Questions and Answers to support Schedule changes October 2020 and updated *Immunisation Handbook* guidance

Implementation of Schedule changes

Why has an extra visit been introduced at 12 months?

Introducing a 12-month visit allows earlier administration of the measles, mumps and rubella vaccine (MMR). This offers early protection against measles with optimum protection offered by administering the second dose at 15 months. This also allows an earlier pneumococcal conjugate vaccine (PCV10) booster to support the new two-dose primary PCV10 course.

How should these changes be implemented for children aged 12 months to 4 years of age?

12-month event

Invite those aged 12–14 months

- Administer PCV10 and MMR dose 1

15-month event

Invite those aged 15 months who attended their 12-month event

- Administer MMR dose 2, *Haemophilus Influenzae* type B vaccine (Hib) and varicella vaccine (VV).

Invite those aged 15 months–2 years who have not attended their 12-month event

- Administer MMR dose 1, PCV10, Hib and VV and recall 4 weeks later for MMR dose 2

4-year event

Invite at 4 years

- Administer DTaP-IPV and MMR dose 2 (if not previously administered)

MMR catch up

Invite children aged 15 months–3 years who attended their 15-month event

- Administer MMR dose 2

NOTE: This catch up will depend on local resources, with the priority being those under 2 years of age initially.

Does this Schedule change apply to the Auckland area who have routinely been giving 15-month immunisations at 12 months?

Yes, this is a change to the National Immunisation Schedule. All vaccinators are recommended to follow the updated Schedule from 1 October 2020, including in Auckland.

Can we give the second year of life vaccines early?

- The MMR and PCV 10 due at 12 months of age, can be given up to 4 days before the child turns 12 months of age
- The Hib and varicella vaccine due at 15 months can be given at 12 months (not more than 4 days before 12 months of age)
- The MMR dose 2 due at 15 months is recommended to be administered on-time at 15 months of age unless there is a high risk of exposure to these diseases, such as during an outbreak. When there is a high risk of exposure to measles, mumps or rubella, MMR dose 2 can be administered as early as 4 weeks after the MMR dose 1.

How early can the 4-year DTaP-IPV be given?

This can be administered a maximum of 4 weeks before 4 years of age. If a child has received a fourth DTaP-containing vaccine prior to this age, please discuss with 0800 IMMUNE or your local immunisation coordinator regarding appropriate catch-up.

Will shifting the 4-year MMR vaccination event to 15 months have any effect on protection against congenital rubella, particularly as women are having children older?

MMR is a live vaccine and as such, the immunological response the body has is very similar to that of wild disease. Although levels of vaccine-induced antibodies might decrease over time, vaccination also induces memory B-cells that can produce circulating antibody when required, in less time than the measles, mumps or rubella viruses take to incubate and cause disease. Data from surveillance of rubella and congenital rubella syndrome suggest that waning immunity with increased susceptibility to rubella disease does not occur (this is usually the primary concern with pregnant women). Ensuring high coverage of MMR vaccine reduces the risk of any of the disease circulating in the community. New Zealand is considered to have eliminated measles and rubella endemic disease.

How can you access VV for those under 12 months of age in special groups?

Varilrix can be ordered through ProPharma by both community and hospital services for administration to high-risk eligible children aged 9–12 months.

Vaccine administration

Why has the guidance on recommend route of administration for herpes zoster (HZV), varicella and MMR vaccines changed?

The updated *Immunisation Handbook* now recommends that HZV, varicella and MMR vaccines are administered via the intramuscular (IM) route instead of subcutaneously (SC).

Most live vaccines (except BCG and rotavirus vaccines) are now recommended to be administered IM rather than SC. The advice to administer live vaccines SC was based on the evidence from the original vaccine trials. However, more recent evidence shows that equivalent immunogenicity is achieved when live vaccines are administered IM, with fewer injection site reactions and reduced discomfort during administration. These benefits are especially noted when HZV is administered IM. Other countries, including Australia and the UK, now recommend IM injection in preference to SC for a range of vaccines and most data sheets include the IM option.

NOTE: There is no change to the recommendation for BCG vaccine. BCG must be administered intradermally by specialist BCG vaccinators. IPOL will still be given SC and rotavirus vaccine administered orally.

What evidence shows live vaccines can now be administered via the IM route?

Various studies informed the decision, including the following:

Dennehy PH, Reisinger KS, Blatter MM, Veloudis BA. Immunogenicity of subcutaneous versus intramuscular Oka/Merck varicella vaccination in healthy children. *Pediatrics.* 1991 Sep 1;88(3):604-7.

"Varicella vaccine given by either intramuscular or subcutaneous route is immunogenic and well tolerated. Although varicella vaccine is recommended to be given subcutaneously, the results of this study indicate that inadvertent intramuscular administration of varicella vaccine is not reason for revaccination."

Reaction	*Subcutaneous (n = 65) No. (%)*	*Intramuscular (n = 67) No. (%)*
Injection site reaction*	17 (26.2)	11 [16.4)
Injection site rash	8 (12.3)	1 (1.5)†
Varicella-like rash	5 (7.7)	4 (6.0)
Nonspecific symptoms	52 (80.0)	58 (86.6)
Fever ≥38.3°C	20 (30.8)	13 (19.4)

* Pain, redness, and/or swelling

† P = .03 by c^2

Diez-Domingo J, Weinke T, de Lomas JG, Meyer CU, Bertrand I, Eymin C, Thomas S, Sadorge C. Comparison of intramuscular and subcutaneous administration of a herpes zoster live-attenuated vaccine in adults aged≥ 50 years: A randomised non-inferiority clinical trial. *Vaccine.* 2015 Feb 4;33(6):789-95.

Zostavax	*SC (n = 177)*	*IM (n = 177)*
Injection site reactions	52.5%	15.9%
Pain	39.5%	25.6%
Swelling	37.3%	13.6%

When does the change from SC to IM for MMR, VV and HZV vaccines start?

These changes take effect from 1 October 2020 with the changes included in the 2020 *Immunisation Handbook*. It will take time for vaccinators to adapt their practice. All training and clinical assessments will swap to IM for live vaccines from October 2020. As the immunogenicity for IM or SC is the same, giving via the SC route is not considered an error; however, all vaccinators are expected to follow the *Immunisation Handbook* guidance.

What are the recommended injection sites at the 12-month event and beyond?

The choice between the two sites (deltoid and vastus lateralis [VL]) for IM injections at the 12-month event and beyond will be based on the vaccinator's professional judgement, and include consideration of muscle bulk and ease of positioning and holding. Some vaccinators consider the VL preferable for young children when the deltoid muscle bulk is small and because of the superficiality of the radial nerve. Discuss the options with the parent/guardian when making your decision.

NOTE: When using the deltoid site for IM injections in children under 7 years of age, a 23–25 G × 16 mm needle is recommended for most children. See the *Immunisation Handbook* Table 2.8.

Is there a recommended order for vaccines for the 12-month vaccination event?

MMR and PCV10 are the vaccines scheduled at the 12-month immunisation event and both can be given IM in the VL. It is recommended to follow a systematic process each time (eg, give PCV10, followed by MMR).

If requested, how can an extra vaccine be included in the 12-month visit?

Some parents may request other non-funded vaccines at this visit, such as meningococcal B or ACWY or early varicella vaccine. In this case, it is appropriate to use the deltoid as well as the VL. If two injections are needed in the same limb, the VL is preferred because of its greater muscle mass, with the two injection sites separated by at least 2 cm so potential localised responses do not overlap.

Is there a recommended order for vaccines given at 15 months?

MMR dose 2, varicella and Hib vaccines are scheduled at the 15-month event. The suggested vaccine administration sequence and location is to give Hib vaccine IM in the VL followed by VV IM in the deltoid, and MMR IM in the other deltoid. Alternatively, the other VL may be used for the MMR. Which vaccines are given on right or left side of the body is not important except if a BCG vaccine has been given in past 3 months, in which case you must avoid the injection site (usually the left deltoid area).

If parents request splitting the vaccines due at the 15-month event, what is the recommended process?

We recommend giving all vaccines due at the 15-month event together and discourage delaying any vaccines due to the risk of getting the diseases while unprotected. However, if parents/guardians insist on delaying one or more of these vaccines, then it is recommended to give the MMR and VV IM at the same time, followed by the Hib vaccine IM as soon as possible. NOTE: a 4-week gap is required between MMR and VV if not given on the same day. There is no minimum interval between MMR/VV and Hib vaccine.

Does it matter if HZV, MMR or varicella vaccines are administered SC instead of IM?

Although administering via the SC route does not affect the efficacy of the vaccines and is allowed by the data sheet, the reviewed research supports IM administration for all cases except if contraindicated eg, bleeding disorders. Because of the expected reduction in local responses/reactions, we recommend that all vaccinators follow the new guidance.

What length of needle is required when administering an IM injection in the deltoid?

A 23–25 G × 16 mm needle is recommended for deltoid injections for children up to 7 years of age- see the *Immunisation Handbook* Table 2.8. From this age, the vaccinator must assess the size of the arm/deltoid muscle and refer to Table 2.8 for recommended needle sizes.

Will the SC vaccine administration route still be used routinely for any vaccines?

SC vaccine administration is still recommended for IPOL vaccine and for other vaccines if their data sheet allows/recommends, or on specialist recommendation for those with bleeding disorders.

When do we refer children to Outreach Immunisation Services (OIS)?

This varies between DHBs/OIS services but a 12- or 15-month immunisation is defined as ‘delayed’ if not received within 6 weeks of the due date. The 4-year event is considered ‘delayed’ if not received within 6 months of the due date.

When will the HealthEd resources be available to order?

Updated HealthEd resources are now available for order at www.healthed.govt.nz

When will the new 'Three in a Row' poster be available?

Copies of this will be available to download from the Immunisation Advisory Centre (IMAC) website (www.immune.org.nz).

Where can I find more information and guidance on all these changes?

See the 2020 *Immunisation Handbook* available online by the end of September 2020 (exact date TBC, on the Ministry of Health website www.health.govt.nz).

IMAC resources will be available on www.immune.org.nz under 'Hot topics' or 'Written resources'. Providers can call 0800 466 863 or local immunisation coordinator to seek clarification.

Many fact sheets available on the IMAC website have recently been updated to support Schedule changes and new immunisation advice. Please check you are using the latest versions of these.

Patient management system (PMS) questions

How do I claim for Boostrix and administration costs?

Auto bill should work in the normal way for Boostrix vaccine administered to those aged 45 and 65 years.

When will PMSs be upgraded to reflect these changes?

All providers are expected to have updates ready for 1 October. PMS vendors will send out information to their users regarding updates and information on how to enter the vaccines. Please contact your PMS vendor if you are having trouble.

Emergency management changes in 2020 *Immunisation Handbook*

What are the changes to adrenaline administration?

The dose chart has been revised (weight calculation is not recommended for babies under 10 kgs); adrenaline is administered in the VL; and the limit on the total number of doses has been removed.

Why is there a new adrenaline dose chart?

The adrenaline dose chart now matches the Resuscitation Council NZ chart.

Why are we no longer calculating dose by weight for babies?

It is now recommended that you should use the age-related dose chart for babies under 10 kgs. This is quicker and easier than weight-based calculations. The latter have the potential for errors to occur and it is impossible to be accurate when drawing up these small, calculated volumes of adrenaline. The dose chart amounts have been agreed upon by experts as being safe and effective.

Why is it recommended to administer adrenaline via the VL route?

It is recommended adrenaline be administered into the VL to enquire best absorption, following national and international guidance. The maximum dose continues to be 0.5ml of 1;1,000 (500 mcg).

Why has the limit of 3 doses of adrenaline been removed?

This is to allow for the unlikely situation where medical help is delayed and the patient has responded initially to adrenaline but then deteriorates. This can occur due to the short half-life of adrenaline. In these circumstances, extra doses of adrenaline could be beneficial.

Does authorisation allow me to give these extra doses?

As an authorised vaccinator you are able to administer adrenaline to manage anaphylaxis according to the *Immunisation Handbook* guidelines, which now has no limit on the number of doses.

What are the changes to resuscitation training requirements?

Training updates are required every 2 years but no longer need include use of oxygen or airways. They do need to cover the use of adrenaline to treat anaphylaxis. Employers may still require you to complete Core Immediate training, but this is no longer essential training for vaccinators. Appendix A4.2 in the *Immunisation Handbook* covers the required content for resuscitation training updates.

Why do resuscitation courses need to cover anaphylaxis and use of adrenaline?

It is important that anaphylaxis management is also considered in the context of managing a cardiac arrest; hence, it needs to be included in this training as well as in the update training.

What level of training is likely to cover these new requirements?

There are no formally agreed resuscitation training levels below Core Immediate although some providers do offer 'Level 3 Resuscitation' or 'AED for Professionals' that cover anaphylaxis management. We encourage vaccinators to contact providers prior to booking training to confirm it will meet requirements.

Who is responsible for checking that a resuscitation training certificate covers the required skills?

All vaccinators are responsible for ensuring they attend an appropriate training course as part of their professional accountability. By including their training certificate when applying for reauthorisation, they are taking responsibility for ensuring they are maintaining the required standard of training. Some DHB regions may choose to update their reauthorisation form to include a box to tick to confirm the training attended met the requirements set out in Appendix A4.2.

What is immunisation stress-related response (ISRR) and where can I find out more information on it?

ISRR is a term that covers a spectrum of responses to stress experienced in relation to by immunisations. These responses vary from fainting and hyperventilation through to dissociative neurological symptoms, including non-epileptic seizures. These usually occur in individuals but have also been identified in clusters; this can be referred to as mass psychogenic illness. These stress responses are complex and involve both physiological and psychological factors. For more information see the WHO manual synopsis (available from **www.who.int/vaccine_safety/en/)**.