

## Childhood Immunisation

Children and young people in Ireland are entitled to certain vaccinations and immunisation services free of charge under the Primary Childhood Immunisation Programme, which are administered in general practice.

This factsheet aims to highlight to GPs the principles and best practice surrounding childhood immunisation, which are important to be aware of to avoid inadvertent errors and possible complaints relating to childhood immunisation.

### Primary Childhood Immunisation Programme

In order to provide routine childhood immunisations, a GP must hold a current contract under the Primary Childhood Immunisation Programme. Once the contract is in place, the GP should make contact with the HSE National Cold Chain Service, complete a set up form and they will then receive a vaccine delivery schedule. Changes in practice addresses, additional practices or movement between practices must be notified in writing to the HSE.

The National Immunisation Advisory Committee (NIAC) has published Immunisation Guidelines which can be [accessed here](#).

The HSE Guidelines provide that GPs should ensure that all general practice staff involved in the provision of vaccination are aware of all relevant guidelines and should facilitate any training required. This should include training in Basic Life Support and management of anaphylaxis. The BLS Provider programme is recommended every two years for all healthcare professionals.

The HSE Guidelines also highlight the role of the GP in the immunisation process, to include:-

- Avail of every opportunity (including the post-natal check/6 week visit) to promote vaccination.
- Have a medication protocol within the practice for the nurse administration of the vaccines. In the absence of a medication protocol, an individual prescription for each vaccination would be necessary.
- Carry out an individual medical assessment of the patient if requested by the practice nurse working under a medication protocol.
- Answer queries from parents/legal guardians of children being vaccinated and other members of the general practice team.
- Be present in the building while vaccines are being administered by nurse vaccinators and for 15 minutes after the last vaccine is administered, to provide for rare adverse outcomes such as anaphylaxis.
- Take queries from and give advice to parents/legal guardians/patients about possible side effects which may occur after they have left the general practice venue.
- Ensure that any adverse event is notified to the Health Products Regulatory Authority (HPRA).

### Vaccine Storage

The following are some practical tips to ensure safe vaccine storage:

1. **Remove** out of date vaccines and return them to the HSE National Cold Chain Service at next delivery. Vaccinations that are supplied outside this service should be disposed of as per local policy.
2. **Reorganise** the refrigerator: Ensure vaccine shelves are clearly labelled and not overfilled to allow air to circulate the packages. Vaccines should not be stored on the shelves or storage

compartments of the door of non-pharmaceutical refrigerators. Manufacturers' recommendations on the storage of individual vaccines should be observed.

3. **Rotate** your existing stock ensuring vaccines close to expiry date are stored to the front and used first.
4. **Regular** stock take: Closely monitor your vaccine stock to ensure your supplies can meet the demand at the practice.
5. **Read** the refrigerator temperatures (current, maximum, and minimum) twice daily in line with the national guidelines. Vaccines must be kept at temperatures between 2-8 degrees Celsius. The door opening should be kept to a minimum. Consider purchasing a data logger that will record the internal refrigerator temperature in the event of power failure. Remember a data logger does not remove the need to check the vaccine refrigerator temperatures twice daily. The practice should consider nominating a member of staff to undertake this duty including cover when they are on leave. Remember to lock the refrigerator door when not in use.
6. **Record** temperature readings in a logbook or electronically, including date and time, and sign each entry.
7. **Reset** the thermometer after each reading. The maximum/minimum reading should be cleared from refrigerator memory and reset after each reading.
8. **React** the person making the recording should take action if the temperature falls outside the +2°C to +8°C range and document this action. Guidance on the procedure following a breakdown in the Cold Chain is available on the HSE website.
9. **Routine** maintenance: the vaccine refrigerator should be cleaned every two months with a 1:10 solution of sodium hypochlorite. Annual maintenance and calibration should be carried out as per the manufacturers' guidance. Records should be kept of refrigerator maintenance and servicing and practice staff should know where to access them in the event of an issue.

## Avoiding errors

It is important for GPs and practice nurses to familiarise themselves with the HSE Guidance and ensure that best practice protocols are followed when administering childhood vaccines in their clinic. Knowledge and implementation of such protocols are important to avoid errors such as a breakdown in the cold chain, or expired / incorrect vaccinations being administered.

In addition, the following checks should always be carried out with the parent / legal guardian to establish the "Five Rights of Vaccine Administration" :-

1. The right patient
2. The right vaccine
3. The right dosage
4. The right route
5. The right time

## If an error does occur

If an expired or incorrect vaccine is administered, the baby / child's parents / legal guardians should be informed accordingly. Guidance can be sought from the HSE National Immunisation Office regarding any potential side-effects or adverse events as a result of the vaccine error;.

This information can be very helpful information to have when informing and reassuring the parents / legal guardians that no harm should result from the error.

The baby/child's parents / legal guardians should be reassured that a review will take place to ascertain how the error occurred and that steps will be put in place to reduce the risk of reoccurrence.

Arrangements should be made to re-administer the vaccination when appropriate, as per guidelines/advice received from the HSE National Immunisation Office.

Any vaccination error in a practice should be logged on an incident report form and filed in the practice risk management file. A review should take place to see how the error occurred and it should be discussed with staff at a practice risk management meeting as a learning experience to avoid future errors.

Medisec strongly advocates for open disclosure in the event of a vaccine error – i.e., that the child's parents / legal guardians be informed immediately as to what occurred. The GP should offer to meet with them to answer any questions they may have and review the child if required.

## Consent to Childhood Immunisation

Vaccination is not mandatory in Ireland; however, it is strongly advised by the Department of Health. It is important; however, to bear in mind that consent from parents / legal guardians is required for the administration of vaccinations to children and young people up to the age of 16 years.

Consent must be informed. The person providing consent to a vaccination should be offered as much information as they reasonably need to make their decision. The Medical Council's Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition 2019; available on the Medical Council's website, provides:

*"You must give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. Consent is not valid if the patient has not been given enough information to make a decision."*

The HSE Guidelines state that *"Under normal circumstances the parent(s) of a child can give consent for vaccination on their child's behalf. For students aged under 16, consent must be obtained from a parent or legal guardian.....Those aged 16 years of age and over can consent on their own behalf."*

The HSE Guidelines include a vaccination refusal form for parents/legal guardians who do not wish to have their child vaccinated. GPs can send a copy of this signed form to the HSE and they should keep a copy for the child's clinical record.

## Disagreement between legal guardians

The HSE National Consent Policy, updated in March 2022 and available on the HSE website, provides guidance where there is a disagreement between parents / legal guardians in respect of childhood immunisation and states that:

*"In general, the consent of one parent to vaccination will suffice unless both parents or all legal guardians have expressly indicated a wish to be involved in the process."*

*If the vaccinator has been expressly notified that one parent agrees to vaccination but the other disagrees, the vaccination should not be carried out until both parents reach agreement (or, rarely, there is a specific Court approval that vaccination is in the best interests of the child)....."*

*In such situations, the parents or legal guardians should be advised to discuss matters between themselves to seek to resolve their dispute. Discussion with the child's General Practitioner may be helpful to address any concerns. The parents should also be encouraged to discuss vaccination with their child, whose own views are also important."*

Ultimately, we advise not to administer a vaccine where you are on notice of a disagreement between parents / legal guardians on the matter. Should you find yourself in these circumstances, please contact MediseC for specific advice on your legal and ethical obligations and guidance on how best to proceed.

For further information in respect of legal guardianship, please see our factsheet entitled “*Guardianship of Minors*”, available on our website. You will also find more detailed guidance regarding the principles of consent in our factsheet entitled “*Consent to Medical Treatment*”.

The contents of this publication are indicative of current developments and contain guidance on general medico legal queries. It does not constitute and should not be relied upon as definitive legal, clinical or other advice and if you have any specific queries, please contact MediseC for advice.