National Patient Safety Agency

Promoting safer use of injectable medicines

Multi-professional safer practice standards for: prescribing, preparing and administering injectable medicines in clinical areas

1. Introduction

The use of injectable medication has many healthcare benefits for patients. The complexities associated with prescribing, preparing and administering injectable medicines means that there are greater potential risks for patients than for other routes of administration. Weak operating systems increase the potential risk of harm and safe systems of work are needed to minimise these risks.

2. The main risks

2.1 Incomplete and/or ambiguous prescriptions which do not include important information, for example, details of the solution to be used to dilute the injectable medicine (diluent), the final volume of medication to be administered, the final concentration or intended rate of administration.

2.2 Presentations of injectable medicines that may require complex calculation, dilution and handling procedures before the medicine can be administered.

2.3 Lack of information about injectable medicines available to healthcare professionals at the point of use. This information may not always be included in the manufacturer's pack or in commonly available reference sources.

2.4 Selection of the wrong medicine or diluent.

2.5 Use of a medicine, diluent or infusion after its expiry time and date.

2.6 Calculation errors made during prescription, preparation, administration of the medicine, leading to administration of the wrong dose and/or at the wrong concentration or rate.

2.7 Unsafe handling or poor aseptic (non-touch) technique leading to contamination of the injection and harm to, or infection of, the patient.

2.8 Incompatibility between diluent, infusion, other medicines and administration devices.

2.9 Failure to follow patient identification procedures leading to administration to the wrong patient.

2.10 Failure to follow administration checking procedures leading to administration via the wrong route.

2.11 Health and safety risks to the operator or environment.

2.12 Variable levels of knowledge, training and competence amongst healthcare practitioners.

3. Recommended safer practice

3.1 Prescribing

3.1.1 Medicines should be given by injection only when the practicality and appropriateness of other routes of administration have been excluded. The use of this route should be regularly reviewed in favour of switching to oral administration as soon as clinically appropriate.

3.1.2 Prescriptions for injections must clearly specify the medicine name, dose, frequency and route of administration. Where relevant, the prescription, or a readily available local protocol, must specify the following: name and volume of diluent and/or infusion fluid, concentration of final infusion, rate of administration, duration and rate control pump or device to be used.

3.1.3 When two or more prescription charts are in use, it is essential that they are cross-referenced so that practitioners are aware of *all* prescribed medicines.

3.2 Supply and storage

3.2.1 A risk assessment of all injectable medicines must be undertaken by a pharmacist and senior practitioner to determine the safest presentation and location for storage and preparation.

3.2.2 Injectable cytotoxics and parenteral nutrition must be supplied to clinical areas only as ready-to-administer products.

3.2.3 Ready-to-administer or ready-to-use products should be stocked in all clinical areas in preference to those needing preparation before use, or those which are classified as high-risk. Concentrates should only be supplied where safer alternatives are not available.

3.2.4 Multiple use of an unpreserved injectable medicine should be eliminated. Most injectable medicines are licensed for 'once-only' use. Unless the manufacturer's label specifically indicates that the injection contains a preservative, the container should only be used to prepare a single dose for a single patient on one occasion.

3.3 Preparation

3.3.1 Injections should be prepared only by healthcare staff who: understand the risks involved; have been trained to use safe procedures; and have demonstrated their competence for the task. Preparation should only take place if: there is a prescription; a Patient Group Direction or other written instruction; and essential information is available about the product(s) and processes needed for safe preparation and administration. As a minimum, this should consist of the information listed in table 1.

3.3.2 Aseptic (non-touch) technique should be used during preparation and administration. Injectable medicines prepared in clinical areas should always be administered immediately after preparation. They should not be stored for a period of time before use. Administration of infusions prepared in clinical areas should be completed within 24 hours of preparation. In exceptional circumstances where infusion from a single container is intended to continue for more than 24 hours, a risk assessment should be undertaken to determine the safest course of action. Every effort should be made to use a ready-to-administer product.

3.3.3 All syringes, including flushes and infusions, must be labelled immediately after preparation by the person who prepared them. 'Flag labelling' should be used to ensure that volume graduations on small syringes are not obscured. The only exception to this is in situations where preparation and bolus (push) administration is

one uninterrupted process and the unlabelled product does not leave the hands of the person who prepared it. Only one unlabelled medicine must be handled at one time.

3.3.4 Medical devices with luer connectors must be used only for preparation and administration of injections.
Medicines for oral/enteral use must be prepared and administered using only devices with non-luer connections.

3.3.5 Risk assessment will have identified those products representing the highest risk to patients at the time of preparation. Consideration must be given to the use of safer products and systems, for example, double-checking.

3.4 Administration

3.4.1 Injections should be administered only by healthcare staff or patients/carers who understand the risks involved, have been trained to use safe procedures, and who have demonstrated their competence for the task.

3.4.2 Before administration, the following should be available: a current prescription, a Patient Group Direction or other written instructions, essential technical information and a prepared and labelled injectable medicine. The patient's identity and details should be confirmed according to local policy.

3.4.3 The person administering the medicine should personally make a record of administration as soon as possible after the event. This is extremely important in circumstances such as in theatres, where the person administering the medicines may also be the prescriber and there may be no written prescription.

3.4.4 Risk assessment will have identified those products representing the highest risk to patients at the time of administration. Consideration should be given to the use of safer products and systems of administration, for example, double-checking, the use of ‘smart’ infusion pumps or similar rate control technologies.

3.4.5 Infusions should be monitored according to local policy to ensure safe administration of prescribed treatment

4. Annual injectable medicines audit

Organisations should include an audit of medication practice with injectable medicines as part of their annual medicines management report. It should also include the results of risk assessments of injectable medicine practices and the ranges of products used in clinical areas, incident reports and associated harm, compliance with NPSA recommendations and action taken to minimise risks. It should also describe further action required to improve poorly performing aspects of the system and be approved by the Clinical Governance and Drugs and Therapeutics Committees. This report will form part of the organisation’s assurance framework and be used for the patient safety performance management assessment process by external organisations.

Healthcare staff need to have full technical information about the following for all injectable medicines products used in clinical areas:

Reconstitution	Manufacturer's recommended solution (diluent) for diluting and reconstituting a freeze-dried powder.
Concentration of final solution	Recommended concentration and volume for adminstration, stating maximum concentration where applicable.
Example calculations	Examples of dose, preparation and rate of administration calculations.
Dilution/flush solutions	Information concerning physical and chemical compatibility with diluents and infusion fluids.
Stability in solution	Recommended expiry for the prepared final injection or infusion.
Administration rate	For bolus administration and infusion for all routes of administration.
Compatibility information (for commonly used mixtures in specialist areas only)	Mixed in the same syringe or infusion, in administration tubing and at Y-sites and three-way taps where mixing occurs.
Special handling information	If special precautions and handling methods have to be used during preparation and administration e.g. protect from light.
Specialist technical information (where relevant)	pH, osmolarity, sodium content and displacement values.

Glossary

Administration devices	Medical devices designed to regulate or control, mechanically or electronically, the administration of injections or infusions of medicines.
Aseptic technique (non-touch technique)	Handling technique designed to minimise the risk of microbial contamination of a sterile medicine during preparation.
Bolus (push)	Administration from a syringe of a small volume of a single dose of a sterile solution directly into a tissue, organ or vein, over a short period of time usually, between 30 seconds and 10 minutes.
Clinical areas	Wards, clinical departments, operating theatres, clinics, GP surgeries. In the context of homecare, the term may also be considered to include the patient's home.
Closed system	Packaging and presentation of an injectable medicine, and/or procedures followed, to prepare doses for use which are designed to ensure that the injection solution never comes into direct contact with the open air.
Diluent	Any sterile injection solution, such as water for injection or sodium chloride 0.9%, commonly used to dissolve (reconstitute) or dilute a medicine immediately before administration.
Flush, flushing solution	A sterile solution of diluent such as sodium chloride injection 0.9%, used to purge (flush) access devices (e.g. cannulae) before and/or after injection of a medicine or between injections of different medicines.
Hazard, risk	Any factor, such as a difficult procedure or a complex calculation, with the potential to cause harm if carried out incorrectly.
High-risk procedures	Generic procedures involving the preparation and administration of (medicinal) products that have been identified by risk assessment as most likely to pose a significant risk to patients.
High-risk products	Those (medicinal) products whose preparation and/or administration have been identified by risk assessment as most likely to pose a significant risk to patients.
Infusion	Administration, from a syringe, or other rigid or collapsible container e.g. plastic bag, of a volume of sterile solution of an injectable medicine directly into a tissue, organ, vein or artery, at a constant rate, under gravity or by means of an electronic or mechanical pump or other means of rate control, over a defined period usually of at least 10 minutes.
Injectable medicines	Sterile medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intraventricular, epidural, intravesicular, intravitreal, intrapleural, intraocular
Latent risk	Flaws within the overall healthcare system. They can result from decisions made in almost any field that impacts on the delivery of healthcare. For example, environmental building and design, written procedures and management decisions. These strategic decisions can unknowingly create error-provoking conditions and system weaknesses in the workplace.
Licensed medicine	Medicines (medicinal products) placed on the market in the UK require a Marketing Authorisation formerly called a Product Licence. Marketing Authorisations are granted under European Community Council Directives and Regulations by the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Evaluation Agency (EMEA). Licensed

	medicines are manufactured or assembled by commercial organisations that have a Manufacturing Licence and operate Good Manufacturing Practice.
Low-risk products	Those (medicinal) products whose preparation and/or administration have been identified by risk assessment as least likely to pose a significant risk to patients.
Luer	A type of connection used to allow connection of syringes and similar medical devices to catheters, cannulae and other access devices.
Multi-dose injectable medicines vs single-dose injectable medicines	Most injections do not contain an antimicrobial preservative and are licensed for single use only, i.e. for the preparation of a single dose for administration to one patient on one occasion. Use of single-dose products to prepare more than one dose for the same patient means that a prepared injection or a part-used container must be stored before use and increases the risk of infection: use for more than one patient also adds a risk of cross-infection. Injectable medicines should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
Multi-professional	Doctors, nurses, pharmacists and all other healthcare professionals involved with prescribing, preparing or administering injectable medicines.
'Off-label' use	Use of a licensed medicine in a way not covered by its Manufacturing Authorisation (Product Licence).
Open systems	Packaging and presentation of an injectable medicine, and/or procedures followed, to prepare doses for use which do not prevent the injection solution from coming into direct contact with the open air. Excludes a single withdrawal of solution from an open ampoule into a syringe.
'Purchasing for safety'	Procuring presentations and formulations of medicines approved for use in local medicine formularies. In this process, medicine products are reviewed by purchasing and pharmacy groups and products that are designed in such a way as to promote safer practice are selected. This process does not involve therapeutic substitution.
Ready-to-administer injectable products	These products require no further dilution or reconstitution and are presented in the final container or device, ready for administration or connection to a needle or administration set. For example, an infusion in a bag with no additive required.
Ready-to-use injectable products	These products require no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampule, of the required concentration, that only needs to be drawn up into a syringe.
'Specials'	Unlicensed medicines custom-manufactured to order, by hospital pharmacies or other facilities licensed by the MHRA. 'Specials' themselves are not licensed, cannot be advertised for sale and have not been formally assessed for quality, safety or efficacy, responsibility for which rests solely with the prescriber and purchaser.
Unlicensed medicine	A medicine (medicinal product) that does not have a Marketing Authorisation (Product Licence). Unlicensed medicines may be manufactured or assembled (prepared) from licensed products in clinical areas by clinical staff in order to be able to administer a medicine to a patient. Unlicensed medicines may also be manufactured or assembled in controlled environments in

	hospital pharmacy departments. Units with Specials Manufacturing Licences in hospital pharmacies and commercial organisations are also able to manufacture or assemble unlicensed 'Specials' in controlled environments that are inspected by the MHRA.