Professional, Legal and Ethical Aspects of the Schools Immunisation Programme
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. An example of this are nurse-led vaccination programmes in schools (ABA, 2007).

• An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect.
Medicine protocols

• The legislative basis for medicine protocols for the supply and administration of medicines is the Medicinal Products (Prescription and Control of Supply) Regulations of 1996, as amended, which provides authority for hospitals to utilise medicine protocols in order to meet patient need for medicines management.

(ABA, 2007)
Revised 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 care information;
5. Staff authorised to use protocol (ABA 2007).
Role of Nurses and Midwives in the Administration of School Vaccinations

Nurses and midwives employed in the HSE who have completed the relevant education programmes and working within their scope of practice framework are authorised under medicine protocols developed by the ONMSD and the NIO administer the following vaccines:

I. IPV Boostrix (Tdap/IPV)
II. MMRvaxPRO (MMR)
III. Priorix Vaccine (MMR)
IV. Boostrix (Tdap)
V. Gardasil (HPV)
VI. Menjugate (Men C)

For the 2018/2019 HSE School Immunisation Programme
Responsibility of Registered Nurse/Midwife administering vaccines

- Undertake education in relation to this medication protocol and in the ‘Management of a patient who Develops Anaphylaxis and the Medicine Protocol for the administration of Epinephrine’ (2018)
- Work within Scope of Nursing and Midwifery 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 the SIP including:
  - Care and management of the child/student 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 SIP & safe disposal of equipment.
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- Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI, 2014).
- Scope of Nursing & Midwifery Practice Framework (NMBI, 2015).
- Guidance to Nurses and Midwives on Medication Management (ABA, 2007).
- Recording Clinical Practice Guidelines (NMBI, 2015).
- Nurses and Midwives Acts 2011.
- Practice Standards for Midwives (NMBI, 2015).
- Recording Clinical Practice Guidelines (NMBI 2015).
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- The Health (Pricing and Supply of Medical Goods) Act 2013
- Medicinal Products (Prescription and Control of Supply) (amendment 2007) Regulations 1996
- 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
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- Irish statute ‘Children and Family Relationship Act 2015.
- Children First Act, 2015
- Child Care Act, 1991
- Children Act, 2001
- The Criminal Justice (Withholding of Information on Offences against Children and Vulnerable Persons) Act, 2012
- National Vetting Bureau (Children and Vulnerable Persons) Act 2012.
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 vaccination 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;
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).
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.
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 Nursing & Midwifery Practice Framework (NMBI, 2015).
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/registered midwife is legally and professionally accountable for his/her:
  • Practice;
  • Decisions made;
  • Consequences of those decisions.

• 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 (Cowan et al. 2008).

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

• Competent nurses/midwives think critically, practice safely and effectively based on evidence (Butler et al. 2011).

• Competence is not constant, relates to division of the Register, 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 about the proposed intervention. Seeking consent is part of a good practice in communication and decision-making and should usually occur as on-going process rather than a once–off event.

(HSE National Consent Policy, 2016)
Why is consent required?

Consent acts as protection for both health professionals and individuals so if any questions are asked in the future there is a record available to show what the individual agreed to on the day of consent. (HSE, 2016)
For Consent to be Valid (Legal)

The individual must:

• have received sufficient information 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.

National Consent Policy (HSE, 2016)
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 protocols.
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 vaccines prior to administration.

• If consent is obtained before the day of vaccine consent must be reconfirm in child friendly terms to the child.

• 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

- Individuals personal details.
- Consent is correctly completed by parent/legal guardian/individual to give vaccine.
- 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.
What is the Age of Consent?

• Irish Law permits a person aged 16 years and upwards to consent to treatment (medical, surgical, dental)  
  (Section 23 Non Fatal Offences Against the Person Act, 1997)

• For children under 16, consent is given by the parent(s) or a legally recognised guardian.  
  (HSE National Immunisation Office, 2013)
Consent - Parents with literacy difficulties

• If parent/guardian 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.

(HSE National Immunisation Office, 2008)
Who can give consent for a child?

- Parental and legal guardians.

- Legal guardianships refer to the rights and responsibilities of a parent to be involved in all major decisions affecting the child including education, health and moral concern.

- Under Irish law the following rules apply:
  - Where the parents are married, both the mother and father are the legal guardians.
  - Where the child has been jointly adopted by a couple, the adoptive parents are both legal guardians.
Who can give consent for a child?

• After separation or divorce, both parents remain legal guardians.
• If parents are not married, the child's mother is the only automatic legal guardian, but the child's father may also be legal guardian by agreement with the mother effected by way of 'statutory declaration' under the Guardianship of Children (Statutory Declaration) regulation.
• The child's father (unmarried and without statutory declaration) may apply to the court to be appointed legal guardian; this application will be determined on the basis of the best interest of the child.
• An unmarried father will automatically be a guardian if he has lived with the child’s mother for 12 consecutive months after Jan 2016, including at least 3 months with the mother and child following child's birth (Irish statute ‘Children and Family Relationship Act 2015').
Consent

• Where a child accesses a health or social service with an adult, the adult should be asked to confirm that they are the parent or legal guardian.
• This should be documented in child’s records.
• If they are not the parent/legal guardian, contact must be made with the appropriate person to seek consent.
Consent

- Where a child’s parent is a minor, he/she is presumed to be the best decision maker for the child.
- If required an assessment of their maturity may be considered in their decision, as appropriate another person may be consulted (the child’s grandparents).
- If agreement cannot be reached, legal advice should be sought.
Consent for Medical Treatment for Foster-Children?

- Child Care (Amendment) Act, 2007 which updates the Child Care Act 1991.
- At all times consent should first be sought from the mother of the child.
- A foster parent who has been taking care of a child for not less than five years may apply to the Court for an order giving them more control and authority over the child, including authority to consent to any necessary medical treatment.
- Must have the consent of the HSE.

(HSE National Immunisation Office, 2008)
Recording clinical practice: guidance (NMBI 2015)

• Good recording 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.

Office of the Nursing & Midwifery Services Director
Health Service Executive
Healthcare Risk Management

As part of schools immunisations programme, registered nurses/midwives are in a prime position to:

- Observe and report suspected adverse reactions.
- Identify and report any adverse reactions (medications and medical devices) to the Health Products Regulatory Authority [www.hpra.ie](http://www.hpra.ie).
- Information and direction in reporting adverse reactions should be incorporated into medication management policies (ABA, 2007).
- Report to Schools Immunisations Team Leader/Line Manager.
Regulation (HSE 2012)
Regulation

• Clinical Governance
  – Clinical governance is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver
  – A key characteristic of clinical governance is a culture and commitment to agreed service levels and quality of care to be provided
  
  (HSE 2012: 2)
Achieving Excellence in Clinical Governance (HSE 2010)

- Accountability applies at two levels—the individual staff level and the healthcare organisation level (HSE 2010: 10).

**Individual staff level:**

I have personal responsibility for the following:

- Being competent in all aspects of my work
- Recognising and working within the limits of my competence
- Reviewing and auditing the standards of care which I provide
- Co-operating fully with external reviews, audits and enquiries
- Where I am not satisfied with the standards of care/service, nor have the capacity, I am responsible for taking steps to resolve problems and having explored all other options, I shall draw the matter to the attention of my line manager (HSE 2010: 10).
Any Questions?