they follow?

Children born before 1st October 2024 should follow the schedule that was in place when they were born i.e. the schedule prior to 1st October 2024.

This applies also to catch-up schedules. If children need to catch up with vaccines, they should catch-up with the vaccine schedule recommended for them at the time they were born.

6. Is there a catch-up program for Varicella (Chickenpox) vaccine for children born before 1st October 2024?

No. NIAC did not recommend a Varicella (Chickenpox) vaccine catch-up program for children born before 1 October 2024, and there is no government funding for this.

If a parent of a child born before 1st October 2024, requests Varicella (Chickenpox) vaccine for their child, they should be informed that this will have to be under a private arrangement.

7. What are the symptoms and signs of Varicella (Chickenpox) infection?

Every year in Ireland, between 75-100 people are hospitalised as a result of chickenpox, the majority of them children.

Varicella (Chickenpox) is a highly contagious virus, with a household attack rate of 90% for non-immune individuals who come into close contact.

Varicella (Chickenpox) is characterised by a generalised pruritic vesicular rash. The rash usually starts on the head and progresses to the trunk and extremities. The rash may involve mucous membranes (mouth, respiratory tract, vagina, conjunctiva and cornea). The rash progresses from macules to papules to vesicular lesions that crust over as they dry, usually resolving in 5-7 days from the onset of the rash.

Clinical course in healthy children is generally mild, but children are required to stay away from school or childcare facilities for at least six days, until all skin lesions have crusted over, to prevent transmission. This results in a significant disruption to the child and family. Secondary infection of skin lesions is relatively common, occurring in 5-10% of children.

Severe complications can be serious. They include:

- toxic shock syndrome and necrotising fasciitis (usually associated with Group A streptococcus superinfection)
- encephalitis
- stroke-Varicella (Chickenpox) is the leading infectious cause of stroke in children and can occur up to 12 months following infection
- pneumonia
- glomerulonephritis
- myocarditis
- hepatitis
- coagulopathy.

Recovery from Varicella (Chickenpox) usually results in lifelong immunity. Recurrent disease is rare but is more likely in immunocompromised individuals.

8. What are the complications of Varicella (Chickenpox) in pregnancy?

Varicella (Chickenpox) infection in non-immune pregnant women can result in serious complications for both mother and baby.

Infection in the first or second trimester can result in congenital varicella syndrome (CVS).

Feature of CVS include:

- neurological abnormalities
- eye disease
- limb hypoplasia
- gastrointestinal and genitourinary abnormalities.

Maternal varicella infection near term or soon after delivery can lead to severe neonatal varicella with fatal outcomes reported in approximately 20% of infants.

Pregnant women themselves, particularly in the third trimester are at increased risk of complications associated with varicella pneumonia compared to non-pregnant adults.

It is therefore important that children living with non-immune pregnant women are vaccinated against chickenpox, to help protect the pregnant woman from infection.

9. What type of vaccine is Varicella (Chickenpox) vaccine?

Varicella (Chickenpox) vaccine is a live-attenuated vaccine.

10. Is the Varicella (Chickenpox) vaccine a new vaccine?

No, Varicella (Chickenpox) vaccine was licensed for general use in Japan and Korea in 1988 and in the United States in 1995, for persons aged 12 months or older.

The European Medicine Agency has licensed Varicella (Chickenpox) vaccine for many years (since 2003).

Germany was the first European country to introduce universal Varicella (Chickenpox) vaccination in 2004.

11. What is the efficacy and effectiveness of Varicella (Chickenpox) vaccine?

A 2022 review of efficacy of Varicella vaccine concluded that efficacy for Varicella vaccine is as follows:

- 1 dose has an efficacy of 60-85% in preventing varicella infection,
- 2 doses have an efficacy of 87-95% in preventing varicella infection.

However, in the prevention of moderate to severe varicella disease both one and two dose strategies have similarly high levels of efficacy (90-100%).

Germany observed a 50% reduction in Varicella-related hospitalisations and a 70% reduction in all Varicella cases following the introduction of the vaccine.

12. What are the recommendations on Varicella (Chickenpox) vaccine from the National Immunisation Advisory Committee?

NIAC recommend the inclusion of Varicella (Chickenpox) vaccine in the PCIP for children born on or after 1st October 2024.

- The first dose of Varicella (Chickenpox) vaccine is recommended to be given to children at 12 months of age,
- The second dose of Varicella vaccine will be offered to these children when they are aged 4-5 years in junior infants in school. It will be given as a combined live attenuated Measles, Mumps, Rubella and Varicella vaccine, the MMRV vaccine.

12. Why are we giving separate MMR and Varicella (Chickenpox) vaccines at the 12- month visit, and not the combined MMRV?

This is because, in clinical studies, the risk of febrile convulsion after vaccination at 12 months, although low, was higher in infants who received the combined MMRV versus those who received separate MMR and Varicella (Chickenpox) vaccines. For this reason, many countries do not administer MMRV to children under the age of 4 years.

13. What are the commonest side effects after vaccination against Varicella (Chickenpox)?

The most common associated side effects in clinical trials were pain and redness at the injection site. A non-injection-site Varicella (Chickenpox) like rash was reported in 2.2% of vaccine recipients.

Febrile seizures are a rare side effect (incidence between 1 in 10,000 and 1 in 1,000).

The risk of febrile seizure is higher if MMRV vaccine is given as a first dose compared to Varicella (Chickenpox) vaccine, but it is still an uncommon side effect.

The risk of fever and febrile convulsion is lower after the second vaccine dose.

14. What are the contraindications to Varicella (Chickenpox) vaccine[2]?

Varicella (Chickenpox)-containing vaccines are contraindicated in children who have a history of:

- anaphylaxis after a previous dose of any Varicella (Chickenpox)-containing vaccine,
- anaphylaxis after any component of a Varicella (Chickenpox)-containing, vaccine, including gelatin and neomycin,
- immunocompromise due to disease or treatment,
- in adolescents and adults, Varicella (chickenpox) vaccine is contraindicated in pregnancy.

[2] Please refer to the National Immunisation Advisory Committee's Immunisation Guidelines for contraindications to varicella vaccine.

15. What are the precautions to Varicella (Chickenpox) vaccine?

- Acute severe febrile illness, defer until recovery,
- Recent (3-11 months) receipt of a blood products or antibody-containing product (Chapter 2, Table 2.6 in NIAC guidelines),
- Receipt of some antivirals (e.g. acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination,
- If giving vaccine to a female of reproductive age, they should be informed pregnancy should be avoided for one month following vaccination,
- If not given at the same time as MMR vaccine, the vaccines should be separated by at least four weeks. The risk of breakthrough Varicella (Chickenpox) infection is increased if Varicella vaccine is administered less than four weeks following MMR vaccine.

16. Should there be an interval between the administration of blood products and giving Varicella (Chickenpox) (or MMR) live vaccine?

Yes, see recommended intervals below in Table 2.6 of the immunisation guidelines. This depends on which blood product was administered.

Table 2.6 Recommended intervals between blood products and MMR or Varicella vaccines

This table is not intended for determining correct indications and doses for using antibody-containing products

Preparation	Route	Dose	Estimated IgG mgs/kg	Interval (months)
Blood products				
Washed RBCs	IV	10mls/kg	Negligible	0
Packed RBCs and wholeblood	IV	10mls/kg	60	6
Plasma & platelets	IV	10mls/kg	160	7
HNIG				
Immune deficiencies	SC, IM, IV		300-400	8
ITP treatment	IV	400mgs/kg/day	400	8
		1,000mgs/kg/day	1,000	10
Kawasaki disease	IV		1,600-2,000	11
Measles *Immunocompetent contacts*	IM	0.6ml/kg	80	6
Immunocompromised contacts	IV	3ml/kg	400	8
Specific immunoglobulins				
Cytomegalovirus	IV	3mls/kg	150	6
Hepatitis B	IM	100-500 IU	10	3
Rabies	IM, wound	20 IU/kg	22	4
Tetanus	IM	250-500 IU	10	3
Varicella	IM	15-25 IU/kg		5

17. What are NOT contraindications to Varicella (Chickenpox) vaccine?

The following are NOT contraindications to vaccine:

- Pregnancy of recipient's mother or other close or household contact (see advice below regarding chickenpox vaccine-associated rash),
- Immunodeficient family member or household contact (see advice below regarding chickenpox vaccine-associated rash),
- Treatment with low dose (less than 2 mg/kg/day) alternate-day, topical, replacement, or aerosolised steroid preparations. (See Chapter 3 NIAC guidelines),
- Asymptomatic or mildly symptomatic HIV infection (CD4 count ≥15%). (See Chapter 3 NIAC Guidelines),
- Humoral immunodeficiency (e.g. agammaglobulinaemia),
- Breast-feeding.

18. What is the advice for children living with a non-immune pregnant woman or with an infant in the first week of life, whose mother is not immune to chickenpox?

It is very important that children living with non-immune pregnant women or non-immune neonates are vaccinated with Varicella (Chickenpox) vaccine, to reduce the risk of exposure to the pregnant woman or infant to Varicella (Chickenpox) infection, and its severe complications.

Living with a non-immune pregnant woman, or a non-immune neonate in the first year of life is not a contraindication to vaccination of a child with Varicella (Chickenpox) vaccine.

19. What is the advice for children living with an immunocompromised person?

It is very important that children living with an immunocompromised person are vaccinated with Varicella (Chickenpox) vaccine, to reduce the risk of exposure to Varicella (Chickenpox) infection to the immunocompromised person, and its severe complications.

Living with an immunocompromised person is not a contraindication to vaccination of a child with Varicella (Chickenpox) vaccine.

20. Is previous Varicella (Chickenpox) infection a contraindication to vaccination?

No. Previous Varicella (Chickenpox) infection is not a contraindication to Varicella (Chickenpox) vaccination. Children who have had Varicella (Chickenpox) infection can receive Varicella (Chickenpox)-containing vaccines.

21. Should a child who has had confirmed chickenpox prior to the first birthday get the first dose of Varicella (Chickenpox) vaccine at age 1 year?

Yes, the Varicella (Chickenpox) vaccine is still recommended at 12 months of age, as children may get sub-optimal natural immunity from Varicella (Chickenpox) infection before 12 months of age.

22. Can Varicella (Chickenpox) breakthrough infection occur after vaccination?

Yes, it can occur. Breakthrough Varicella (Chickenpox) is defined as Varicella (Chickenpox) due to infection with wild-type Varicella (Chickenpox) virus occurring more than 42 days after Varicella (Chickenpox) vaccination (1 or 2 doses). Breakthrough Varicella (Chickenpox) is less severe than Varicella (Chickenpox) infection in unvaccinated persons, with the median number of skin lesions commonly less than 50; vesicular lesions are less common and the lesions are commonly papules that do not progress to vesicles.

23. Can Varicella (Chickenpox) vaccine be given with other vaccines?

Yes. Children can receive Varicella (Chickenpox) vaccine at the same time as other live attenuated parenteral vaccines (e.g. MMR), or other inactivated vaccines[3].

If for some reason the MMR and Varicella (Chickenpox) vaccines are not administered on the same day, they should be separated by an interval of 28 days.

Varicella (Chickenpox) can be given together with or at any interval from other non-live vaccines.

[3] Varicella vaccine can also be given with or at any interval from non-parenteral live vaccines such as LAIV

24. What is the advice for children who develop a rash after the Varicella (Chickenpox) vaccine?

Approximately 2.2% of people who receive the Varicella (Chickenpox) vaccine will develop a Varicella (Chickenpox)-like rash. The onset of this rash is between 5-26 days after immunisation. The rash tends to be mild. The rash is usually near the injection site (median 2 lesions), but there may be a generalised rash (median 5 lesions). The rash resolves spontaneously.

If a vaccinated child develops a Varicella (Chickenpox)-like rash, after vaccination, NIAC advise that as a precaution, they should not come into contact with:

- people who have severe immunocompromise from disease or treatment (see Table 3.7 of the NIAC Immunisation Guidelines gives examples of conditions associated with severe immunocompromise)
- women who are pregnant and non-immune to Varicella (Chickenpox), and
- non-immune neonates in the 1st week of life.

They should avoid contact with these at risk people until all lesions crust over and no new lesions have appeared within a period of 24 hours (usually 5-7 days from rash onset).

This is because in theory, the attenuated/weakened vaccine virus in the Varicella (Chickenpox) vaccine, could cause Varicella (Chickenpox) infection in these vulnerable groups.

However, this may not be feasible, for example if they are the parent of the child who has been vaccinated. It is important to note that the risk of transmission of the attenuated vaccine virus is extremely low or negligible:

Over a 10-year period in the USA, 56 million doses of Varicella (Chickenpox) vaccine were administered[4]. Only five cases of transmission of the attenuated vaccine virus from a vaccinated individual with a rash were documented, resulting in 6 cases of secondary infection. All of these cases were mild. It means that there would be one case of mild chickenpox infection for every 9 million doses of vaccine administered.

Vaccinating children reduces the risk of exposure of non-immune pregnant women, non-immune infants and immunocompromised individuals to varicella infection, which can have serious, life-threatening complications for these groups.

The benefits of reducing exposure to infection through vaccination, far outweighs any theoretical risks of transmission of the attenuated vaccine virus.

25. What if a child with a post-Varicella (Chickenpox) vaccine rash cannot avoid contact with a non-immune pregnant woman or her infant, or a person with severe immunocompromise?

The risk of healthy children transmitting the weakened vaccine virus is negligible.

However, if a pregnant non-immune woman, non-immune infant or person with severe immunocompromise is exposed to a Varicella (Chickenpox) vaccine recipient with a post-vaccine rash, NIAC advise that they should contact their treating specialist to see if post-exposure prophylaxis against Varicella (Chickenpox) could be required[5].

It is important to note that the risk of transmission of vaccine virus is negligible (see above).

26. If a child gets a Varicella like rash after the vaccine, can they attend their usual childcare?

It can be difficult to know if the rash was caused by the vaccine or if this could be a mild case of chickenpox.

If the rash is generalised the safest approach is to keep them home from childcare until all lesions have crusted over (5-7 days usually from rash onset).

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[4] American Academy of Pediatrics. Varicella-zoster virus infections In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. Red Book: 2015 report of the Committee on Infectious Diseases. 30th ed.

Grossberg R, Harpaz R, Rubtcova E, et al. Secondary transmission of varicella vaccine virus in a chronic care facility for children. Journal of Pediatrics 2006;148:842-4.

[5] See NIAC guidelines for more information. In pregnancy, oral antivirals may be given from day 7 to day 14 post-exposure

27. If children receive the Varicella (chickenpox) vaccine, are they be more likely to develop shingles later in life?

Like the wild varicella virus, the attenuated varicella vaccine virus can remain latent in cranial nerve, dorsal root and autonomic nerve ganglia. However, concerns that vaccination of children against varicella might result in either deferral of infection to an older age or increase in incidence of shingles have proved unfounded. Countries with well-established universal varicella vaccine programmes have not reported a significant increase in shingles.

28. Do other countries offer a booster dose of tetanus, diphtheria, pertussis and polio in the 2nd year of life?

Yes, most countries recommend a tetanus, diphtheria, pertussis and polio vaccine between 11 and 24 months to boost protection.

Ireland was an outlier in the European Union/ European Economic Area (EU/EAA) region with regard to the length of the interval between primary 6 in 1 series and the booster 4 in 1 dose offered in junior infants. Therefore introducing this booster in the second year of life brings Ireland more in line with other schedules in the EU. The UK are also introducing a booster in the second year of life.

29. Is the introduction of a 4th 6 in 1 associated with an increased risk of side effects?

The addition of a further dose of tetanus and diphtheria vaccine as part of the 6 in 1 vaccine in the second year of life may be associated with a modest increase in reactogenicity.

This increased risk is balanced against the known benefits of enhanced protection against diphtheria, invasive haemophilus influenzae type b, pertussis and paralytic polio.

NIAC recommends Paracetamol may be administered in response to fever, pain or irritability following vaccination.

Order of Vaccine administration

Standardising the order and site of administration of vaccines is recommended in the event of a local reaction, and to reduce vaccine errors. The following serves as a guide:

At 2 months

- Give Men B vaccine first in the LEFT anterolateral thigh.
- Then give 6 in 1 vaccine in the RIGHT anterolateral thigh.
- Then give the PCV vaccine in the RIGHT anterolateral thigh. This allows the most painful vaccine (PCV) be given last.

At 4 months

- Give Men B vaccine first into the LEFT anterolateral thigh.
- Then the 6 in 1 vaccine in the RIGHT anterolateral thigh.

At 6 months

- Give the 6 in 1 vaccine in the RIGHT anterolateral thigh,
- Then give the PCV vaccine in the LEFT anterolateral thigh. This allows the most painful vaccine (PCV) to be given last.

At 12 months

- Give Men B vaccine first in the LEFT anterolateral thigh,
- Then give Varicella (Chickenpox) vaccine in the RIGHT anterolateral thigh,
- Then give MMR vaccine in the RIGHT anterolateral thigh. This allows the most painful vaccine, MMR to be given last.

At 13 months

- Give MenC vaccine first in the LEFT anterolateral thigh.
- Then 6 in 1 vaccine in the RIGHT anterolateral thigh,
- Then give PCV vaccine in the RIGHT anterolateral thigh. This allows the most painful vaccine (PCV) to be given last.

Questions on the PCI schedule:

What questions should be asked before administration of rotavirus vaccine now the newborn bloodspot programme screens for ADA-SCID?

- Are there any diseases in the family that affect the immune system?
- Did anyone in either parents' family need a bone marrow transplant aged < 12 months?
- When your baby had their newborn bloodspot screening (heel prick test) was there any follow up needed because of the results of the test?

If the parent/caregiver answers "Yes" to any of these questions:

- Check if a full blood count (FBC) was taken at birth and confirm the results.
- If a FBC was not taken, a full blood count with differential white cell, including lymphocyte count should be ordered. If the lymphocyte count is below <2.0/109 litre referral to a consultant paediatrician should be made urgently.
- If follow-up was needed after newborn bloodspot screening, check if any of the concerns raised from the newborn bloodspot screening are to do with ADA-SCID?

Any baby at risk of SCID should **NOT** be given rotavirus oral vaccine.