

Childhood Immunisation

It is important for doctors to be aware of the principles and best practice surrounding childhood immunisation in order to avoid errors and complaints.

Primary Childhood Immunisation Programme

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.

In order to provide childhood immunisations, a doctor must hold a current contract under the Primary Childhood Immunisation Programme. Once the contract is in place the doctor 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 HSE National Immunisation Office has published “*Guidelines for Vaccinations in General Practice*” (available on the HSE website) (the “Guidelines”) which provide best practice guidance. The 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 and retraining in Basic Life Support on a regular basis in accordance with best practice.

The Guidelines 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 given 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 the client has left the general practice venue.
- Ensure that any adverse event is notified to the Health Products Regulatory Authority (HPRA).

Avoiding errors

It is important that GPs and practice nurses are familiar with the Guidance and that the protocols set out therein are followed. The protocols are important in order 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 / 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, guidance can be sought from the HSE National Immunisation Office regarding any potential side-effects or adverse events as a result of a vaccine error and the patient's parent / guardian should be informed accordingly. This can be very helpful independent information to have when informing and reassuring the parents / guardians that no harm should result from the error.

Medisec strongly advocates for open disclosure in the event of a vaccine error – i.e. that the child's parent / guardian 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.

The patient's parent / guardian should be reassured that a review will take place to ascertain how the error occurred and that steps will be put in place to ensure it will not happen again.

Arrangements should be made to re-issue the vaccination when appropriate. Paragraph 7.7 of the Guidelines state that if an expired vaccine is administered, a further dose should be given one month after the expired dose. It also states that the administration of an expired vaccine should be reported to the Health Products Regulatory Authority as a medication error.

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

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/guardians is required for the administration of vaccinations to children and young people up to the age of 16 years. The 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 Guidelines include a vaccination refusal form for parents/legal guardians who do not want to vaccinate their child. GPs can send a copy of this signed form to the HSE and keep a copy for the practice file.

➤ Legal Guardianship and Consent

Consent for childhood vaccinations (under the age of 16) must be obtained from the child's legal guardian. Please see Medisec's factsheet on *Guardianship* (available on our website) for full details of who can consent to treatment of children.

In summary, under current Irish law, a child's natural mother is an automatic guardian. A father who is married to the child's mother is also an automatic guardian.

If not married to the child's mother, the child's father is an automatic legal guardian if he has lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the

child's birth. This provision is not retrospective, so guardianship will only be acquired automatically where the parents live together for at least 12 months after 18 January 2016.

Under certain circumstances an unmarried father can become a joint guardian if both parents sign a statutory declaration or if it is directed by the court.

Where guardians cannot reach agreement on important issues concerning the child including childhood immunisation, it would be advisable for a GP to speak with both guardians together if possible to go through the options and answer any questions they may have. If agreement cannot be reached, the child's guardians can consider mediation and/or collaborative law and/or can apply to the Court for direction. This is a matter for the guardians and the child's doctor would not necessarily become involved. For example, one guardian can apply to the Court for an Order dispensing with the need for consent of the other guardian. A Court can use its discretion to dispense with a guardian's consent if it is found to be unreasonably withheld; the Court will make its decision based on the child's best interests.

➤ Informed Consent

Consent must be fully informed. Section 5.2 of the *Guidelines for Vaccinations in General Practice* provides:-

Informed consent must be obtained prior to vaccination. The person providing consent to a vaccination should be offered as much information as they reasonably need to make their decision.

In accordance with Paragraph 11 of the Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (available on the Medical Council website), information must also be given in a way they can understand.

The above is reiterated in the *HSE National Consent Policy*, (available on the HSE website) which states:-

For the consent to be valid, the service user must have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service.

➤ Informed Valid Consent from Parents/Legal guardians to vaccinate

The HSE National Consent Policy also states that: "*where both parents/legal guardians have indicated a wish and willingness to participate fully in decision making for their child, this must be accommodated as far as possible by the service provider. This also imposes a responsibility on the parents/legal guardians to be contactable and available at relevant times when decisions may have to be made for the child. Even where both parents/legal guardians have not clearly indicated their wish to be involved in decision making, if the decision will have profound and irreversible consequences for the child, both parents/legal guardians should be consulted if possible. However if urgent care is required and the second parent/legal guardian cannot be contacted despite reasonable efforts to do so, the service provider has a paramount duty to act in the best interests of the child.*"

Medisec frequently receive queries from GPs where a child's joint legal guardians are not in agreement with childhood vaccinations. In these circumstances, we can provide you with specific advice on your legal and ethical obligations and how you should proceed. Please do not hesitate to contact Medisec for advice.

"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".