

MEDICINES STATEMENT A8: PRESCRIBING & ADMINISTRATION OF INJECTABLE MEDICINES

INTRODUCTION

This policy contains guidance and instructions to ensure that the risk of errors in prescribing, preparing and administering injectable medicines is reduced to the lowest possible level. This should also ensure that appropriate and up to date risk assessments and risk reduction methods are in place where appropriate and necessary.

This document is underpinned by, and should be read in conjunction with, the documents listed in the references

ROLES AND RESPONSIBILITIES

- All healthcare professionals working with injectable medicines must ensure that there are SOPs in place for that activity and that the SOPs are adhered to.
- The Prescriber is responsible for ensuring that the medicines are only administered by the injectable route when no other route is suitable. The decision will be based upon the clinical condition of the patient and the available formulations of the specific medication required and the suitability of routes.
- The prescriber, where appropriate, will prescribe within local and national formulary.
- Non-medical prescribers will prescribe in accordance with their prescribing status.
- It is the responsibility of the prescriber to ensure that the injectable route is reviewed regularly and changed to a less hazardous route at the earliest clinically appropriate opportunity.
- Staff responsible for the storage of injectable preparations will store them in accordance with the summary of product characteristics.
- The prescriber will ensure the patient details are correct on the instruction to administer including allergy status of patient.
- All healthcare professionals involved with preparations and administration should:
 - ensure adequate records are maintained at all times
 - be able to demonstrate competencies in the administration of an injectable medication and be authorised to undertake this procedure.
 - be aware of the medication being administered, including dose range, side effects, contra-indications, route and method of administration
- A second person is required to check medication given by the intravenous route and all injectable controlled drugs. The exception will be in the patient's home environment where a second person is not always available to check the medication.

- Following administration, all equipment will be disposed of in accordance with infection control policy, waste management policy and manufacturers' guidelines.

INFECTION CONTROL

- Before preparation all infusion ports, additive ports, necks of ampoules and tops of vials must be disinfected using an alcohol swab and allow to dry for a minimum of 30 seconds.
- Tamper evident caps or metal covers that protect vials, do not ensure sterility and must be removed before swabbing.
- Medicines for injection shall be prepared using a "no touch" technique. This means being aware of and avoiding touching the critical areas, such as needles, syringe tips, vial tops, infusion ports, additive ports and the necks of ampoules.

GENERAL PREPARATION GUIDELINES

- Medicines should be given by injection only when the practicality and appropriateness of other routes of administration has been excluded.
- All medicines prepared for administration shall be administered immediately by the person who has prepared the medicine or in their presence. (NMC 2007).
- Medicines for injection in clinical areas must not be prepared in advance and stored for later administration.
- Injections should only be prepared by Healthcare Professionals who understand the risks involved and have been trained to use safe procedures.
- When only a part of the medication in an "un-preserved" ampoule or vial is required, the remainder must be discarded and not used for another patient.
- For the ward/clinic preparation of an injection that is not available on a "ready to administer" presentation, an aseptic, non-touch technique should be used. Ideally preparation should take place in an area dedicated to this process. The area in which the injectable drug is to be prepared must be clean, uncluttered and free from interruption and distraction as possible.
- When preparing more than one product for administration, the practitioner shall work in systematic way to reduce the risk of error; preparing one product completely before commencing the next.

BEFORE PREPARATION THE PRACTITIONER SHALL:

- Check the prescription to ensure they understand precisely what is required
- Check the dose (this includes checking the weight of the patient if the dose is weight related)
- Check the medicine has not already been given
- Read and understand any relevant information leaflet concerning preparation, safety, handling or reconstitution of the medicine being prepared
- Assemble the appropriate materials
- Prepare any relevant labels
- Check that the components have not expired
- Check that the components are physically compatible
- Check that there are no therapeutic interactions with currently prescribed medicines or other contra-indications

- Check the integrity of the packaging of any components being used

RISK ASSESSMENTS

- Annual risk assessment of clinical practice shall be carried out using the National Safety Patient Agency template ([appendix 1](#)). The template includes 3 proformas to risk assess local practice, individual medicines, and to prepare a summary of moderate and high risk injectable medicines.
- The risk associated with an individual product will vary dependent upon a number of factors. These will include:
 - The potential toxicity to the patient resulting from maladministration
 - The use of a concentrate to prepare the product
 - The need for a complex calculation to obtain the dose for administration
 - The complexity of the preparation
 - The use of a reconstituted vial or ampoule
 - The use of part or multiple ampoules or vials
 - The use of a pump or syringe driver
- If a member practice in the CCG identifies a specific risk highlighted by a medicines safety alert or incident, then they should undertake risk assessments as appropriate for their practice
- **The following factors should be checked when preparing an injectable medicine:**
 - Expiry dates are checked.
 - The calculation must be repeated independently and recorded.
 - The medication and dose are prepared for use correctly.
 - The patient to whom the medication is to be administered is identified correctly using the prescription
 - Consent is obtained by the person administering the injection.
 - The selected route is correct.

ADVERSE DRUG REACTIONS

- The patient should be monitored for any adverse reaction. If this occurs immediate action will be taken to:
 - Inform the prescriber of the medicine that is suspected of causing the reaction (and the patient's GP if different)
 - Complete a "Yellow Card" if appropriate to report the reaction to the MHRA – for serious reactions to established medicines, or any reaction to a new medicine
 - Document the event and actions taken by completion of a significant event form

REFERENCE

National Patient Safety Agency Patient Safety Alert 20 "[Promoting safer use of injectable medicines](#)" (March 2007)

Appendix 1

RISK ASSESSMENT TOOL FOR THE PREPARATION AND ADMINISTRATION OF INJECTABLE MEDICINES IN CLINICAL AREAS

1. Carry out a risk assessment in all clinical areas where injectable medicines are prepared and administered
2. A pharmacist and a senior clinical practitioner from the area being assessed should carry out the risk assessment
3. Risk assessments should be conducted annually, and when new injectable products or practices are introduced
4. Risk assess local practice, i.e. how injectable medicines are prepared and administered (see [proforma 1](#))
5. Risk assess individual injectable medicine products used in the clinical area (see [proforma 2](#)) – there are examples to assist with this
6. A summary of products with high and moderate risk assessments should be completed (see [proforma 3](#))
7. Identify risk reduction methods to minimise these risks (see guidance)
8. Where possible, implement appropriate risk reduction methods
9. Re-assess high and moderate-risk practices and products, and record the new scores following the introduction of risk reduction methods (see proformas [1](#) and [3](#))
10. Identify any remaining high-risk products and practices for consideration by the Drugs and Therapeutics Committee (or equivalent) and, if these risks cannot be minimised, they should be recorded in the organisation's risk register

Proforma 1: Risk assessment of injectable medicine procedures – how medicines are prepared and administered

Clinical area:			Clinical directorate:	Hospital site:	
Date of first assessment:				Date of second assessment:	
High-risk practice Tick when high-risk practice is found		✓	Suggested risk reduction method	Comments/revised score Tick if high-risk practice remains unchanged	✓
1	Inadequate technical information or written procedures for preparing and administering injectable medicines		Provide essential technical information and written procedures		
2	Use of unlabelled bolus syringes (including flushes) and infusions – see guidance in multidisciplinary standard		Reinforce and audit policy to ensure all syringes and infusions containing injectable medicines that leave the hands of practitioners during use are labelled		
3	Use of 'open systems'. Is the injection or infusion transferred into an open container?		Introduce 'closed systems'		
4	Preparation of a cytotoxic drug outside of the pharmacy department		Prepare all cytotoxic drugs in the pharmacy department or use closed system products designed for use in clinical areas		
5	Preparation of, or addition to, total parenteral nutrition (TPN) outside of the pharmacy department		Prepare and make all additions to TPN in the pharmacy department or use closed system products designed for use in clinical areas		

6	Administration of an injectable medicine, prepared more than 24 hours previously in the clinical area	Introduce procedures to ensure that all injectable medicine products prepared in clinical areas have expiry dates of 24 hours or less to minimise the risk of microbial contamination unless specifically permitted by a written organisationally approved protocol		
7	Admixture of two or more active medicines without information from the pharmacy service concerning compatibility of the medicines	Obtain compatibility information or administer as separate infusions		
8	Failure to use infusion pump or syringe driver for injectable medicines that require their rate of infusion to be controlled	Ensure that adequate numbers and types of infusion pumps and syringe drivers are available for use, and users have knowledge and training of when and how this equipment should be used		
9	Use of an injectable medicine ampoule, vial or infusion to prepare more than a single dose (unless the product is specifically licensed for use in this way)	Reinforce and audit policy to ensure that single-use products are only used to prepare a single dose (unless specifically permitted by an organisationally approved protocol)		
10	Unauthorised use of unlicensed medicines or 'off-label' use of licensed medicines (unless specifically permitted by a written organisationally approved protocol or BNF-C)	Reinforce and audit policy on the use of unlicensed or 'off-label' injectable medicines. Ensure approved protocols are used, include BNF-C recognised off-label usage		
	Total number of high-risk practices identified in baseline assessment		Total number of high-risk practices remaining after risk reduction initiatives	

Proforma 2: Risk assessment of individual injectable medicine products prepared in clinical areas

Clinical area:	Directorate:	Hospital or Practice site:	Date:
Name and strength of prepared injectable product	Diluent	Final volume	Bag or syringe

	Risk factors	Description	✓
1	Therapeutic risk	Where there is a significant risk of patient harm if the injectable medicine is not used as intended.	
2	Use of a concentrate	Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate.	
3	Complex calculation	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/kg/hour, dose unit conversion such as mg to mmol or % to mg.	
4	Complex method	More than five non-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.	
5	Reconstitution of powder in a vial	Where a dry powder has to be reconstituted with a liquid.	
6	Use of a part vial or ampoule, or use of more than one vial or ampoule	Examples: 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose.	
7	Use of a pump or syringe driver	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.	
8	Use of non-standard giving set/device required	Examples: light protected, low adsorption, in-line filter or air inlet.	
	Total number of product risk factors	Six or more risk factors = high-risk product (Red). Risk reduction strategies are required to minimise these risks. Three to five risk factors = moderate-risk product (Amber). Risk reduction strategies are recommended. One or two risk factors = lower-risk product (Green). Risk reduction strategies should be considered.	
	Risk assessment undertaken by:	Name of pharmacist:	Name of clinical practitioner:

SUGGESTED RISK REDUCTION METHODS THAT CAN BE USED TO MINIMISE RISKS WITH INJECTABLE MEDICINES

1	Simplify and rationalise the range of products and presentations of injectable medicines. Where possible, reduce the range of strengths of high-risk products and provide the most appropriate vial/ampoule sizes
2	Provide ready-to-administer or ready-to-use injectable products – this will minimise preparation risks and simplify administration
3	Provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations
4	Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines
5	Consider the provision of pre-printed prescriptions or stickers – this will help to ensure that information on the prescription about preparation and administration of high-risk products is clearer
6	Provide locally approved protocols that clarify approved unlicensed and ‘off-label’ use of injectable medicines
7	Use double-checking systems – an independent second check from another practitioner and/or the use of dose-checking software in ‘Smart’ infusion pumps and syringe drivers
8	Use an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration

Proforma 3: Risk assessment summary for high and moderate-risk injectable medicines products

Name of clinical area					Directorate:									Date:	
					Risk factors										
					Prepared injectable medicine	Strength	Diluent	Final volume	Bag/syringe	Therapeutic risk	Use of concentrate	Complex calculation	Complex preparation		
					✓	✓	✓	✓	✓	✓	✓	✓			
Risk assessment undertaken by:			Name of pharmacist:							Name of clinical practitioner:					