

# Why we must be vigilant with vaccinations

**General practice teams play a crucial role in vaccination programmes. Suzanne Creed signposts potential medico-legal risks**

**VACCINATIONS ARE DESCRIBED** by the World Health Organization (WHO) as a global health success story.<sup>1</sup> They are a cornerstone of public health strategy, preventing countless deaths and reducing the burden of infectious diseases. According to a recent *Lancet* publication, since 1974, vaccinations have averted 154 million deaths, of which 146 million were children under five and 101 million infants younger than one year of age.<sup>2</sup> The WHO has also identified vaccination as a key strategy in sepsis prevention.<sup>3</sup>

General practice teams in Ireland are at the forefront of vaccination efforts and an integral part of this global success story, administering vaccines to patients of all ages. However, with the responsibility of such vaccinations comes the potential for medico-legal risks. This article explores the role of the GP practice team in vaccinations and offers some practical strategies for reducing your medico-legal risk.

## The role of the GP team

Each year over one million COVID-19 vaccinations and over one million flu vaccines are administered in the community.<sup>4</sup> The birth rate in Ireland was 54,678 births in 2023<sup>5</sup> and GP teams routinely deliver the Primary Childhood Immunisation Programme to these infants. GPs and general practice nurses (GPNs) are often the first point of contact for patients seeking information about vaccines, making their role in public health education and vaccine advocacy crucial. They also play a vital role in educating patients about the benefits of vaccinations, addressing concerns, and ensuring that patients receive timely immunisations. Addressing vaccine hesitancy can sometimes pose a significant challenge and GPs and GPNs have to be mindful of apprehension that can be caused by misinformation.

Administrative staff also play an integral role in supporting vaccine administration in general practice; scheduling vaccination appointments, assisting with setting up vaccine clinics, tracking vaccination payments and other such administrative duties.

## Who can administer vaccines in general practice?

It is important to ensure there is adequate cover in place for vaccinators in practice teams. With the ever-changing landscape of general practice, the role of clinical and non-clinical staff is continually evolving. Practice teams sometimes include phlebotomists and/or trained health care assistants (HCAs) sometimes referred to as primary care assistants (PCAs) who support clinical staff with specific tasks/procedures they have been trained to undertake.

Medisec frequently receives queries from our members about whether phlebotomists or HCAs can administer vaccines in general practice. In some other countries including the UK, HCAs administer vaccines in primary care, such as influenza and pneumococcal vaccines.<sup>6</sup>

However in Ireland, the current HSE guidance states: "Vaccinations must be administered by healthcare professionals who have completed the appropriate training and competencies (ie. general practice nurses or general practitioners)".<sup>7</sup> In accordance with these guidelines, cover for administering vaccines under the Medisec with MedPro GP and GP practice entity policies extends only to GPs and GPNs (subject to policy terms and conditions).

## Medico-legal risks with vaccinations

Despite the widespread benefits of vaccinations, GPs and practice staff may face potential medico-legal risks in the absence of robust systems surrounding vaccination procedures. These risks can arise from various factors, including, but not limited to:

- **Informed consent:** Patients or their parent(s)/legal guardian(s) in the case of a child must provide informed consent before receiving a vaccine. This involves ensuring that patients understand the benefits, risks and potential side-effects of the vaccine. Failure to obtain appropriate informed consent may give rise to a complaint or claim
- **Adverse reactions:** While serious adverse reactions to vaccines are rare, they can occur and result in a claim or complaint. Practice teams should be able to recognise and treat serious adverse reactions in emergency situations and consider whether any HPRA notification and/or guidance from the National Immunisation Advisory Committee (NIAC) is necessary
- **Record-keeping:** Contemporaneous and comprehensive record-keeping is essential in all aspects of safe patient care. Inadequate documentation may lead to disputes regarding whether a vaccine was administered, and whether proper procedures were followed. A poor standard of documentation may be viewed as a reflection of the standard of care provided
- **Vaccine storage and handling:** Vaccines must be stored and handled according to specific manufacturer and HSE guidelines in order to maintain their efficacy. Improper storage can lead to ineffective vaccines, resulting in potential liability for the practice
- **Communication and administration of vaccines:** Poor communication or miscommunication with patients or other members of the practice team may result in a vaccine error, omission, duplication of a vaccine or administration of an expired vaccine. Failure to adhere to vaccine schedules, recommendations, or changes in guidelines may also lead to missed vaccinations or vaccination errors potentially causing patient harm, ultimately giving rise to a claim or complaint.

## Vaccination vigilance – Reducing your medico-legal risk

The following are some practical risk management strate-

gies that you may wish to consider in order to reduce your medico-legal risk.

#### *Obtain informed consent*

Obtaining informed consent is a fundamental aspect of medical practice. Before administration, vaccinators should provide clear and comprehensive information about the vaccine, including its benefits, risks, and potential side-effects. Patient-friendly language should be used and medical jargon avoided. Patients or legal guardians should be encouraged to ask questions or raise concerns.

Document details of the consent process, including the information provided and the patient's understanding. The use of a consent form may be helpful but does not eliminate the necessity for detailed discussion around the consent process. Where there are issues regarding capacity or disagreement between legal guardians, the HSE consent policy should be consulted, and it may be necessary to seek medico-legal advice on how to proceed.

#### *Vaccine administration*

All staff should be familiar with HSE guidance and protocols around vaccination schedules. This is particularly pertinent in light of the recent changes to the Primary Childhood Immunisation Programme.<sup>8</sup> In addition, the following checks should always be carried out with the patient or parent/legal guardian to establish the 'Five Rights of Vaccine Administration': The right patient; the right vaccine; the right dosage; the right route; and the right time.<sup>9</sup>

#### *Keep detailed contemporaneous medical records*

Keep detailed records of all vaccinations administered, including the date, type of vaccine, batch number, route and site of administration, and the name of the person administering the vaccine. The use of electronic health records systems has multiple benefits. Good medical records should reflect the key details of the patient consultation. They are essential for safe patient care in addition to providing protection in the event of medico-legal claims or complaints.

#### *Follow guidelines for vaccine storage and handling*

Correct storage and handling of vaccines is critical to their efficacy. Adhere to the guidelines provided by the HSE and the NIAC<sup>11</sup> regarding vaccine storage, temperatures and conditions, thus ensuring the cold chain is maintained. Recording of vaccine fridge temperatures (current maximum and minimum) should be undertaken daily in line with national guidelines. A regular stocktake of vaccines will ensure supplies meet the demand at the practice while also facilitating stock, with a close-to-expiry date used first.

#### *Effective communication*

Effective communication is key to ensuring that patients are well-informed about vaccinations. GPs and practice nurses should avail of every opportunity to promote vaccination using multiple channels such as face-to-face discussions, printed materials and digital resources. Keeping patients informed about changes in vaccination schedules or guidelines as well as fostering a culture where patients feel comfortable discussing their concerns about vaccines will also enhance vaccine uptake.

#### *Keeping up to date*

All staff involved in vaccinations should receive appropriate training relevant to their role and keep abreast of any relevant updates issued by the HSE, NIAC or other relevant

bodies. This includes having up-to-date certification in basic life support (BLS) and anaphylaxis.

#### *Managing adverse events*

Where adverse events occur, it is important that they are investigated appropriately, and any necessary actions taken to prevent future incidents. Any suspected adverse reactions associated with medicine errors should be reported to the HPRA.<sup>12</sup> Vaccinators should also consider contacting their indemnifiers/insurers.


#### *Policies and protocols*

Having clear vaccination policies and protocols within the practice can help standardise procedures and reduce risks. You may wish to consider the following key issues: guidelines for obtaining informed consent; procedures for documenting vaccinations and adverse reactions; protocols for vaccine storage and handling; and medication protocols for vaccine administration.

Medication protocols should be in place for all vaccinations. Staff authorised to use the medication protocol should ensure they are familiar with the details of the protocol and sign a copy of the protocol evidencing that they understand and agree to adhere to it. Template medication protocols are available from the HSE.<sup>7</sup>

#### *Conclusion*

Vaccinations are a vital component of public health in Ireland, and general practice teams play a crucial role in providing information and administering vaccines. However, with this responsibility comes the potential for medico-legal risks.

By implementing the strategies outlined above, general practice staff may significantly reduce their medico-legal risk while continuing to provide essential vaccination services to their patients. Ultimately, a proactive approach to managing these risks enhances patient safety and public health outcomes, while also protecting the practice. 

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#### References

1. World Health Organisation, Vaccines and immunization: [https://www.who.int/health-topics/vaccines-and-immunization/#tab=tab\\_1](https://www.who.int/health-topics/vaccines-and-immunization/#tab=tab_1)
2. Shattock, Andrew J et al. Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization: The Lancet, 2024: 403(10441): 2307-2316
3. WHO, Global Report on the epidemiology and burden of sepsis, Current evidence, identifying gaps and future directions (2020): 9789240010789-eng.pdf
4. HSE, Vaccination Primary Care Contractors Programme (COVID-19 and Influenza): Vaccination Primary Care Contractors Programme – HSE.ie
5. CSO, Vital Statistics Yearly Summary 2023: <https://www.cso.ie/en/releasesandpublications/ep/p-vs/vitalstatisticsyearlysummary2023/data/>
6. Public Health England, National Minimum Standards and Core Curriculum for Immunisation Training of Healthcare Support Workers (2015): [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/464033/HCSW\\_Train](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/464033/HCSW_Train)
7. HSE, Supporting Information for Vaccinations in General Practice (Applicable from October 2024): <https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf>
8. HSE, Primary Childhood Immunisation Schedule, October (2024): <https://www.hse.ie/eng/health/immunisation/pubinfo/currentschedule.html>
9. HSE, National Immunisation Office, Guidelines for Vaccinations in General Practice, (September 2016): <https://www.hse.ie/eng/health/immunisation/pubinfo/pcischedule/gpguidelines.pdf>
10. HSE, Vaccine Ordering and Storage, (Updated September 2024): Vaccine Ordering and Storage – HSE.ie
11. NIAC, Immunisation Guidelines for Ireland, (Updated December 2024): Royal College of Physicians of Ireland Website > Healthcare Leadership > NIAC > Immunisation Guidelines for Ireland
12. HPRA, Reporting Suspected Side Effects: <https://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects>