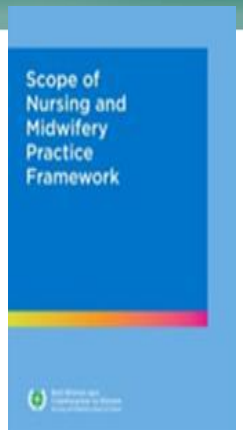
Office of the Nursing & Midwifery Services Director

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Professional Legal and Ethical Aspects of the Seasonal Influenza

Peer Vaccination Programme 2020/2021

Professional, Legal and Ethical Guidance



STATUTORY INSTRUMENTS
SI 715 of 2011
Commencement Orders on Sections 1&2 & Part 12 of Nurses & Midwives Act 2011

PROTECT PREVENT IMMUNISE

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

NURSING & MIDWIFERY
Quality Care-Metrics

Health Service Executive Standards & Recommended Practices for Healthcare Records Management (Version 3, May 2011)

Health Information and Quality Authority
Fhaisnéis Sláinte

Bord Altranais agus Cnáimhseachais na hÉireann
Nursing and Midwifery Board of Ireland

THE FLU VACCINE
www.immunisation.ie

hi Healthy Ireland

Tús Áite do Shábháilteacht Othar
Patient Safety First

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

hpsc

Medicine Protocols

- “Medicine protocols are written directions that allow for the supply and administration of a named medicine by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse or midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment” (ABA, 2007 p.35)
- An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect (ABA, 2007)
- Seasonal Influenza Vaccine is a prescription only medicine which can be administered under an approved Medicine Protocol.

Framework for Medicine Protocols

- Medicine protocol use should be considered in the context of the clinical situation, safety assurance for the patient, and acceptance of accountability by the healthcare professional involved.

- In operationalising a medicine protocol, a nurse or midwife who is authorised to supply, is also responsible for administration of the medicine. This activity cannot be delegated.

- NMBI supports the development of medicine protocols using a nationally recognised template based on international evidence and best practice. Responsibility for developing and quality-assuring medicine protocols rests with health service providers (ABA ,2007).

Medicine Protocol Framework Template

1. Critical elements
2. Clinical criteria
3. Details of medicine to be supplied
4. Patient/Service-user care information
5. Staff authorised to use protocol (ABA, 2007).

Role of Registered Nurse/Midwife in the Administration of Seasonal Influenza Vaccine

- Nurses and midwives employed by the HSE who have completed the relevant education programmes and working within their scope of practice framework, are authorised under **medicine protocol** developed by the ONMSD, HSE and the NIO to administer the Seasonal Influenza Vaccine to Recipient HCWs as part of the Seasonal Influenza Peer Vaccination Programme

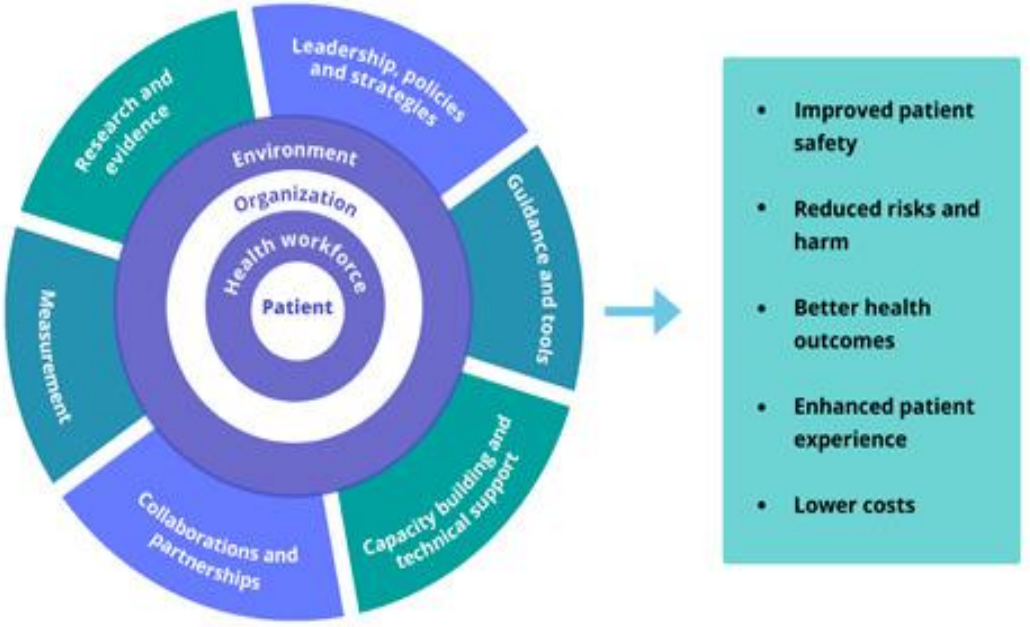
Responsibility of the Registered Nurse/Midwife administering vaccines

- Undertake the relevant education and training
- Complete the *Self-Assessment of Competency* to administer the seasonal influenza vaccine under medicine protocol.
- Work within scope of practice (NMBI 2015)
- Maintain and update professional competence through relevant continuing professional development
- Comply with local Policies, Procedures and Protocols and Guidelines
- Be competent and maintain competence in all aspects of SIPVP including:
  - Care and management of recipient HCW throughout the procedure;
  - Completion of all associated documentation;
  - Be familiar with & comply with HSE infection prevention & control, health & safety procedure & risk management policies as they apply to the SIPVP & safe disposal of equipment.

NMBI Professional Guidance

- Code of Professional Conduct and Ethics for Registered Nurses & Registered Midwives (NMBI, 2014).
- Scope of Nursing & Midwifery Practice Framework (NMBI, 2015).
- Practice Standards for Midwives (NMBI, 2015).
- Guidance to Nurses and Midwives on Medication Management (ABA, 2007)
- Recording Clinical Practice Guidelines (NMBI, 2015).

WHO Publication Patient Safety (2017)



Vision: A world where every patient receives safe healthcare, without risks and harm, every time, every where.

Mission: To facilitate sustainable improvements and managing risks to prevent harm (WHO 2017:4)

www.who.int/patientsafety/en/

Legal Guidance

- Assisted Decision-Making Capacity Act 2015
- Data Protection Acts 1988, 2003, 2018 (GDPR, HSE LanD).
- Freedom of Information Act 2014, 2017.
- Nurses and Midwives Acts 2011
- National Consent Policy (HSE, 2019).
- The Health (Pricing and Supply of Medical Goods) Act 2013
- Irish Medicines Board (Miscellaneous Provisions) Act 2006
- Irish statute 'Children and Family Relationship Act 2015.
- Medicinal Products *(Prescription and Control of Supply)* Regulations 2003 as amended 2007
- Medicinal Products *(Control of Placing on the Market)* Regulations 2007
- Medicinal Products *(Control of Advertising)* Regulations 2007
- Mental Health Act 2001
- Misuse of Drugs Regulations 2017

Guidance to Nurses and Midwives on Medication Management (ABA, 2007)

Key Principles:

- Competence
- Accountability & Autonomy
- Continuing Professional Development
- Support for professional nursing and midwifery practice
- Delegation
- Emergency situations.

Guidance to Nurses and Midwives on Medication Management (ABA, 2007).

Standard:

- Nurses and midwives involved in immunisation programmes (including vaccine administration) should maintain their competency and current knowledge with all aspects of this practice

This Encompasses:

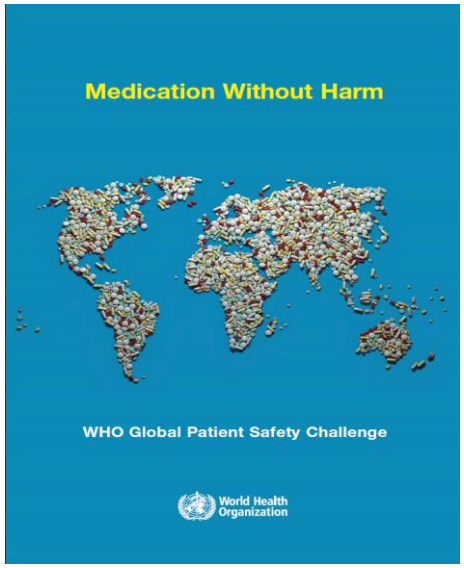
- Obtaining consent
- Vaccine handling and delivery
- Storage and stock control
- Proper techniques of administration
- Recognition and intervention with side effects, adverse events and/or complications post immunisations
- Management of anaphylaxis or suspected anaphylaxis.

Guidance to Nurses and Midwives on Medication Management (ABA, 2007)

Standard:

- "The nurse or midwife should be able to manage adverse reactions including anaphylaxis as first line providers in emergency situations. Anticipation of this may require basic life-support training, additional resources, skills and equipment. Anaphylaxis may also necessitate the administration of emergency medicines (for example, epinephrine) and nurses and midwives should be knowledgeable about treatment with these medicines" (ABA, 2007, p30).

WHO Publication Medication Without Harm (2017)



Overall goal

The Global Patient Safety Challenge on Medication Safety focuses on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm (WHO 2017: 5)

www.who.int/patientsafety/medication-safety/en/

HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority

HPRA requests in particular that healthcare professionals would report the following:

- All suspected reactions to newly authorised medicines (i.e. those on the market for less than 2 years)
- Serious, suspected reactions to established medicines
- Any suspected reactions to vaccines
- Any suspected teratogenic effects
- Any suspected reactions to exempt medicinal products

www.hpra.ie

Online Reporting

- Human Medicines Adverse Reaction Report
- https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form
- Suspected Medicinal Product Quality Defect Form
- https://www.hpra.ie/homepage/about-us/report-an-issue/suspected-medicinal-product-defect
- Medical Device Incident User Report Form
- https://www.hpra.ie/homepage/about-us/report-an-issue/mdiur

Irish Medication Safety Network

IMSN
IRISH MEDICATION SAFETY NETWORK

Patient Safety First
Working together for quality services

Briefing Document:
Reducing Preventable Harm to Patients with Known Drug Allergies

This document is intended as a briefing document and is not to be regarded as a document offering definitive legal advice in relation to the subject matter

Publication Date: Oct 2012

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www.imsn.ie

Irish Medication Safety Network

Patient Safety First
Working together for quality services

Safety Alert

Allergy and Anaphylaxis to Known Drug Allergens

Issue

Allergic and anaphylactic reactions may occur when known drug allergens are prescribed, dispensed and administered to patients. This harm is preventable. Rapid recognition and treatment is essential. Anaphylaxis to drugs begins and progresses rapidly. Severe hypotension +/- tachycardia is common, as are extreme anxiety, agitation and GI disturbance. Respiratory and skin signs may be absent. The most common causes of fatal drug anaphylaxis are neuromuscular blockers, cephalosporins, contrast media, penicillins and NSAIDs[1,2].

Evidence of Harm

- Drug allergies and adverse drug reactions led to 62,000 hospital admissions in England annually[2]
- In the UK between 2005 and 2013 18,079 patient safety incidents involved drug allergy. These included 6 deaths, 19 'severe harms', 4980 'other harms' and 13,071 'near-misses'. The majority of these incidents involved a known drug allergen[2]
- In Ireland over one-quarter of all medication-related claims intimated to the Clinical Indemnity Scheme from January 2004 - December 2010 arose as a result of a known allergen being prescribed / administered. This led to 4 patient deaths, with others experiencing significant morbidity[3].

How to Reduce the Risks

1. **Check allergy status immediately before prescribing, dispensing or administering drugs**:
   Every drug, every patient, every time.
2. **Understand cross-allergies:**
   Use reliable references to check which drugs are contra-indicated.
3. **Ensure patients understand their allergies, which drugs to avoid and the nature of their reaction.**
   Provide patients with written detailed information on their reaction.
   Encourage patients to share their allergy status with all health care professionals they encounter.
   Referral to an immunologist may be required where there is difficulty determining the drug allergen.
4. **Ensure drug allergies are clearly documented and shared at the point of drug use (Drug Chart/Prescription)** before prescribing / administering any drug.
   Document the drug / class and nature of the reaction.
5. **Maximise the impact of computerised prescribing, where available:**
   a. Require input of allergies or NKDA (No Known Drug Allergies) before the first prescription.
   b. Generate automated alerts to prescribers if an allergen is selected.
   c. Ensure alerts for contra-indicated allergens cannot be overridden without amending allergy status.
6. **Configure healthcare databases to allow recording of allergy information.**
   Clarify who is responsible for completing this step.
   Ensure that allergy status automatically displays on all screens referred to during medication-related processes.
7. Ensure that guidelines and facilities for diagnosis, treatment and follow up of allergies and anaphylaxis **are accessible, clear and that healthcare professionals are trained in their use.**

See the Briefing Document on "Reducing Preventable Harm to Patients with Known Drug Allergies' at http://www.imsn.ie/all-news/18-briefing-documents/62-allergies for further information

References
1. Pumphrey, RS. Anaphylaxis: Can we tell who is at risk of a fatal reaction? Curr Opin Allergy Clin Immunol. 2004; 4 (4)
2. NICE. *Drug allergy: diagnosis and management* (CG 183). London: NICE 2014. Available at: (https://www.nice.org.uk/guidance/cg183/chapter/Introduction);
3. Clinical Indemnity Scheme Newsletter, Dublin: CIS; March 2011

Prepared in 2012 by: C Kirke, Tallaght Hospital, M Creed, MMUH, R Lynch, Louth County Hospital & M O'Connor, OLCHC on behalf of the IMSN.
Updated in 2016 by: M Creed, MMUH on behalf of the IMSN

Scope of Nursing and Midwifery Practice Framework (NMBI, 2015)

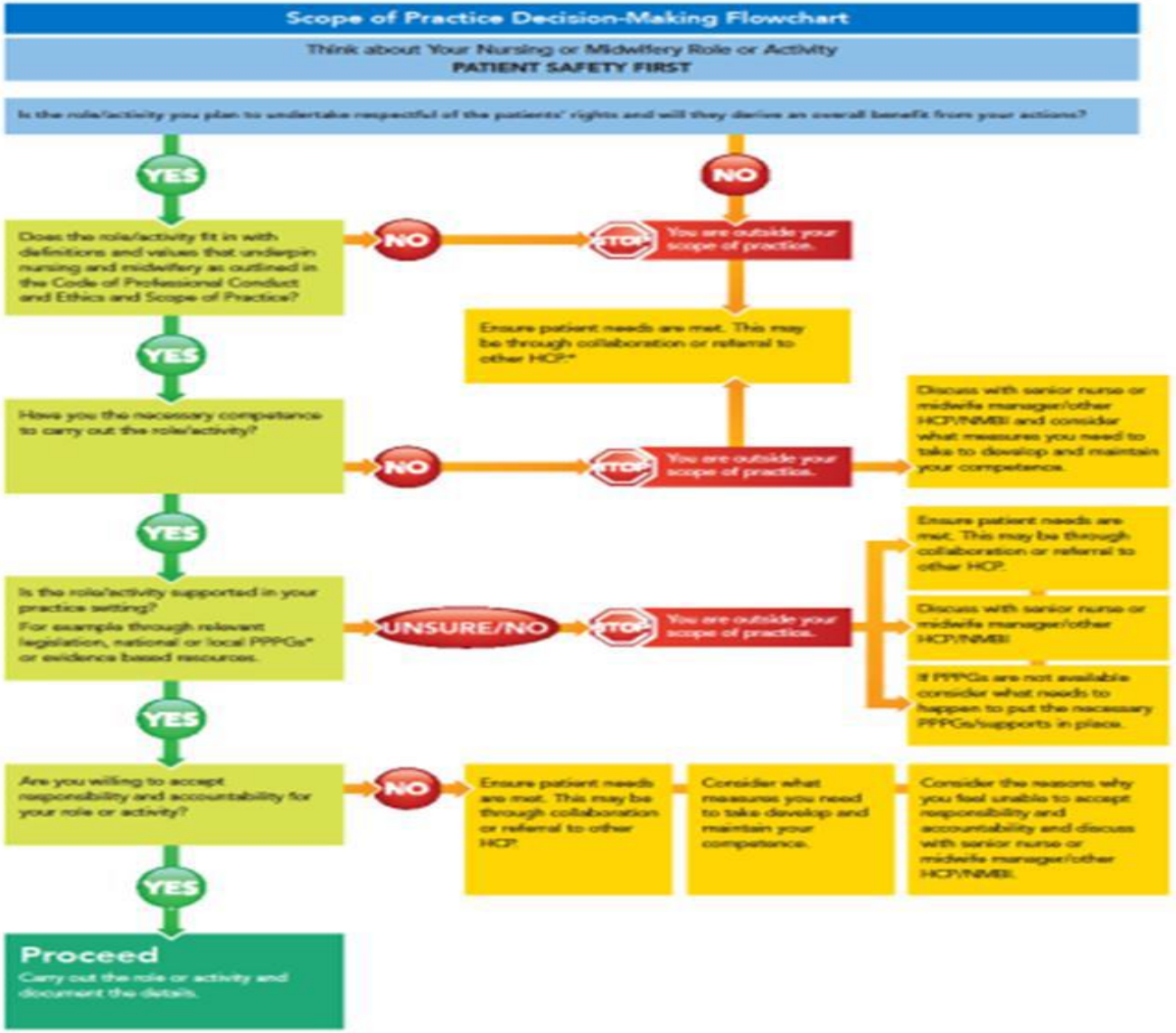
- Provides guidance to all nurses and midwives in determining their roles and responsibilities in relation to the provision of safe, quality patient care.

- It encourages nurses and midwives to critically examine their scope of practice and expand it, where appropriate, cognisant of a changing health care environment and the patient.

Scope of Nursing & Midwifery Practice Framework (NMBI, 2015)

Considerations in determining the scope of nursing and midwifery practice

- Competence
- Accountability and Autonomy
- Continuing Professional Development
- Support for Professional Nursing and Midwifery Practice
- Delegation and Supervision
- Practice Setting
- Collaborative Working
- Role Expansion
- Emergency (life threatening) Situations
- Decision Making Framework (NMBI, 2015)


Scope of Practice Decision-Making Flowchart
Think about Your Nursing or Midwifery Role or Activity
PATIENT SAFETY FIRST
Is the role/activity you plan to undertake respectful of the patients' rights and will they derive an overall benefit from your actions?
YES
NO
Does the role/activity fit in with definitions and values that underpin nursing and midwifery as outlined in the Code of Professional Conduct and Ethics and Scope of Practice?
NO
STOP
You are outside your scope of practice.
YES
Ensure patient needs are met. This may be through collaboration or referral to other HCP.*
Have you the necessary competence to carry out the role/activity?
NO
STOP
You are outside your scope of practice.
Discuss with senior nurse or midwife manager/other HCP/NMBI and consider what measures you need to take to develop and maintain your competence.
YES
Is the role/activity supported in your practice setting?
For example through relevant legislation, national or local PPPGs* or evidence based resources.
UNSURE/NO
STOP
You are outside your scope of practice.
Ensure patient needs are met. This may be through collaboration or referral to other HCP.
Discuss with senior nurse or midwife manager/other HCP/NMBI
If PPPGs are not available consider what needs to happen to put the necessary PPPGs/supports in place.
YES
Are you willing to accept responsibility and accountability for your role or activity?
NO
Ensure patient needs are met. This may be through collaboration or referral to other HCP.
Consider what measures you need to take develop and maintain your competence.
Consider the reasons why you feel unable to accept responsibility and accountability and discuss with senior nurse or midwife manager/other HCP/NMBI.
YES
Proceed
Carry out the role or activity and document the details.

Principles for Determining Scope of Practice guided by the Code of Professional Conduct & Ethics for Registered Nurses & Midwives (NMBI, 2014)

1. Respect for the Dignity of the Person
2. Professional Responsibility and Accountability
3. Quality of Practice
4. Trust and Confidentiality
5. Collaboration with others

Legal and Professional Accountability

- The registered nurse/midwife is legally and professionally accountable for his/her:
  - Practice
  - Decisions made
  - Consequences of those decisions.
- The registered nurse/midwife is accountable to:
  - Patient
  - Public
  - Regulatory Body
  - Employer
  - Relevant supervisory authority (NMBI, 2014).

Competence

- Attainment of knowledge, intellectual capacities, practice skills, integrity and professional and ethical values required for safe, accountable and effective practice as a registered nurse or registered midwife (NMBI, 2015)

- Nursing/Midwifery competence is both a professional issue and central to patient-care outcomes (Cowen et al., 2008)

- Competence is the ability of the registered nurse/midwife to practice safely & effectively fulfilling his/her professional responsibility within his/her scope of practice (NMBI, 2015)

Competence

- Competent nurses/midwives think critically, practice safely and effectively based on evidence (Butler et al., 2011)
- Competence is not constant, it relates to division of the Register, and maintained through CPD (NMBI, 2015)
- Levine & Johnson (2014) suggests that skills may lapse if not used regularly.

What is Consent?

"Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication in which the service user has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention or service" (HSE, 2019, p.20)

Available on http://52.169.106.200/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf

Why is Consent Required?

This requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and international law (HSE, 2019)

For Consent to be Valid (Legal)

The individual must:

- have received sufficient information, communicated clearly in plain English, in a comprehensible manner about the nature, purpose, benefits and risks of an intervention or service and alternative options;
- be acting voluntarily (that is, not under undue duress from anyone);
- have the mental capacity (be ‘competent’) to make a particular decision at that time.

(HSE, 2019)

Informed Consent in Vaccination

The individual must be informed of the best current information on:

- The vaccine to be administered and against which disease they provide protection
- the benefits and risks of the vaccine and the risk of diseases
- the possible side effects of vaccination, when might they occur and how should be treated.

What information about risks & side effects of an intervention should be provided?

In general, information includes the likelihood of the following:

- Side effects or complications of an intervention;
- Failure of an intervention to achieve the desired aim
- The risks associated with taking no action or with taking alternative approach
- Minor side effects and serious adverse outcomes should be disclosed.

 Refer to medicine protocol.

Informed Consent

- Individuals must be given the opportunity to ask questions, before agreement to proceed or not with immunisations.
- Consent is required for each individual vaccine prior to administration.
- Further information can be obtained from:

– Information Fact Sheets,
– National Immunisation Guidelines,
– Health Products Regulatory Authority,
– National Immunisation Office,
– Manufacturers Summary of Product Characteristics (SmPC).

Vaccination Consent Form

- Individual's personal details.
- If vaccine not administered - reason why.
- Date & time vaccine given, batch number, injection site.
- Prescriber/vaccinator signature & PIN/MCRN
- Clinic name and location
- Record all decisions and discussions that have taken place with the individual
- Record all information that has been supplied to support decision making
- Consent form is signed by the recipient HCW.

Consent – Recipient HCWs with Literacy Difficulties

- If recipient HCW has literacy difficulties but is competent they can be asked to make their mark on the “Consent Form”.
- This mark must be witnessed by an adult other than the vaccinator.
- Translated information leaflets are available.

Recording Clinical Practice: Guidance (NMBI, 2015)

- Good record keeping is part of the professional and legal accountability of registered nurses and midwives.
- The purpose of good record management.
- Confidentiality.
- Documenting consent to treatment.
- Legal considerations.
- Use of records in research.

- -

Healthcare Risk Management

As part of Seasonal Influenza Peer Vaccination Programme, registered nurses/midwives should:

- Observe and report suspected adverse reactions
- Advise the recipient healthcare worker to contact relevant medical personnel in the event of adverse reaction occurring following administration of the vaccine (GP/out of hours/Emergency Department/Occupational Health Department).
- Identify and report any adverse reactions (medications and medical devices) to the Health Products Regulatory Authority www.hpra.ie in conjunction with the Occupational Health Department or to local risk management as per local health service provider PPPG.
- Complete National Incident Report Forms (NIRF-01-v11)(NIMS, 2020) available at https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf
- Refer to HSE Incident Management Framework (2018)

The Framework for Improving Quality

Governance for quality involves having the necessary structures, processes, standards and oversight in place to ensure that safe, person centred and effective services are delivered (HSE, 2020) available at https://www.hse.ie/eng/about/who/qid/governancequality

The Framework for Improving Quality in Our Health Service (the Framework) (HSE, 2016) shares six drivers of quality improvement

The six drivers for improving quality are:

- leadership for quality,
- person and family engagement,
- staff engagement,
- use of improvement methods,
- measurement for quality, and
- governance for quality.

Available at https://www.hse.ie/eng/about/who/qid/strategic-plan-2019-2024/strategic-approach-2020-2024.pdf

Clinical Governance

- Governance

- In the interest of quality and safety each service provider must develop a governance framework based on:
  - Legalisation;
  - Organisational Policies and Procedures;
  - Risk Management;
  - Clinical Audit;
  - Evidence-based Practice

Any Questions?