

**Professional,  
Legal and Ethical Aspects  
2020**

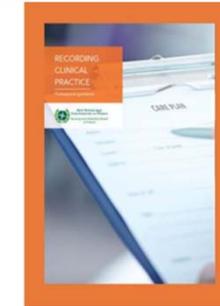
# Professional, Legal and Ethical Guidance

## STATUTORY INSTRUMENTS

SI 715 of 2011

Commencement Orders on Sections 1&2 & Part 12 of Nurses & Midwives Act 2011

Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives



Practice Standards for Midwives



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



NATIONAL CLINICAL EFFECTIVENESS COMMITTEE



Feidhmeannacht na Seirbhíse Sláinte Health Service Executive



HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority



Tús Áite do Shábháilteacht Othar Patient Safety First

# 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**

- 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).
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# **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).
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# 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;

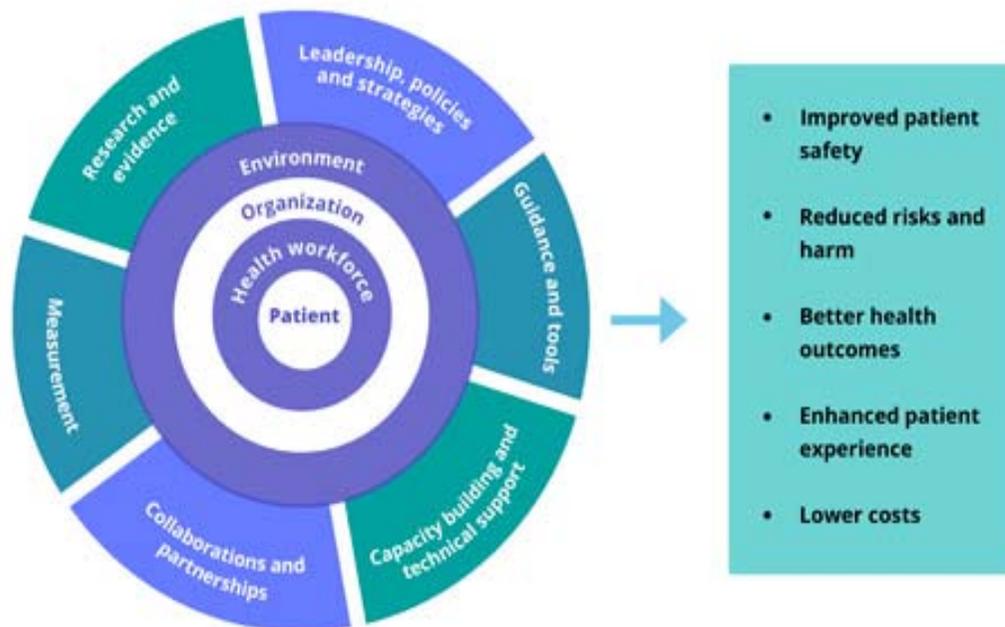
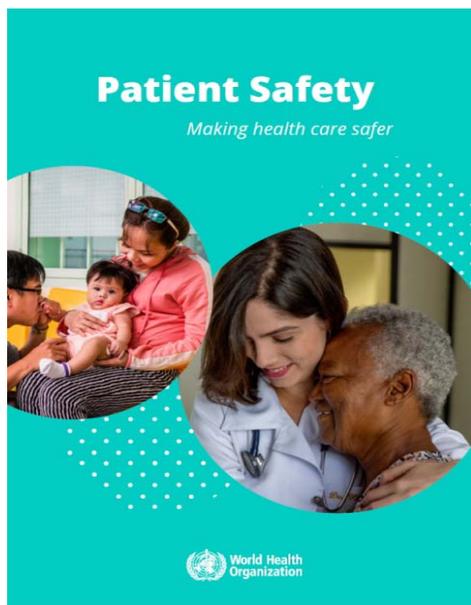
- I. IPV Boostrix (Tdap/IPV)
- II. MMRvaxPRO (MMR)
- III. Priorix Vaccine (MMR)
- IV. Boostrix (Tdap)
- V. Gardasil (HPV4/9)
- VI. Menjugate (Men C)
- VII. Meningococcal group A,C,W and Y (Men ACWY).

*For the 2019/2020 HSE School Immunisation Programme*

## Responsibility of Registered Nurse/Midwife administering Vaccines

- Undertake education in relation to this medicine protocol and in the '*Management of a patient with 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;
- 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.

# 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/](http://www.who.int/patientsafety/en/)

## **Professional, Legal and Ethical Aspects of Schools Immunisation Programme**

- 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).
- Health technology assessment (HTA) of extending the national immunisation schedule to include HPV vaccination of boys (HIQA, 2018).
- Recording Clinical Practice Guidelines (NMBI, 2015).
- Nurses and Midwives Acts 2011.
- Practice Standards for Midwives (NMBI, 2015).
- Standards & Recommended Practices for Healthcare Records Management (HSE 2012).
- Recording Clinical Practice Guidelines (NMBI 2015).

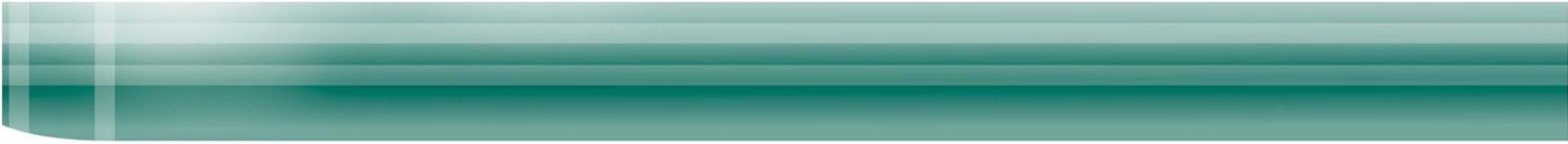
## Professional, Legal and Ethical Aspects

- The Health (Pricing and Supply of Medical Goods) Act 2013
- Irish Medicines Board (Miscellaneous Provisions) Act 2006
- 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
- Assisted Decision-Making (Capacity) Act 2015.
- Data Protection Acts 1988, 2003, 2018 (GDPR, HSE LanD).
- Freedom of Information Act 2014, 2017.

## Professional, Legal and Ethical Aspects

- Legal Aspects of Immunisation. Chapter 6. National Immunisation Guidelines (HSE, 2014).
- Informed Consent : National Consent Policy, (HSE, 2016).
- 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.
- Open Disclosure Policy (HSE, 2019; 2020).
- Infection Prevention and Control Precautions for COVID-19 (HPSA, 2020)

<https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/>



## **Guidance to Nurses and Midwives on Medication Management NMBI, 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:**

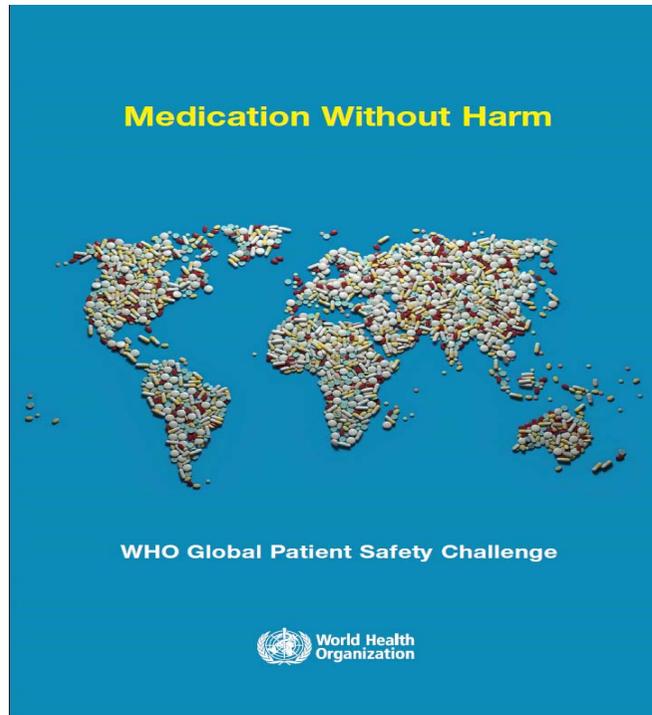
- Obtaining consent;
- Vaccine handling and delivery;
- Storage and stock control;
- Proper techniques of administration;
- Recognition and intervention with side effects, adverse events and/or complications post immunisations;
- Management of anaphylaxis;

# 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).

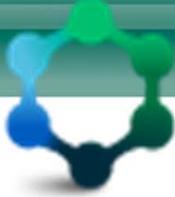
## WHO Publication Medication Without Harm (2017)



### 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/](http://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 unlicensed medicines

[www.hpra.ie](http://www.hpra.ie)



An tÚdarás Rialála Táirgí Sláinte  
Health Products Regulatory Authority

## 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



## 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](http://www.imsn.ie)



## 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<sup>1,2</sup>.

### Evidence of Harm

- Drug allergies and adverse drug reactions led to 62,000 hospital admissions in England annually<sup>2</sup>
- 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<sup>2</sup>
- 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<sup>3</sup>.

### 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, RB. 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/inroduction>
3. Clinical Indemnity Scheme Newsletter, Dublin: CIS; March 2011

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

Updated in 2016 by: M Creed, MMUJH on behalf of the IMSN.

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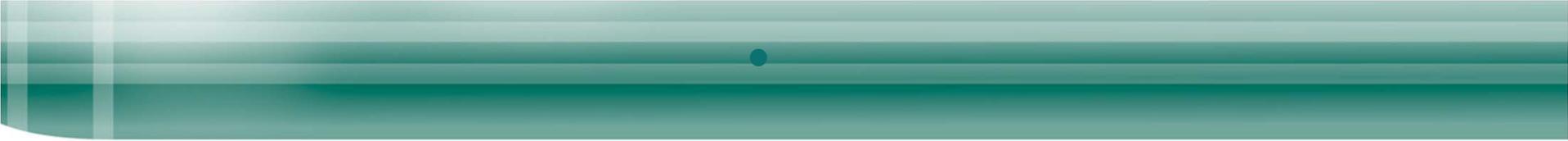
It is recommended that you also refer to [www.imsn.ie](http://www.imsn.ie) as the document may have been updated since this was accessed.

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

Website: [www.imsn.ie](http://www.imsn.ie)

Email: [imsn@imsn.ie](mailto:imsn@imsn.ie)

Version 2 Publication Date: 30<sup>th</sup> September 2016



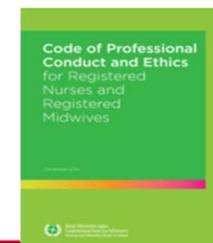
## **Scope of Nursing and Midwifery Practice Framework (NMBI, 2015)**

- 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.
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# 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



# 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, 2019)



# 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, 2019)

## 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, 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 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.  
National Consent Policy (HSE, 2019)

## 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.

National Consent Policy (HSE, 2019)

# Who can give consent for a child?

- Parental and legal guardians.
- Legal guardianships refers 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 18<sup>th</sup> 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?

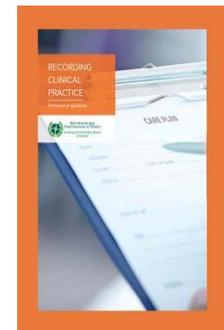
- Child Care (Amendment) Act, 2007 which updates the Child Care Act 1991.
- At all times consent should first be sought from the mother of the child.
- A foster parent who has been taking care of a child for not less than five years may apply to the Court for an order giving them more control and authority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

National Consent Policy (HSE, 2019)

- Must have the consent of the HSE.

# 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 (NMBI, 2015).





**ANY QUESTIONS?**