Guidance to Nurses and Midwives on Medication Management

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An Bord Altranais

Guidance to Nurses and Midwives on Medication Management July 2007 supersedes Guidance to Nurses and Midwives on Medication Management June 2003. This document comes into effect on October 1 2007.

CONTENTS

INTRODUCTION

An Bord Altranais has prepared these guidelines to assist nurses and midwives to understand their roles and responsibilities in medication management. They are written to enable nurses and midwives to reflect on the key points associated with medication management and the related principles, and thus support effective, safe and ethical practice. The professions' responsibilities, activities and accountability involving medications are intrinsically linked to the individual's scope of practice. It is, therefore, important to consider the guidelines outlined in this document in association with the *Scope of Nursing and Midwifery Practice Framework* (An Bord Altranais, 2000), which provides the foundation for this guidance document. The scope of practice for nurses and midwives in Ireland is determined by legislation, EU directives, international developments, social policy, national and local guidelines, education and individual levels of competence. The fundamental concepts of accountability, autonomy, competence and delegation that are considered in determining scope of practice also relate to the professions' role in medication management.

Medication management, broadly defined, is the facilitation of safe and effective use of prescription and over-the-counter medicinal products (Bulechek and McCloskey, 1999). The nursing, midwifery, medical and pharmaceutical professions are all participants in medication management and contribute to patient/service-user care. Medication management is a comprehensive intervention which encompasses the knowledge of nurses and midwives (and that of other health care professionals) and the activities that are performed to assist the patient/service-user in achieving the greatest benefit and best outcomes involving medications (Naegle, 1999). The responsibilities of medication management incorporate the assessment, planning, implementation and evaluation of the nursing and midwifery process in collaboration with other health care professionals in providing care.

The nurse/midwife should have knowledge of the relevant statutes and legislation regarding the practices of prescribing, dispensing, storing, supplying and administering scheduled medicinal products. (This includes controlled, prescription-only and over-the-counter medications). There is an obligation to practice according to the legislation governing nursing and midwifery practice, and the current standards and policies of regulatory bodies and health service providers[1]. Nurses and midwives should be aware of their legal and professional accountability with regard to medication management. It is acknowledged that local need may dictate specific policies and protocols authorising the practices of individuals involved with medicines. The health service provider and health care regulatory and professional organisations have a responsibility to the patient/service-user to assure safe and effective medication management practices.

[1]Appendix A sets forth the relevant legislation and statutes and Appendix B details the pertinent An Bord Altranais documents relating to medication management by nurses and midwives.

It is best practice that policies and protocols are devised collaboratively by nursing, midwifery, medical, pharmacy and management staff where health care is provided. Consultation with the drugs and therapeutics committee (where available), or similar governance structures, and other relevant personnel is advised in determining local policies and protocols involving medicinal products. Medication management practices should be audited on a regular basis to ensure effective and safe patient/service-user care.

SECTION 1
Medication Management – General Principles and Responsiblities

1.1 Legislation

The activities associated with medication management involve the nursing, midwifery, medicine and pharmacy professions and the patient/service-user. Medicinal products legislation authorises the registered medical practitioner or dentist to prescribe medication through the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (Statutory Instrument (SI) 540 of 2003).*

More recently, the *Irish Medicines Board Act (Miscellaneous Provisions) Act, 2006 (No. 3 of 2006),* and the *Medicinal Products (Prescription and Control of Supply) (Amendment), Regulations 2007 (SI 201 of 2007)* give legal authority to nurses and midwives to prescribe medications. However, this authority is based upon the following conditions being satisfied:

1. The nurse/midwife is employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home).
2. The medicinal product is one that would be given in the usual course of the service provided in the health service setting in which the nurse/midwife is employed.
3. The prescription is issued in the usual course of the provision of that health service.

In addition, the 2007 Regulations allow a health service provider to determine further conditions in limiting the prescriptive authority of the nurse/midwife. The An Bord Altranais registration number (also known as the Personal Identification Number (PIN)) must be stated on the prescription.

Nurse/midwife prescribing of controlled drugs is detailed in the *Misuse of Drugs (Amendment) Regulations, 2007 (SI 200 of 2007)* which requires the above conditions to be met and details additional restrictions for the prescribing of MDA scheduled medications 4, and 5. A specific schedule – Schedule 8 - has been devised, composed of four parts, which names the Schedule 2 and 3 drugs that a nurse/midwife is authorised to prescribe and also dictates administration routes and care settings or conditions[2]. Additional information concerning nurse and midwife prescribing is

[2]Refer to Appendix C for Schedule 8 details.

provided in the *Practice Standards for Nurses and Midwives with Prescriptive Authority* (An Bord Altranais, 2007).

The *Irish Medicines Board (Miscellaneous Provisions) Act, 2006,* the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003* and *2005* and the *Misuse of Drugs Acts, 1977* and *1984,* and subsequent regulations authorise the nurse/midwife to possess, supply and administer medicinal products to a patient/service-user.

The *Pharmacy Act, 2007,* makes provision for the regulation of pharmacy, including authority for the sale and supply of medicinal products.

1.2 Key principles

Medication management activities performed by the nurse/midwife may vary, depending upon the individual patient/service-user situation, the health care setting, its policies and protocols and the scope of practice of the nurse/midwife. The key factors to be considered when determining the scope of practice for nursing and midwifery care also apply to the scope of practice for medication management. These include:

- Competence
- Accountability and autonomy
- Continuing professional development
- Support for professional nursing and midwifery practice
- Delegation
- Emergency situations.

Standard

Each nurse/midwife is expected to develop and maintain competence with regard to all aspects of medication management, ensuring that her/his knowledge, skills and clinical practice are up to date. The activities of medication management require that the nurse/midwife is accountable to the patient/service-user, the public, the regulatory body, her/his employer and any relevant supervisory authority. This relates to both actions and omissions.

Supporting Guidance

The nurse/midwife has a responsibility to ensure her/his continued professional development, which is necessary for the maintenance of competence, particularly with regard to medicinal products. She/he should seek assistance and support where necessary from the health service provider concerning continued professional development.

Standard

Nurses or midwives who require a medication for a personal health condition should acquire it through appropriate means, i.e., from a pharmacy if an over-the-counter, non-prescription medication or on foot of a prescription from a medical practitioner or registered nurse prescriber who has assessed this need.

It is not acceptable practice for a nurse or midwife to remove or take medication from her/his workplace for personal use or for supplying for use by family, friends or significant others. This is applicable to all forms of medicinal products (e.g., prescription medication including analgesia, antibiotics and non-prescription/over-the-counter medication).

Supporting Guidance

It is not appropriate for a nurse or midwife to ask a work colleague with prescriptive authority to write a prescription for them. In addition, nurses or midwives who remove medications from their place of employment for personal use may be subject to a fitness to practise inquiry by An Bord Altranais for professional misconduct, employment disciplinary procedures and/or criminal charges.

1.3 Five rights of medication administration

There are guiding principles for medication management that each nurse/midwife should adhere to in their delivery of care related to medicinal products.

Standard

The prescription or medication order should be verified that it is correct, prior to administration of the medicinal product. Clarification of any questions regarding the prescription/medication order should be conducted at this time with the appropriate health care professional. The expiration date of the medication should be checked prior to administration. Expired medications should not be administered.

The five rights of medication administration should be applied for each patient/service-user encounter: Right medication, patient/service-user, dosage, form, time.

Supporting Guidance

The five rights considerations:

1. The right medication:
    - Matching the prescription/medication order against the label of the dispensed medication

- Being aware of look-alike and similar sounding medications
- Best practice indicates using generic names of medications whenever possible.

2. The right patient/service-user:
   - Being certain of the identity of the individual who is receiving the medication
   - Checking the medical record number and/or identification band
   - Asking the patient/service user to state her/his name
   - Confirming that the name and age are means of ensuring the correct identity
   - Maintaining a photo of the individual on the medication administration record.
3. The right dosage:
   - Considering if the dosage is appropriate based on age, size, vital signs or other variables
   - If it is necessary to measure the dose (e.g., liquid form) the appropriate equipment should be used.
4. The right form:
   - Ensuring that the correct form, route and administration method of the medication are as prescribed
   - If this information is not indicated on the prescription or on the label of the medication, it should be clarified with the prescriber, as many medications can be given by various routes.
5. The right time:
   - Ensuring the correct timing, frequency and duration of the prescribed order
   - The timing of doses of medications can be critical for maintaining specific therapeutic blood-drug levels (e.g., antibiotics) and avoiding interactions with other medications
   - Accurately documenting medication administration times.

For each patient/service-user encounter, medicinal products may normally be administered by a nurse/midwife on her/his own. As evidenced by best practice, the preparation and administration of a medicinal product should be performed by the same nurse/midwife.

Student nurses/midwives may administer medicinal products under the supervision of a nurse/midwife and should follow the principles of supervision. The registered

nurse/midwife retains accountability for the administration of medicinal products.

The principles of aseptic technique and appropriate precautions (e.g., universal precautions, safety precautions with the management of cytotoxic therapy) should be observed during the preparation and administration of the medicinal product.

1.4 Double-checking medications

Double-checking is the process/activity of having a second colleague *independently* check the preparation of a medication for administration. This may involve verification of the medication against the medication prescription order, performing calculations for dosing of the correct volume or quantity of medication and/or other aspects of medication administration as appropriate. Double-checking is a significant nursing/midwifery activity to facilitate good medication management practices and is a means of reducing medication errors.

Standard

The use of double-checking medications should be implemented purposefully in situations/indications that most require their use – particularly with high-alert medications[3].

Supporting Guidance

Registered nurses/midwives are accountable for their professional decisions and do not need another professional colleague to routinely check their work. There is no legal or professional requirement that a nurse/midwife must double-check the preparation of a medication with a colleague prior to administration. However, a nurse/midwife may consider asking another nurse/midwife to double-check a medication preparation if she/he determines that assistance is needed.

For patient/service-user safety and risk management purposes health service providers may have a policy for double-checking preparations, particularly for those that are considered high-alert medications (such as insulin, heparin and chemotherapy) or that require complex calculations in preparation for administration.

If double checking is required the Institute of Safe Medication Practice (ISMP) in the USA advocates that double-checking should be performed independently, without knowledge of any prior calculations, as problems or errors can occur with sharing previous calculations or completing the double-check together (ISMP, 2003).

[3]High-alert medications are drugs that bear an increased risk of causing significant patient harm when they are used in error (ISMP, 2003).

In determining whether or not double-checking of a medication is required, the following points should be considered by the nurse/midwife:

- Existence of a health service/employer policy for double-checking preparations
- Self assessment of competence.

If it is identified by the nurse/midwife that a policy should be established, he/she should first examine the practice and patient/service user population. Consult with colleagues, nursing/midwifery managers, pharmacists and others as appropriate for this process. This may include identifying the high-alert medications used in the practice setting.

1.5 Monitoring and documentation of medication management

Standard

The assessment and evaluation of the administered prescribed medicinal product should encompass the observation of the patient/service-user for the following:

- Vital signs and laboratory values prior to administration (as applicable)
- Effectiveness of medication administration method (e.g., is the oral route appropriate for this patient/service-user?)
- Awareness and observation for medication allergies, possible side effects, adverse reactions, toxicity, interactions and contraindications of medicinal products administered
- Monitoring the effectiveness of the administered medicinal products.

Standard

The administration of a medicinal product and the patient/service-user response should be accurately documented according to local health service policy.

Supporting Guidance

Monitoring and documentation are key responsibilities for nurses and midwives in medication management; they incorporate the activities of assessment, planning, implementation and evaluation. These responsibilities require effective and efficient communication with the patient/service-user and other health care professionals involved in her/his care.

1.6 Patient/service-user education

Standard

Education should be provided to the patient/service-user and/or carer in relation to the use of medicinal products. It should be explained to the person in a way that is accessible and understandable.

Supporting Guidance

Consideration should be given to the appropriate timing of teaching, including patient/service-user or carer readiness to learn. Best practice would indicate that this information should include:

- The expected mechanism of action of the medicinal product
- Potential side effects
- Signs and symptoms of potential adverse effects and actions to take if they occur
- Possible interactions of the medicinal product with other medications, particular foods or other substances
- Precautions or instructions to follow, including time, route, and method of administration and storage of medicinal products
- Significance of adherence to prescribed therapy (duration and frequency)
- Recommendations for follow-up and reporting of potential side effects or adverse reactions.

1.7 Considerations for withholding of medication

Standard

It is appropriate to exercise professional judgement to withhold a medicinal product if relevant in a specific patient/service-user case. The medical practitioner or registered nurse prescriber should be contacted with details if contraindications of administration exist, thereby communicating changes in the condition of the patient/service user.

Accurate and contemporaneous documentation should be made for any medicinal product withheld or refused. Any information or advice given to a patient/service-user about the possible consequences of such a refusal should also be documented.

Supporting Guidance

It may be necessary to consult with a peer, medical practitioner, registered nurse

prescriber, pharmacist or manager, as applicable regarding withholding medication.

The decision by a patient/service-user or parent/guardian to refuse administration of a medicinal product (after having been provided with information about the drug and the risks and benefits of the therapy) should be respected and the medical practitioner or registered nurse prescriber should be notified.

1.8 Use of complementary therapies

Complementary therapies include, but are not limited to, acupressure, acupuncture, aromatherapy, herbalism, homeopathy, massage therapy, reflexology and yoga. The use of complementary therapies is increasingly more common in the delivery of health care with many nurses and midwives providing these therapies.

Standard

The nursing/midwifery care plan should capture if patients/service-users use complementary therapies and medicines routinely. If a nurse/midwife is providing complementary therapies the patient/service-user consent and care plan should be documented in her/his chart. This information should also be communicated to the members of the health care team involved in the patient/service-user's care.

Supporting Guidance

The nurse/midwife using complementary therapies should be competent in the specific therapy, having undergone an education programme that provides her/him with the required skills and knowledge to practise such therapies.

Prior to the initiation of the complementary therapy, the patient/service-user should be assessed and any co-existing conditions and treatments noted, as these therapies may interact with prescribed medicinal products by increasing or decreasing their effect or by combining to create a toxic effect.

SECTION 2
The Cycle of Medication Management

2.1 Transcription of prescription/medication order

Standard

Best practice would indicate that the responsibility for documenting the prescription/medication order is with the medical practitioner and/or the registered nurse prescriber to prevent the possibility of error by another individual. The decision to transcribe a prescription should only be made in the best interests of the patient/service user.

A nurse/midwife who transcribes is professionally accountable for her/his decision to transcribe and the accuracy of the transcription.

Supporting Guidance

Transcribing is the act of transferring a medication order from the original prescription to the current medication administration record/prescription sheet. This activity should be directed by local health service provider policy which must stipulate required systems (i.e. a second person checking the prescription transcribed) in order to minimise the risk of error.

Transcribed orders should be signed and dated by the transcribing nurse or midwife and co-signed by the prescribing doctor or registered nurse prescriber within a designated timeframe. If a nurse or midwife is unclear about a transcribed prescription/order she or he should verify or confirm the prescription with the prescriber or pharmacist before administering the medication to the patient/service user. The practice of transcribing should be the subject of audit.

2.2 Emergency situations and the use of verbal and telephone orders

Standard

The only acceptable time a verbal or telephone order for medication should be taken from a medical practitioner is in an emergency situation, where there is an immediate unplanned patient/service-user need.

A registered nurse prescriber should not communicate a medication order through the use of a verbal or telephone order.

Supporting Guidance

A verbal or telephone order from a medical practitioner should not be considered an acceptable substitute for a comprehensive medication policy or protocol for routine medication management. The best interests of patient/service-user care and safety should be considered. A nurse/midwife who accepts a verbal or telephone order in these situations should consider her/his own competence and accountability.

A nurse or midwife accepting a verbal or telephone order should repeat the order to the medical practitioner for verification. A record of the verbal or telephone order should be documented in the appropriate section of the patient's/service-user's medical chart/notes. This should include the date and time of the receipt of the order, the prescriber's full name and her/his confirmation of the order. The justification and rationale for accepting a verbal or telephone medication order should also be documented by the nurse/midwife involved to establish the clinical judgement exercised in the emergency situation.

Best practice indicates that, where possible, the medical practitioner should repeat the order to a second nurse or midwife. This should be followed by the nurses/midwives confirming the order between them. The medical practitioner is responsible for documenting the written order on the prescription sheet/medication administration record within an acceptable timeframe as determined by the health service provider. This responsibility also applies in the case of electronic record keeping.

2.3 Use of facsimile

Standard

A medicinal product prescription provided via facsimile (fax) by a medical practitioner for a patient/service user under her/his supervision should be signed by the practitioner, with the original prescription supplied for insertion in the patient's/service-user's chart/notes within a specified timeframe. Nursing, health service and medical management should ensure adherence to this policy through systematic audit and evaluation.

Supporting Guidance

Exemptions for emergency supply as detailed in the *Medicinal Products (Prescription and Control of Supply Regulations), 2003* require that a medical practitioner must provide an original prescription within 72 hours to the dispensing pharmacist.

2.4 Electronic prescribing

Electronic prescription writing is considered acceptable if the clinical standards for legal and best practices are realised.

Standard

The computer-generated prescription must be dated and signed by the medical practitioner or registered nurse prescriber in her/his own handwriting. A prescription for controlled drugs must adhere to the requirements of the *Misuse of Drugs Acts of 1977* and *1984* and subsequent regulations and therefore must be handwritten in its entirety for it be dispensed by a pharmacist and subsequently administered by a nurse/midwife.

2.5 Supply of medicinal products

Standard

A nurse/midwife may supply medicinal products under the direction of a registered medical practitioner or a registered nurse prescriber in the course of a service provided by a hospital other than a hospital providing community mental health services (which is limited to three days supply).

Supporting Guidance

This activity is authorised in the *Irish Medicines Board (Miscellaneous Provisions) Act, 2006* and the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003.*

The following should be adhered to by nurses and midwives in these supply situations:

- Local written policies/protocols, agreed upon following consultation and collaboration with relevant stakeholders, should be observed when a nurse/midwife is to supply a medicinal product
- The policy/protocol should include directions on labelling of medicinal products as per Article 9(2) of the Regulations.

Consideration should be given to the further education and training required by any nurse/midwife involved in the supply of medicinal products.

Circumstances may arise when the nurse/midwife may be required to supply a medicine without previous dispensing of the medicinal product by a pharmacist. An example of this is the use of a medication protocol to supply and administer a specific medication.

In these situations, the nurse/midwife must be aware of the responsibilities involved with this practice in the overall management of medications. The nurse/midwife must consider the scope of practice framework (and specific medication protocol if applicable) in determining her/his own competence to undertake this activity.

2.6 Dispensing of medicinal products

Best practice suggests that medications should be dispensed by the pharmacist and should only be undertaken by the nurse/midwife in exceptional circumstances.

Standard

Dispensing represents an extension to professional nursing/midwifery practice. The determination for nurses/midwives to dispense must be supported by organisational policy with the involvement of the nursing/midwifery, pharmacy and medical professions.

Supporting Guidance

In-service training and education should be provided to those staff involved in dispensing, followed by assessment of the nurse's/midwife's competency in this activity. (See dispensing activities in the Glossary of Terms)

Quality assurance procedures should be in place to ensure safe dispensing practice.

These include:

- Availability of a qualified pharmacist for consultation, either on-call or at another location
- Independent second check by another professional colleague
- Documentation of dispensing practice
- Evaluation and audit performed on an on-going basis.

Nurses and midwives are advised to consult with their health service provider regarding indemnity insurance to cover their dispensing practice.

2.7 Self-administration of medicinal products by patients/service-users in health care facilities

Self-administration of medications involves the independent use of a medication by a patient/service-user in a manner that supports the management and administration of her/his own medications.

Standard

The nurse/midwife should detail in the patient's/service-user's care plan the decision-making associated with, and the support and supervision required to facilitate a patient/service-user with self-administration. Continual collaboration and communication should occur with the medical practitioner concerning the patient's/service-user's medication management.

Supporting Guidance

Key points associated with this activity are:

- Health service providers should have written policies for self-administration of medicinal products, which should detail the assessment of patients/service-users, the documentation requirements for their chart/notes and for the storage and supply of medicinal products
- The assessment process includes the evaluation of the patient's/service-user's ability to self-administer as appropriate, with ongoing assessment of their ability to perform this activity
- The patient/service-user should be adequately supervised so that they adhere to the medicinal product therapy and treatment plan and this should be recorded as necessary in the care plan
- Appropriate, safe and secure storage should be provided for the patient's/service-user's medicinal products and access should be limited to the patient/service-user
- The practice of self-administration of medications should be evaluated and audited at regular intervals in the health care setting.

2.8 Medication administration compliance aids/monitored dosage systems

Different names have been used to describe medication administration compliance aids, such as monitored dosage systems, blister packs, medication systems, unit dose packages and multi-dose packages, and dose administration aids. They are used solely for oral solid dosage medications.

Compliance aids are designed to aid self-administration by patients/service-users. However, there may be circumstances where compliance aids are used by nursing/midwifery staff to administer medications, for example in health care settings where there is no on-site pharmacy support.

Standard

The patient's/service-user's individual requirements should be assessed to ensure there are no contraindications related to using the compliance aid. Systems for evaluation of the appropriateness of the compliance aid should be documented in local policy, based upon the patient's/service-user's

- Condition and
- Prescribed medications.

There are two distinct care areas where nurses/midwives may be using compliance aids or monitored dosage systems:

1. *Assisting patients/service users in self-administration of medications in the community setting using dosette boxes.*
   This involves the nurse's/midwife's use of a dosette box or weekly pill box which she/he fills from the patient's/service-user's original medication containers dispensed by the pharmacist. Consultation with the patient's/service-user's pharmacist and general practitioner should be considered for guidance if supplying medicines in this manner and in assessing the need for using such a system. The nurse/midwife must be aware of the decision-making associated with using such a system, having regard to the medication prescribed and the ability of the patient/service-user to use the system.
2. *The use of compliance aids/monitored dosage systems by nurses/midwives in health care settings where there is no on-site pharmacist.*
   Health service providers may employ an external pharmacy to dispense many medications to patients/service-users in pre-packaged compliance aids/monitored dosage systems ready for administration by the nurse/midwife to the patient/service-user.

Supporting Guidance

- Caution should be exercised and the professional judgment of the nurse/midwife must remain the guiding factor when these systems are utilised
- Nurses and midwives should have appropriate in-service education regarding these systems. The nurse/midwife employing such an aid in the practice of medication management is accountable for her/his actions. She/he should be competent in undertaking this activity
- The use of compliance aids is not supported in acute care settings, areas where the range and type of medications is extensive or changes frequently (e.g., warfarin); for the administration of p.r.n.s (as needed); or where the professional judgment of

the nurse/midwife is required in respect of omission of a medication dose

- Medications that could potentially be withheld should not be included in a compliance aid
- Optimally, the compliance aid should be filled by the pharmacist
- The compliance aid should be labelled in accordance with statutory labelling requirements to enable identification of individual medications to be made
- The ability of the nurse/midwife quickly and correctly to identify a specific medication among several medications in a package is essential. References and resources should be readily accessible for the nurse/midwife to confirm prescribed medication in the compliance aid with identifiable drug information, e.g., physical description of the medication (red, oblong scored tablet or colour photograph of the medication)
- Arrangements should be in place to ensure that a medical practitioner and pharmacist can be contacted at all hours and that urgent repacking of medications can be undertaken when required
- The documentation requirements for each medication administered via the compliance aid should be identical to those for administration from the original dispensed container (e.g., it is not acceptable to document *8 am blister pack given*).

2.9 Supply and administration of over-the-counter medications

Standard

The practices of nurses and midwives advising, supplying and/or administering over-the-counter (OTC) medications should be consistent with the established policies of the health service provider in which they practice and medicines legislation pertaining to non-prescription medications.

Supporting Guidance

When determining to supply/administer or recommend an OTC medication or non-prescription medication to a patient/service-user, the nurse/midwife is accountable for having the appropriate knowledge of the OTC medication and its interaction with the patient's/service-user's other current medications (OTC and prescription), therapies and treatments. These practices should be supported by locally devised medication protocols where appropriate. See Section 4 for guidance on the development of medication protocols.

Inherent in this independent clinical decision by the nurse/midwife is her/his

responsibility to educate the patient/service-user about the non-prescription medication, specifically

- Its use
- Its effects and side effects
- Contraindications
- Potential drug interactions with the over-the-counter medication
- Signs to discontinue using the medication
- Signs that would prompt the patient/service-user to contact her/his doctor.

The nurse/midwife should monitor the patient/service-user, document the nursing/midwifery action and communicate her/his actions with other members of the health care team, consistent with the health service provider's policies and the patient's/service-user's overall plan of care.

2.10 Scheduled controlled/MDA drugs

The *Misuse of Drugs Acts, 1977* and *1984* and the *Misuse of Drugs Regulations, 1988, 1993* and *2007* determine the conditions of production, possession, supply, importation and exportation of controlled drugs. The drugs are categorised into five schedules with different controls applicable to each category. The legal term for these drugs is the abbreviation MDA accompanied by the appropriate schedule of the drug. For example, MDA Schedule 2 replaces the previous term of CD2. These schedules are listed in Appendix C. The storage of scheduled drugs is referenced in Section 2.17.

2.11 Supply and possession of controlled/MDA drugs to and within institutions

In institutions where a pharmacist is not employed, the director of nursing/midwifery (or acting director) may be supplied with MDA drugs. In these circumstances, before delivering any MDA drug, the supplier must receive a written requisition that complies with the general requirements for requisitions and is countersigned by a medical practitioner employed or engaged in the institution concerned.

The nurse/midwife manager (or acting manager) in charge of a ward, theatre or department may be supplied with a controlled drug, solely for the purpose of administration to patients/service-users in that ward, theatre, or department, on foot of a requisition issued by her/him in accordance with the directions of a medical practitioner.

In circumstances where the pharmacist (or director/acting director of nursing/midwifery

where a pharmacist is not employed) supplies a controlled drug to the nurse/midwife manager (or acting manager) she/he must:

- Obtain a requisition signed by the nurse/midwife manager (or acting manager) that clearly specifies the total quantity of the drug to be supplied
- Mark the requisition in such a manner to show that it has been complied with
- Retain the requisition for two years in the pharmacy which supplied the controlled drug.

2.12 Supply and possession of controlled drugs to and within private hospitals or private nursing homes

The *Misuse of Drugs Regulations, 1988* Article 8 (1) (a) does not pertain to private hospitals and private nursing homes and, therefore, they have no authority to be in possession of controlled drugs or to be supplied with such drugs. Supplies of controlled drugs for patients/service-users in private hospitals and private nursing homes should be obtained by way of a medical prescription as if the patients/service-users were in their own homes. Private hospital and private nursing home patients/service-users are considered to be in the same position as a patient/service-user in her/his own home.

Private hospitals and private nursing homes may hold licenses under the *Misuse of Drugs Acts, 1977* and *1984.* These licenses legally permit the supply, distribution and control of scheduled controlled drugs for private hospitals and private nursing homes similar to the arrangements in use in institutions as detailed above.

2.13 Management of MDA Schedule 2 drugs

Standard

The general principles of medication management should be employed when administering MDA Schedule 2 drugs. The following additional guidelines are provided as evidence of best practice with the management of these drugs:

- The local health service provider policy may require two persons to conduct the administration of MDA Schedule 2 drugs, one of whom is a nurse/midwife. This is not a legal requirement. It is recommended that local health service providers should consider including requirements expected for the checking, preparation, administration or destruction of these drugs when establishing medication management policies. They should also consider whether these activities are to be witnessed and by whom (i.e., another nurse/midwife or other member of the health care team)

- Access to the keys of the controlled drugs storage should be the subject of local policy, bearing in mind responsibility and accountability issues. The nurse/midwife manager or her/his nurse/midwife designee should keep the keys of the controlled drugs storage on their person. Policies and procedures should be in place for monitoring/checking a stock balance at each transaction of MDA Schedule 2 drugs. At changeover of shifts, a nurse/midwife from each shift should complete the count of these scheduled drugs
- Appropriate documentation of the administration of MDA Schedule 2 drugs should be entered in the patient's/service-user's chart/notes and in the ward controlled drugs register
- The nurse/midwife manager should keep requisition copies (or a note) detailing the requested MDA Schedule 2 drugs submitted to the pharmacist, or nursing/midwifery director who supplies the drugs.

2.14 Community care involving MDA Schedule 2 drugs

Standard

Nurses/midwives practising in the community who are administering MDA Schedule 2 drugs to a patient/service-user for whom they have been prescribed should communicate with the prescriber to ensure that the patient's/service-user's requirements for these drugs are regularly and frequently reviewed.

Supporting Guidance

An MDA Schedule 2 drug may be obtained on prescription and retained in the patient's/service-user's home. In the community, individually prescribed medicinal products, including controlled scheduled drugs, are the property and responsibility of the individual patient/service-user.

2.15 Transport of MDA Schedule 2 drugs in the community

Standard

Where the patient/service user resides in the community:

- Nurses/midwives are authorised to transport the drug to a person for whom the drug has been properly prescribed for and dispensed by a pharmacist
- They are not otherwise permitted to have the drug in their possession or storage.

Where the patient/service user is being transported in the community:

- The drugs must be dispensed by the pharmacist to the patient/service user on an individual basis as per the written prescription
- The drugs should not be supplied from the stock of MDA drugs on the ward.

Supporting Guidance

The *Misuse of Drugs Regulations, 1988* allows for the supply of MDA scheduled drugs to patients/service-users while in the hospital/nursing home setting but not once they leave and enter the community. These drugs should be stored securely for transport.

Unused or expired controlled drugs should be returned for destruction to the pharmacy from which they were dispensed.

2.16 Community midwifery and MDA Schedule 2 drugs

A community midwife is authorised as per the exemptions to the *Misuse of Drugs (Amendment) Regulations, 2007* to have in her/his possession pethidine or pentazocine for her/his practice.

Standard

There are specific requirements for this possession:

- A written order is signed by the midwife and countersigned by a medical practitioner or registered nurse prescriber practising in her/his area

The medication order must state:

- The name and address of the midwife
- The quantity to be supplied
- The purpose for which it is required.

A record must be kept in a book by the midwife of any supply of pethidine that she/he obtained and administered. The record must include:

- The name and address of the person from whom the drug was obtained
- The amount obtained
- The form in which it was obtained.

After administering the pethidine to the patient/service-user, the midwife must enter into the book:

- The name and address of the patient/service-user

- The amount administered
- The form in which it was administered.

This book should be kept for a period of two years from the date on which the last entry was made.

2.17 Storage of medicinal products

Standard

All medicinal products should be stored in a secure manner, either in a locked cupboard or room. They should be stored in the appropriate environment as indicated on the label or packaging of the medicinal product or as advised by the pharmacist.

Supporting Guidance

MDA scheduled controlled drugs should be locked in a separate cupboard/container from other medicinal products to ensure further security. (Refer to Section 2.13 for additional guidance.)

Medicinal products requiring refrigeration according to package labelling or the pharmacist should be stored in a designated refrigerator that is:

- Not used for any other purpose
- Accessible and reliable
- Capable of being secured.

Medicinal products should be stored separately from antiseptics, disinfectants and other cleaning products. Mobile trolleys and emergency boxes storing medicinal products should be locked and secure when not in use.

Policies and procedures should be in place for:

- Ordering medicinal products from the pharmacy
- Checking delivery and inventory of medicinal products to the ward/unit and maintaining records
- The immediate reporting and investigation of discrepancies in medicinal products' stocks
- The storage of medicinal products for self-administration by patients/service-users.

SECTION 3
Safety in Medication Management

3.1 Medication errors and near misses

Medication error is the most common type of error affecting patient/service-user safety and is the most common single preventable cause of adverse events (National Medicines Information Centre, 2001). Medication errors are defined as preventable events that may cause or lead to inappropriate medication use or patient/service-user harm while the medication is in the control of the health care professional or patient/service-user. These events may be associated with professional practice, health care products, procedures and systems. They include prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use (National Coordinating Council for Medication Error Reporting and Prevention, 1998). For the purposes of this document, the activity of supply is included in this definition. Medication errors can occur at any point in the medication management cycle.

Additionally a "near miss" event or situation may also happen with medications, where the error does not reach the patient/service-user and no injury results (e.g., incorrect dosage is prescribed but is recognised and adjusted before the medication is administered).

Standard

It is of primary importance upon noting a medication error that the patient's/service-user's health is monitored. If a medication error has been identified, medical and nursing interventions should be implemented immediately to limit potential adverse effects/reactions. Patient/service-user safety is paramount.

Supporting Guidance

Health service provider management, and organisations outside of the traditional health care settings where nursing/midwifery care is provided, should support an open culture (non-punitive approach) for error and near miss reporting, while undertaking a comprehensive assessment of the circumstances of the error and, where appropriate, institute action plans to prevent/eradicate the contributing factors to the medication error. This includes educational support for the staff involved.

Medication errors and near miss events should be seen as opportunities to assess practice(s), identify what went wrong, learn from mistakes and institute changes to the

medication system. The prevention, detection and reduction of medication errors and near misses should occur in collaboration amongst the health care team, as errors may reflect a problem with the system and may involve other professions and departments.

Continuous quality improvement programmes for monitoring medication errors and near misses should be in place within risk management systems of the organisation. Fostering cultures of safety and continuing professional development in medication management for nurses and midwives are important in preventing and addressing the causes of medication errors.

3.2 Unlicensed or unauthorised medications

An unlicensed or unauthorised medicine is a medicinal product which is not licensed by the Irish Medicines Board (IMB) or the European Medicines Evaluation Agency (EMEA).

The IMB defines the term "off label use" as:

> "The use of an authorised medicine outside the terms of its product authorisation, e.g., use for an indication not specified in the authorised product information; use at a dose not specified in the authorised product information; use in a specific patient population or a specific age-group not specified in the authorised product information".

The *Medicinal Products (Licensing and Sale) Regulations, 1998 (SI No. 142 of 1998)* provides the statutory authority for a registered medical practitioner or dentist to treat a patient/service-user under her or his care to prescribe an unauthorised/unlicensed medication or to prescribe an authorised medication for an "off label use". The prescriber has the professional responsibility for the use of such medications. This authority does not extend to registered nurse prescribers.

Standard

A nurse or midwife who administers the unauthorised medication or administers a licensed medication for "off label use" should be aware of the indications for the medication's intended use in providing care to the patient/service-user.

Supporting Guidance

This medication management decision should be justified by evidence-based practice. Information should also be available to administer the medication safely.

It is advised that the nurse/midwife refers to the medical practitioner who has prescribed the medication if there are questions regarding the indications for its use for the patient/service-user. Additional information and support may also be available by contacting the pharmacist. It is important that the nurse/midwife has an understanding

of the reasons for administering the medication, particularly as it relates to the assessment and evaluation of the effectiveness of the prescribed medication for the patient/service-user.

The medication management policies of health service providers should address the topic of unauthorised/unlicensed medication use, including "off label" use. If a health service provider does not have such a policy in effect, it is recommended that one be considered. The input of the pharmacy department, drugs and therapeutic committee (if established), nursing and medical management and risk management is critical in the multidisciplinary effort to develop and implement safe practices involving these medications.

If the medication prescribed is part of a clinical trial, additional guidance and information should be sought from the clinical investigator and/or the associated clinical research nurse (if applicable), as there are specific Regulations *(European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2006, SI No. 374 of 2006)* that relate to the implementation of good clinical practice in undertaking clinical trials with patients/service-users.

3.3 Crushing medications

Standard

Nurses or midwives determining to administer medicines to their patients/service-users in a modified form to that prescribed (i.e., crushing an oral medication that is in a tablet or pill form), should ensure that other methods have been considered and that appropriate advice is sought before doing so.

Supporting Guidance

The Irish Medicines Board (IMB) is the regulatory body responsible for the licensing or authorisation of medicinal products for human and veterinary use. The IMB states that, if a medicinal product is used outside of the instructions as provided for in the posology section of the Summary of Product Characteristics, then it is used outside its licensed conditions. This would apply to those medications which are crushed.

Only medical and dental practitioners can legally authorise the administration of 'unlicensed' medicines to humans. Consequently, if a nurse or midwife decides that a change in the form of the drug is necessary for its safe administration, she/he should consult with the medical practitioner and pharmacist to discuss alternative preparations or forms of administration for the patient/service-user. If it is deemed necessary to administer the medication in an unlicensed form, this should be prescribed by the medical practitioner in the patient's/service-user's medication chart/prescription sheet

with the consent of the patient/service-user or carer if applicable. Development of a policy to support the practice of crushing oral medications, inclusive of guidelines and decision-making rationale for individual events, should also be considered.

Considerations for safe practice for crushing include preparing a list of medications which should not be crushed or chewed that is placed in a readily accessible location (e.g., attached to the medicine trolley) for use by the person administering the patient's/service-user's medications. This list should be updated regularly by the pharmacist and whenever a new product which requires specific instructions becomes available. Continuous quality improvement processes should review whether such practices are effective. Occupational health and safety issues regarding the handling, administration and disposal of waste of certain altered dose medications (e.g., cytotoxic drugs) should be considered and included in the policies and procedures of the health service provider.

3.4 Immunisations and vaccinations

Immunisation and vaccination are an accepted mechanism in public health for the prevention and eradication of infectious disease. Nurses and midwives are key health professionals involved in providing immunisations to the patient/service-user and communities in the promotion of public health and prevention of infectious disease. Examples include childhood immunisation programmes, influenza and hepatitis vaccinations and travel vaccinations.

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 technique of administration
- Recognition and intervention with side effects, adverse events and/or complications post immunisation.

Supporting Guidance

The nurse/midwife should possess the ability to manage adverse reactions and anaphylaxis as first line providers in these emergency situations. Anticipation of this

may require additional resources, skills and equipment. Anaphylaxis may also necessitate the administration of emergency medications (e.g., epinephrine, adrenalin) and nurses/midwives should be knowledgeable of treatment with these medications as indicated for the particular vaccine/medication.

Health service providers should have an organisational policy on immunisation/vaccination addressing these areas to support best practice by nurses and midwives. Available resources on this subject are the *Immunisation Guidelines for Ireland* (Royal College of Physicians of Ireland, 2002) and the Health Service Executive website http://www.immunisation.ie.

3.5 Adverse drug reaction reporting

Adverse drug reactions[4] have been identified as a leading cause of morbidity and mortality. As part of their every day care of patients/service-users, nurses and midwives are in prime positions to observe and report on suspected adverse reactions.

Standard

Reporting of suspected adverse reactions is critical for safe medication management and patient/service user care.

Supporting Guidance

The reporting and monitoring of adverse reactions has significant implications for patient/service-user safety. It is not necessary to determine a causal relationship between a drug and subsequent event prior to reporting suspected adverse reactions. Nursing/midwifery staff should liaise with the prescriber about the submission of the report as appropriate. The health service provider's medication management policies should include information and direction for health care professionals in reporting suspected adverse reactions.

The IMB is responsible for the national adverse reaction reporting system, as part of its drug monitoring programme. Post-paid report forms (i.e., the yellow card) are available from the IMB, with a downloadable version accessible from the IMB website. The form is reproduced in Appendix E.

The IMB requests that health care professionals (defined as medically qualified persons - nurses, midwives, doctors, dentists, and pharmacists) report the following:

- All suspected reactions to new products
- Serious suspected reactions to established products (i.e., those available on the market for > 2 years)

[4]See Glossary of Terms for definition of Adverse Drug Reaction.

- Any suspected increase in the frequency of minor reactions
- All suspected reactions to vaccines
- All suspected teratogenic (effecting development of foetus) effects.

3.6 Haemovigilance: Adverse event reporting for blood and blood products

Similar to the reporting of adverse drug reactions, the nurse/midwife should be aware of the need for reporting for adverse events and reactions pertaining to blood and blood components. Haemovigilance is defined as:

> "A set of surveillance procedures, from the collection of blood and its components to the follow-up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence or recurrence." (Irish Blood Transfusion Service).

Nurses and midwives are referred to the *Guidelines for the Administration of Blood and Blood Components* issued by the National Blood Users Group and the Irish Blood Transfusion Service (2004) for specific information and guidance on the subject of blood administration, monitoring and reporting of adverse events and reactions.

Serious adverse events and adverse reactions involving a blood component should be reported to the haemovigilance officer (HVO) and hospital transfusion laboratory as mandated by European Communities *(Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006 (SI 547 of 2006).* Adverse events relating to blood products and near miss events are not covered in this legislation but should be reported to the HVO. These events are usually captured in the hospital quality/risk management systems. Policies should be in place to support the identification, investigation and, where possible, prevention of adverse reactions.

3.7 Reporting of adverse incidents involving medical devices

Medical devices have a significant role in assisting health care professionals in the provision of patient/service-user care.

Standard

As nurses and midwives are often front line users of medical devices and in-vitro diagnostic medical devices, they are key individuals to identify and report any adverse incidents involving medical devices.

Supporting Guidance

Reporting of adverse incidents can assist in increasing patient/service-user safety, and improve the safety profile of the device by prompting a modification in use or design.

The IMB is the designated authority to which a nurse/midwife should report adverse incidents pertaining to medical devices. There is no mandatory reporting system for users; however, users are encouraged to report serious incidents. The IMB provides guidance notes for health care professionals for reporting adverse incidents. The manufacturer of the device should also be notified of the incident. Information on the vigilance system for medical devices, including the responsibilities of the medical device manufacturer and the medical device adverse incident user report form, are available from the IMB medical devices department.

3.8 Patient/service-user sedation for diagnostic and therapeutic procedures

There are varying levels of sedation and analgesia used in patient care, which range from minimal sedation to general anaesthesia. The administration of sedation should be seen as a continuum of stages, as patients/service-users may make the transition from one level to another in a rapid and unpredictable manner, dependent upon the dosage of medication, sensitivities, physical status of the patient/service-user and absence of recovery period stimulation (Somerson, Husted and Sicilia, 1995). The levels of sedation commonly described in the literature are:

- Minimal sedation - a medication-induced state in which a patient/service-user is able to respond normally to verbal commands
- Moderate sedation/analgesia, commonly known as "conscious sedation" – a medication-induced state in which the patient's/service-user's consciousness is depressed but she/he is able to respond to verbal commands singularly or accompanied by light tactile/physical stimulation. No assistance is needed by the patient/service-user to maintain her/his airway and there is adequate spontaneous ventilation. Cardiovascular function is normally maintained
- Deep sedation/analgesia – a medication-induced state of depressed consciousness in which the patient/service-user cannot easily be aroused, although she/he responds purposefully as a result of repeated or painful stimulation. The patient/service-user may have difficulty independently maintaining ventilatory function and assistance may be needed to maintain a patent airway. Cardiovascular function is usually preserved
- General anaesthesia – a medication-induced loss of consciousness. The patient/service-user is not purposefully responsive to verbal or painful stimulation.

Assisting the patient/service-user with ventilator function and maintaining a patent airway may be required. Cardiovascular status may be impaired.

Standard

Conscious sedation requires continual monitoring and assessment of the patient/service-user and requires the nurse/midwife to respond immediately to any adverse events/reactions or complications. The nurse/midwife should be able to demonstrate competency in assessment of the patient/service-user involving complete care requirements before, during and after the administration of conscious sedation, including the recovery period.

Supporting Guidance

The nurse/midwife should consider evidence-based practice guidelines devised by professional organisations with clinical expertise in the administration of medications used for sedation/anaesthesia, as well as advanced airway management and cardiovascular support.

The health service provider should have a written policy for conscious sedation, detailing health care staff responsibilities and involvement in caring for patients/service-users receiving conscious sedation. Multidisciplinary input from nursing, medicine, anaesthesia and pharmacy members should be sought for the development, regular review and audit of this policy and standards of practice for conscious sedation. The health service provider should have in place an educational/competency validation mechanism that includes a process for evaluating and documenting the nurse's/midwife's demonstration of the knowledge, skills and abilities related to the management of patients receiving minimal and moderate sedation/analgesia.

SECTION 4
Medication Protocols

Medication protocols

Medication protocols are written directions that allow for the supply and administration of a named medicinal product[5] by a nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse/midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect.

Care (involving medications), for the most part, should be founded and provided on an individual explicit basis for the patient/service-user. However, the supply and administration of medicines under medication protocol can support more timely delivery of quality health care and optimally utilise the skills of health care professionals. The use of a medication protocol should be reserved for those situations when it offers an advantage for the patient/service-user care and where it is consistent with appropriate professional relationships. Medication protocol use should be considered in the context of the clinical situation, safety assurance for the patient/service-user and acceptance of accountability by the health care professional involved.

Medication protocols must be developed based on evidence of best practice and supported locally by a multidisciplinary team (i.e., senior doctors, pharmacists, nurses, midwives and health care managers). The medication protocol should adhere to particular standards, such as identifying who is responsible and competent to implement the protocol; specific exclusion, and inclusion criteria should be stated and should include a review date for evaluation of the protocol. (Refer to the medication protocol framework.)

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

The legislative basis for medication protocols for the supply and administration of medication is the *Medicinal Products (Prescription and Control of Supply) Regulations of 1996,* and subsequent *Regulations of 2003,* which provides authority for hospitals to utilise medication protocols in order to meet patient/service-user need for medication management. In the course of preparing the *Review of Nurses and Midwives in the*

[5]Controlled drugs cannot be supplied under protocol owing to restrictions in the Misuse of Drugs Act 1984 and subsequent Regulations

Prescribing and Administration of Medicinal Products (An Bord Altranais and the National Council for the Professional Development of Nursing and Midwifery, 2005), the Attorney General determined this legislative basis in an opinion communicated via the Department of Health and Children to An Bord Altranais.

The *Medication Protocol Framework* (See Box 1) has been developed from a project supported by An Bord Altranais and the National Council. An Bord Altranais supports the developments of medication protocols using a nationally recognised template based on international evidence and best practice.

The responsibility for developing and quality-assuring medication protocols rests with health service providers. It is important that local policies are devised to support the development and implementation of any medication protocols for patient/service-user care. Provisions should be made:

- To enable nurses, midwives and members of the multidisciplinary health care team to devise and implement medication protocols where there is a service need
- To enable the education and training of nurses and midwives involved in the use of such protocols
- To disseminate information to all members of the health care team regarding organisational policies underpinning the use of medication protocols
- To establish review and audit processes to evaluate the use of medication protocols as part of quality care provision and risk management programmes.

These key provisions should be in place to facilitate nurses and midwives in safe practices for the supply and administration of medication utilising a medication protocol.

Box 1. Medication Protocol Framework Template

1. Critical elements

1.1 Name of the organisation and/or department where the protocol applies.

1.2 Date the protocol comes into effect and a review date and/or expiration date.

1.3 Names and signatures of protocol author(s) and reviewers, which should include the chair of the drugs and therapeutic committee (if relevant), the medical consultant, a pharmacist and nurses/midwives working within the clinical area.

1.4 Name(s) and signature(s) of the employing authority who is authorising the implementation of the protocol (e.g., health service provider).

2. Clinical criteria

2.1 Clinical condition for use of the protocol:

2.1.1 Definition of the clinical condition including the criteria for confirmation of the condition.

2.1.2 Clearly define in what circumstances the protocol applies.

2.2 Relevant international and national guidelines/evidence-based practice.

2.3 Inclusion criteria for patient/service-user treatment using the protocol.

2.4 Exclusion criteria for patient/service-user treatment using the protocol.

2.5 Actions to be taken for those who are excluded from the protocol, whether by the above exclusion criteria or because the patient/service-user does not wish to receive treatment using the protocol.

2.6 Description of circumstances and referral arrangements when further advice or consultation is required.

2.7 Documentation requirements of the protocol to include specific details of where the supply or the supply and administration of the medication is to be recorded.

3. Details of medication to be supplied

3.1 Name of medication, legal classification, dosage, maximum total dosage, quantity, route and frequency of administration and the minimum and maximum period over which the medication should be administered.

3.2 Warnings, including cautions, contraindications, interactions and side effects.

3.3 Potential adverse reactions and procedures for treatment of same.

3.4 Procedure for reporting adverse drug reactions to the Irish Medicines Board.

3.5 Procedure for the reporting and documentation of errors and near misses involving the medication.

3.6 Validated reference charts to be available in circumstances where calculation of dose is required.

3.7 Mechanism for storage of medication and for obtaining supply.

3.8 Resources and equipment necessary for care under the protocol to be specified. This is dependent on the assessment requirements and best practice guidelines identified for the clinical condition. All involved staff should be familiar with the availability and location of resuscitative equipment.

3.9 Audit process to identify appropriate use of the protocol or unexpected outcomes.

4. Patient/service-user care information

4.1 The advice (including written) to be given to the patient/service-user or carer before and/or after treatment.

4.2 Medication information to be provided to the patient/service-user or carer using the authorised patient information leaflet if one is available. It should include relevant warnings including possible side effects and potential adverse reactions.

4.3 Details of any necessary follow-up action and referral arrangements. This should be as specific as possible, to include how the process of referral is to be done, with whom, when and where it should occur.

5. Staff authorised to use protocol

5.1 Name(s) and signature(s) of nurses/midwives authorised to use the medication protocol, including any necessary criteria:

5.1.1 Professional qualifications, training, experience and competence seen as necessary and relevant to the clinical condition treated using the medication protocol.

5.1.2 Requirements for staff for continuing training and education for supplying medication using the specific protocol.

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APPENDIX A
Relevant legislation and statutes and national guidelines

Legislation and statutes

1. *Nurses Act, 1985*

   Provides for the establishment of a board – An Bord Altranais – that shall provide for the registration, control and education of nurses and to provide for other matters relating to the practice of nursing.

2. *Irish Medicines Board (Miscellaneous Provisions) Act, 2006*

   An Act to amend the *Misuse of Drugs Act, 1977* (as amended by the *Misuse of Drugs Act, 1984*); to amend the *Irish Medicines Board Act, 1995;* to amend the *Control of Clinical Trials Act, 1987;* to amend the *Health Acts, 1947* to *2005;* and to consequentially amend Regulations that are either made under the *Irish Medicines Board Act, 1995* or referred to in Section 34(4) of that Act. This Act provides for amendments to medicines regulations by Ministerial order for nurses and midwives to prescribe medications.

3. *European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations, 2006 (SI No. 374 of 2006)*

   These Regulations implement EU Directive (2005/28/EC) regarding clinical trials involving medications for human use. The Regulations establish the principles of good clinical practice and the detailed guidelines in line with those principles for the design, conduct and reporting of clinical trials on human subjects involving medicinal products. Guidelines are provided concerning the documentation relating to clinical trials and other matters.

4. *European Communities (Quality and Safety of Human Blood and Blood Components) Regulations, 2005 (SI No. 360 of 2005)*

   These Regulations give effect to the EU Directive (2002/98/EC) setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. The Regulations apply to the collection and testing of blood and blood components, whatever their intended purpose. The Regulations also deal with the application of the Directive regarding the processing, storage and distribution of blood and blood components, intended for transfusion.

5. *Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (SI No. 540 of 2003)*

   The Regulations provide a listing of the classes of medicines which require a prescription in order to be supplied. Significant features of these Regulations include:

   - Medicines are strictly regulated as to what is deemed a prescription-only medicine which can only be supplied by a pharmacist
   - Outlines the medications which are exempt from prescription-only status and to be supplied only by a pharmacist
   - States the requirements necessary to dispense a medicinal product based on a prescription
   - Provides exemptions for an emergency supply of medicines
   - Details the labelling requirements of dispensed medicinal products
   - Details the pharmacy record requirements for supplying and dispensing of medicinal products
   - Prohibits the sale, offering or keeping for sale of any medicine after its expiration date
   - Prohibits the supply of medicines by mail order
   - Provides a category of prescription medicines allowed only to be dispensed in a hospital and the medicines listed within the Regulations.

6. *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2005 (SI No. 510 of 2005)*

   The purpose of these Regulations is to update the controls in respect of the supply of medicinal products as set out in the *Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI No. 540 of 2003).* The Regulations provide for a number of issues which include:

   - Clarification with regard to the administration of medicinal products;
   - Clarification of the role of authorised persons with regard to supervision of the supply of prescription-only medicinal products;
   - The availability of certain medicinal products in non-pharmacy outlets;
   - The availability and use of certain medicinal products by various grades of ambulance personnel;

- The addition of certain products to the schedules of prescription-only medicinal products.

7. *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (SI No. 201 of 2007)*

   The Amendment regulates for nurse prescribing by providing the legislative requirements that must be satisfied for a nurse or midwife to prescribe. These are detailed below:

   - The nurse/midwife is employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home)
   - The medicinal product is one that would be given in the usual course of the provision of the health service provided in the health service setting in which the nurse/midwife is employed
   - The prescription is issued in the usual course of the provision of that health service.

   In addition, the Regulations provide additional controls (as detailed in Section 5a (2)) allowing the health service provider to prohibit a registered nurse/midwife employed from issuing a prescription or imposing conditions in addition to those stipulated above.

   These Regulations require that the prescription issued by a registered nurse must state his/her registration number (Personal Identification Number) as assigned by An Bord Altranais.

8. *Medicinal Products (Licensing and Sale) Regulations, 1998 (SI No. 142 of 1998)*

   Details the Regulations for product authorisation and licensure for all medicinal products and certain exemptions. A listing of information to be included in the summary of product characteristics is included.

Collectively the *Misuse of Drugs* Acts and Regulations determine the conditions of production, prescription, possession, supply, importation and exportation of controlled drugs. The drugs are categorised into five schedules with different controls applicable to each category.

9. *Misuse of Drugs Act, 1977*
10. *Misuse of Drugs Act, 1984*
11. *Misuse of Drugs Regulations, 1988 (SI No. 328 of 1988)*
12. *Misuse of Drugs Regulations, 1993 (SI No. 338 of 1993)*

13. *Misuse of Drugs (Supervision of Prescriptions and Supply of Methadone) Regulations, 1998 (SI No. 225 of 1998)*

    Details the regulations involving the prescription and supply of methadone. Specific requirements are provided for the provision of methadone by authorised practitioners, the registration of treatment list and record keeping.

14. *Misuse of Drugs (Amendment) Regulations, 2007 (SI No. 200 of 2007)* authorise nurse prescribing of certain Schedule 2 and 3 controlled drugs through establishing a Schedule 8 of MDAs and provide for the regulatory requirements for prescribing Schedule 4 and 5 MDAs. Refer to Appendix C which details the Schedule 8 for nurse prescribing.

15. *Health Act 2004*

    - Establishes the Health Service Executive
    - Creates mechanisms for involving public representatives, users of health and personal social services and other members of the public in matters relating to those services
    - Founds a statutory framework for handling particular complaints relating to health and personal social services
    - Establishes methods for the future dissolution of certain other health bodies and for the transfer of their functions and employees to the Health Service Executive
    - Provides for related matters.

16. *Health (Family Planning) Act, 1979* and subsequent amendments *1992 and 1993*

    Legislates for the establishment of family planning services and the control, sale and supply of contraceptives.

17. *Mental Health Act, 2001*

    Legislates for the involuntary admission to approved centres of persons suffering from mental disorders, and details the mechanisms for regulating, inspecting and monitoring the standards of care in the mental health service.

18. *Nursing Homes (Care and Welfare) Regulations, 1993 (SI No. 226 of 1993)*

    These Regulations contain provisions for the purpose of ensuring that adequate and suitable care and accommodation are provided for dependent persons in nursing homes. Requirements with regard to facilities for patients, safety, staffing levels and record keeping are described as well as provision for the regular inspection of nursing homes by designated officers of the health boards.

National Guidelines

Guidelines for the Safe Administration of Cytotoxic Medical Preparations in the Treatment of Patients with Cancer (Department of Health, 1996)

Outlines the responsibilities of staff and institutions involved in the preparation and administration of cytotoxic agents for cancer treatment. The verification procedures prior to administration of treatment are detailed. Recommendations concerning the staffing, facilities and setting where treatment is administered are also included.

Guidelines for the Administration of Blood and Blood Components (National Blood Users Group and the Irish Blood Transfusion Service, 2004)

Standard practices regarding the administration of blood and blood components are detailed in the guidelines. Recommendations for pre transfusion sampling, prescription, monitoring of the patient, adverse events and documentation are provided along with other areas.

APPENDIX B
An Bord Altranais documents

1. *The Code of Professional Conduct for each Nurse and Midwife* (2000)

   This document specifies, among other things, that:

   "The nursing profession demands a high standard of professional behaviour from its members and each registered nurse is accountable for his or her practice."

   "…Any circumstance which could place patients/clients in jeopardy or which militate against safe standards of practice should be made known to appropriate persons or authorities."

   "The nurse or midwife must acknowledge any limitations of competence and refuse in such cases to accept delegated or assigned functions..."

   "The nurse shall work in close co-operation with members of the health professions, and others, in promoting community and national efforts to meet the health needs of the public."

2. *Scope of Nursing and Midwifery Practice Framework* (2000)

   "The purpose of this document is to provide nurses and midwives with professional guidance and support on matters relating to clinical practice. It introduces a decision-making framework to assist nurses and midwives in making decisions about the scope of their clinical practice." (p.1)

   (A number of key concepts of scope of practice in relation to medication management are defined in the glossary of terms.)

3. *Guidelines for Midwives* (2001)

   The document has two main objectives:

   "To inform Registered Midwives of the legislation that governs or informs their practice and to make them aware of the responsibilities and accountabilities that accrue to them as a result of that legislation." (p.1)

   "To provide guidance to Registered Midwives and assist their decision-making so that the care they provide is based on the best available evidence and has regard for both the safety of mother and baby and the provision of a satisfactory childbirth experience for women." (p.1)

4. *Guidance to Nurses and Midwives on the Development of Policies, Guidelines and Protocols* (2000)

   Provides an outline for the professions regarding the development and implementation of policies, guidelines and protocols.

5. *Recording Clinical Practice - Guidance to Nurses and Midwives* (2002)

   The objectives of this document are to aid nurses and midwives:

   - To appreciate the professional and legal issues regarding the compilation and management of nursing and midwifery documentation
   - To value professional responsibility associated with good practice in record management
   - To offer practical advice in attaining/maintaining acceptable standards of recording clinical practice.

6. *Guidance to Nurses and Midwives Regarding the Ethical Conduct of Nursing and Midwifery Research* (2007)

   Its purpose is to provide nurses and midwives with general guidance on ethical matters relating to research and to ensure the protection of the rights of all those involved in research.

7. *Practice Standards for Nurses and Midwives with Prescriptive Authority* (2007)

   The objectives of the Practice Standards are:

   - To provide professional guidance for prescriptive authority and associated areas of medication management
   - To enable registered nurse prescribers to demonstrate the key competencies and practice elements associated with this authority and related principles to ensure, safe, competent, effective and ethical practice
   - To ensure mechanisms of clinical and self-governance are in place relating to the prescriber's scope of practice
   - To outline a regulatory framework for nurses and midwives for their continuum of their prescribing authority/practices
   - To assure the public of the competence and professional accountability of the registered nurse prescriber
   - To support the twin track approach to the regulation of registered nurse prescribers.

APPENDIX C
Schedule of controlled MDA medicinal products

MDA Schedule 1

A special license is required for any activity in respect of these drugs. In practice, such activities are strictly limited to scientific research or forensic analysis. Examples of these drugs are: cannabis, coca leaf, raw opium and the major hallucinogenic drugs (LSD, Mescaline, and Psilocin).

MDA Schedule 2

A license is required for the import and export of these drugs and those entitled to produce, supply or possess them are listed. Possession without an appropriate authority is an offence. A pharmacist may supply to a patient only on the authority of a prescription written in the prescribed form. Record-keeping requirements (including CD register) apply in full. Destruction must be witnessed and safe custody maintained. Examples of Schedule 2 drugs are opiates (morphine and heroin), amphetamines and synthetic narcotics (pethidine, methadone, hydrocodone).

MDA Schedule 3

Less strict controls apply to this schedule of drugs. Record-keeping requirements in a CD register do not apply. Destruction of the drug does not need to be witnessed. The safe custody provisions are applicable to these drugs as are the controlled drug prescription writing requirements. Most barbiturates, some potent analgesics, minor stimulants and two benzodiazepines – flunitrazepam and temazepam – are examples.

MDA Schedule 4

Control of these drugs is minimal and in practice they should be supplied in accordance with the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003.* Record keeping in a controlled drugs register, the retention of invoices and the safe custody regulations do not pertain to drugs in this schedule. Most benzodiazepines, phenobarbitone, methylphenobarbitone preparations containing less than 100mg and Selegiline are examples.

MDA Schedule 5

This schedule lists medicinal products exempt from most restrictions under the Regulations. Invoices regarding these products must be retained for two years. The list includes:

a) preparations (not injections) containing codeine, nicocodine, nicodicodine, norcodeine, acetyldihydrocodeine, ethylmorphine pholcodine mixed with other substances and containing less that 100mg per dosage unit or not more than 2.5% in undivided preparations

b) preparations of dihydrocodeine (not being injections) containing not more than 10mg per dosage unit of dihydrocodeine as base and, in the case of undivided preparations, not more than 1.5% as base

c) preparations of cocaine containing not more than 0.1% calculated as cocaine base

d) preparations of medicinal opium or morphine, containing not more than 0.2 % as calculated as anhydrous morphine base

e) preparations of diphenoxylate containing not more than 2.5mg of diphenoxylate calculated as base and a quantity of atropine sulphate equivalent to at least 1% of the dose of diphenoxylate (e.g., Lomotil)

f) preparations for oral administration containing not more than 135mg of dextropropoxyphene (e.g., Distalgesic, Doloxene Co.).

MDA Schedule 8

This schedule establishes which drugs registered nurse prescribers are legally entitled to prescribe within schedules 2 and 3

PART 1 - DRUGS FOR PAIN RELIEF IN HOSPITAL FOR:

1. A person with a probable myocardial infarction
2. A person after trauma suffering from acute or severe pain
3. A person requiring post-operative pain relief in a hospital who has had either 1 or 2

Drug	Route of administration
Morphine sulphate	Oral, intravenous, intramuscular
Codeine phosphate	Oral

PART 2 - DRUGS FOR PALLIATIVE CARE

Drug	Route of administration
Morphine sulphate	Oral, subcutaneous
Hydromorphone	Oral, subcutaneous
Oxycodone	Oral, subcutaneous
Buprenorphine	Transdermal
Fentanyl	Transmucosal, transdermal
Methylphendidate	Oral
Codeine phosphate	Oral

PART 3 - DRUGS FOR PURPOSES OF MIDWIFERY

Drug	Route of administration
Pethidine	Intramuscular

PART 4 - DRUGS FOR NEONATAL CARE IN HOSPITAL

Drug	Route of administration
Morphine sulphate	Oral, intravenous
Fentanyl	Intravenous

APPENDIX D
Glossary of terms relating to medication management

Accountability

The fulfilment of a formal obligation to disclose to referent others the purposes, principles, procedures, relationships, results, income and expenditures for which one has authority (Lewis and Batey, 1982, cited in *Review of Scope of Practice for Nursing and Midwifery*, An Bord Altranais, 2000).

Adverse drug reaction

A response to a drug that is noxious and unintended reaction and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function *(EEC Directive of 2001, [2001/83/EC]).*

Administration

Giving an individual dose of a medicinal product to a patient/service-user via direct contact (e.g., orally, by injection) or by indirect contact (e.g., application of a medicated dressing) and ensuring the completion of this activity.

Competence

The ability of the registered nurse or registered midwife to practise safely and effectively fulfilling her/his professional responsibility within her/his scope of practice (*Review of Scope of Practice for Nursing and Midwifery,* An Bord Altranais, 2000).

Decision-making

The process of evaluating all the accessible information regarding a patient/service-user and arriving at a judgement or conclusion based on that information about the therapeutic plan for a patient/service-user.

Delegation

The transfer of authority by a nurse or midwife to another person to perform a particular role or function (*Review of Scope of Practice for Nursing and Midwifery,* An Bord Altranais, 2000).

Dispensing

The preparation and issuing or transfer of a medicinal product customarily from a

written prescription for administration by another or for self-administration. Dispensing activities may include:

- Receiving/reading the prescription
- Adjusting an order according to approved policy (e.g., substitution)
- Selecting the drug to dispense
- Checking the expiry date
- Reconstituting a product
- Repackaging the drug
- Labelling a product; and
- Completing a final physical check for accuracy of the finished product. (College of Nurses of Ontario, 2005).

External use

Application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina, or anal canal when a local action is intended and extensive systemic absorption is unlikely to occur (shall not include transdermal delivery systems, throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations, or teething products) (*Medicinal Products (Prescription and Control of Supply) Regulations, 2003).*

Health prescription

Prescription issued in connection with arrangements made under section 59 or section 67 of the *Health Act (No. 1 of 1970)* on a form supplied by or on behalf of a health board *(Medicinal Products (Prescription and Control of Supply) Regulations, 2003).*

Health service provider

The Health Service Executive, a hospital, a nursing home, a clinic or other person whose sole or principal activity or business is the provision of health services, or a class of health services, to the public or a class of the public. *(Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007)*

Hospital

Hospital includes a clinic, nursing home or similar institutions *(Medicinal Products (Prescription and Control of Supply) Regulations, 2003).*

Institution

A hospital or a nursing home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions (Article 8 (1) (a) of the *Misuse of Drugs Regulations, 1988*).

Medical practitioner

A person who holds a basic medical qualification *(Medical Practitioners Act, 2007)*

Medication error

Any preventable event that may cause or lead to inappropriate medication use or patient/service-user harm while the medication is in the control of the health care professional, patient/service-user encounter or consumer. These events may be associated with professional practice, health care products, procedures and systems. This includes prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration: education; monitoring and use (National Coordinating Council for Medication Error Reporting and Prevention, 1998). In the Irish health care context, the activity of supply should be included in this definition.

Medication Management

The facilitation of safe and effective use of prescription and over-the-counter medicinal products (Bulechek and McCloskey, 1999). It is a comprehensive intervention which encompasses the nurse's/midwife's knowledge and the activities that are performed to assist the patient/service-user in achieving the greatest benefit and best outcomes involving medications (Naegle, 1999). Responsibilities of medication management incorporate the assessment, planning, implementation and evaluation of the nursing and midwifery process in collaboration with other health care professionals in providing care.

Medicinal product

Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product *(EEC directive of 2001 [2001/83/EC]).*

Medication protocol

A written direction that allows for the supply and administration of a named medicinal

product[6] by a nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse/midwife to supply and administer a medication to groups of patients/service-users in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment.

Midwife

A person whose name is entered in the midwives division of the register *(Nurses Act, 1985).*

Nurse

A woman or man whose name is entered in the register *(Nurses Act, 1985).*

Parenteral administration

Administration by breach of the skin or mucous membrane *(Medicinal Products (Prescription and Control of Supply) Regulations, 2003).*

Pharmacist

A registered member of the Pharmaceutical Society of Ireland.

Practise of medicine

This means to engage in the practice of medicine; this includes the practice of surgery and other disciplines of medicine *(Medical Practitioners Act, 2007).*

Prescribe

To authorise in writing the dispensing, supply and administration of a named medicinal product (typically a prescription–only medicine, but may include over-the-counter medications) for a specific patient/service-user.

Prescription

A prescription issued by a registered medical practitioner for the medical treatment of an individual, by a registered dentist for the dental treatment of an individual, or by a registered veterinary surgeon for the purposes of animal treatment or a registered nurse for the medical treatment of an individual subject to Article 3A of the Regulations *(Misuse of Drugs (Amendment) Regulations, 2007).*

[6]Controlled drugs cannot be supplied under protocol owing to restrictions in the *Misuse of Drugs Act 1984* and subsequent *Regulations*

Register

A bound book; it does not include any form of loose-leaf register or card index *(Misuse of Drugs Regulations, 1988).*

Registered Nurse Prescriber

A nurse or midwife who is registered in the Division of the Register of Nurse Prescribers of An Bord Altranais.

Supply

Distribute, sell, or offer a medicinal product to a patient/service-user under the directions of a registered medical practitioner as noted in an individual prescription or written instructions *(Medicinal Products (Prescription and Control of Supply) Regulations, 2003).*

Transcription

The act of transferring a medication order from the original prescription to the current medication administration record/prescription sheet.

APPENDIX E
Irish Medicines Board adverse reaction report form

ADVERSE REACTION REPORT FORM

IN CONFIDENCE

(FOR COMPLETION BY HEALTHCARE PROFESSIONALS)

PLEASE SEND TO:-
FREEPOST
PHARMACOVIGILANCE UNIT
IRISH MEDICINES BOARD
EARLSFORT CENTRE
EARLSFORT TERRACE
DUBLIN 2

Telephone: 353-1-6764971
Fax: 353-1-6762517
E-mail: imbpharmacovigilance@imb.ie

REPORTER'S NAME & ADDRESS:

_____
_____
_____
_____

AREA OF SPECIALITY:

Patient Initials/Record No:		**Sex: M F**		
Age:		**Weight (if known):**		**Ethnic Origin:**
Indication for Use:				
Suspect Drug/Vaccine: *Please use brand names where possible*	**Daily dose**	**Route**	**Batch No.**	**Dates of Treatment**
Suspected Reaction: (Brief description of the toxic effects or side effects)				
Onset of Reaction: (Date)	**Duration of Reaction:**			
Any other drugs used over this period? (Please state below)				
Drug	**Daily Dose**	**Indication for Use:**		
Recovery from Side Effects: Complete *(Please circle)* **Symptoms Continuing Fatal** **If treatment was required please specify:**				
Drug Discontinued: Y N **Drug Rechallenge: Y N** **Improvement on discontinuation Y N**				
Supply of Report Cards Required: Y N	**Manufacturer Notified: Y N**			

Signature: _____ **Date:** _____

Thank you for taking the time to complete this form

APPENDIX F
Useful contact addresses

An Bord Altranais
18/20 Carysfort Avenue, Blackrock, Co. Dublin
Tel: 01 - 639 8500
www.nursingboard.ie

Department of Health and Children
Hawkins House, Dublin 2
Tel: 01 - 635 4000
www.dohc.ie

Irish Medicines Board
The Earlsfort Centre, Earlsfort Terrace, Dublin 2
Tel: 01 - 676 4971
www.imb.ie

The Pharmaceutical Society of Ireland
18 Shrewsbury Road, Dublin 4
Tel: 01 - 283 7294
www.pharmaceuticalsociety.ie

National Medicines Information Centre
St. James's Hospital, James's Street, Dublin 8
Tel: 01 - 410 3000
www.stjames.ie/clinicalservices/nationalmedicinesinformationcentre

National Poisons Information Centre
Beaumont Hospital, Dublin 9
Tel: 01 - 809 3000
www.beaumont.ie/public/npic

An Bord Altranais

18/20 Carysfort Avenue, Blackrock, Co. Dublin. Tel: 01 - 639 8500
Web: www.nursingboard.ie Email: admin@nursingboard.ie