NATIONAL PATIENT SAFTY AGENCY

Draft Patient Safety Alert On
Safer Use of Injectable Medicines

Appendix 3

A TEMPLATE STANDARD OPERATING PROCEDURE FOR PRESCRIBING, PREPARING AND ADMINISTERING INJECTABLE MEDICINES IN CLINICAL AREAS

- Prescribing and preparation of injectable medicines and their administration by any route, pose risks to patients.
- All human actions are prone to error. It is not possible to train humans to make no errors.
- Safe systems of work are needed to minimise these risks.

Step 1 Prescribing

1.1 All prescriptions for injectable medicines must specify the following:
- patient's name
- prescriber's signature
- the approved medicine name
- the dose and frequency of administration
- the date and route of administration.
- the allergy status of the patient

1.2. Where relevant, the prescription, or a readily available local protocol, must specify the following :
- brand name and formulation of the medicine
- concentration or total quantity of medicine in the final infusion container or syringe
- name and volume of diluent and/or infusion fluid
- rate *and* duration of administration
- type of rate-control pump or device(s) to be used
- the age and weight of any patient under 16 years of age, where relevant
- date on which treatment should be reviewed

Step 2 Preparation

2.1 General

2.1.1 *Read all prescription details carefully* & confirm that they relate to the patient to be treated.

2.1.2 Ensure that the area in which the medicine is to be prepared is as clean, uncluttered and as free from interruption and distraction as possible.

2.1.3 Assemble everything you need : Sharps bin for waste disposal, medicine ampoule(s)/vial(s), diluent, syringe(s), 21g, 23g, 25g needle(s), alcohol wipes, disposable protective gloves, clean re-usable plastic tray. Check
- packing and containers for expiry dates and damage.
- if medicines were stored as recommended e.g. in the 'fridge.

2.1.4 Beware of the risk of confusion between similar looking medicine packs, names & strengths : *read all labels carefully.*

2.1.5 Check that

- the formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information
- the patient has no known allergy to the medicine (see 1.1)
- you understand the method of preparation .

2.1.6 Calculate the volume of medicine solution needed to give the prescribed dose. Write the calculation down and have it checked by another person.

2.1.7 Prepare the label for the prepared medicine. (see standard xx)

2.1.8 Cleanse your hands according to local policy.

2.1.9 Put on a pair of disposable protective gloves.

2.1.10 Use a 70% alcohol wipe or spray to disinfect the surface of the plastic tray

2.1.11 Assemble the syringe(s) and needle(s) : peel open wrappers carefully and arrange all ampoules/vials, syringes and needles neatly in the tray.

2.1.12 Use a "non-touch" technique i.e. avoid touching areas where bacterial contamination may be introduced e.g syringe-tips, needles, vial tops. Never put down a syringe attached to an unsheathed needle.

2.1.13 Prepare the injection by following the manufacturer's product information or local guidelines (see standard 3.3.1) and the relevant guidance in paras. 2.2 to 2.7.

2.2 Withdrawing solution from an ampoule (glass or plastic) into a syringe

2.2.1 Tap the ampoule gently to dislodge any medicine in the neck.

2.2.2 Snap open the neck of glass ampoules, using an ampoule snapper if required

2.2.3 Attach a needle to a syringe and draw the required volume of solution into the syringe. Tilt the ampoule if necessary.

2.2.4 Invert the syringe and tap lightly to aggregate the air bubbles at the needle end. Expel the air carefully.

2.2.5 Remove the needle from the syringe and fit a new needle or sterile blind hub.

2.2.6 Label the syringe (see standard 3.3.3).

2.2.7 Keep the ampoule and any unused medicine until administration to the patient is complete.

2.2.8 If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

2.2.9 The neck of some plastic ampoules is designed to connect directly a syringe without use of a needle, after the top of the ampoule has been twisted off.

2.3 **Withdrawing a solution or suspension from a vial into a syringe**

2.3.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.

2.3.2 With the needle sheathed, draw into the syringe a volume of air equivalent to the required volume of solution to be drawn up.

2.3.3 Remove the needle cover and insert the needle into the vial through the rubber septum.

2.3.4 Invert the vial. Keep the needle in the solution and slowly depress the plunger to push air into the vial.

2.3.5 Release the plunger so that solution flows back into the syringe.

2.3.6 If a large volume of solution is to be withdrawn, use a push-pull technique : repeatedly inject 5-10ml of air and draw up an equal volume of solution until the required total is reached. This "equilibrium method" helps to minimise the build-up of pressure in the vial.

2.3.7 Alternatively, the rubber septum may be pierced with a second needle to let air into the via as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.
2.3.8 With the vial still attached, invert the syringe. With the needle & vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial.
2.3.9 Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial.
2.3.10 Expel excess air from the syringe. Remove the needle and exchange it for a new needle or a sterile blind hub.
2.3.11 The vial(s) and any unused medicine should be kept until administration to the patient is complete.
2.3.12 If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents, immediately before they are drawn into the syringe.

2.4 Reconstituting powder in a vial and drawing the resulting solution or suspension into a syringe

2.4.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.
2.4.2 Use the procedure in 2.2 above to withdraw the required volume of diluent (e.g. water for injections or sodium chloride 0.9%) from ampoule(s) into the syringe.
2.4.3 Inject the diluent into the vial. Keeping the tip of the needle above the level of the solution in the vial, release the plunger. The syringe will fill with the air which has been displaced by the solution. (If the contents of the vial were packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluent is to be added, use a push-pull technique (see above).
2.4.4 With the syringe and needle still in place, gently swirl the vial to dissolve *all* the powder, unless otherwise indicated by the product information. This may take several minutes.
2.4.5 Follow the relevant steps in 2.3 above to withdraw the required volume of solution from the vial into the syringe.
2.4.6 Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.
2.4.7 If a purpose-designed reconstitution device is used, the manufacturer's instructions should be read carefully and followed closely.

2.5 Adding a medicine to an infusion

2.5.1 Prepare the medicine in a syringe using one of the methods described in 2.2 to 2.4 above.
2.5.2 Check the outer wrapper of the infusion container is undamaged.
2.5.3 Remove the wrapper and check the infusion container itself in good light. It should be intact and free of cracks, punctures/leaks.
2.5.4 Check the infusion solution which should be free of haziness, particles and discolouration.
2.5.5 (Where necessary),remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol wipe and allow to dry for at least 30 seconds.
2.5.6 If the volume of medicine solution to be added is more than 10% of the initial contents of the infusion container, (more than 50ml to a 500ml or 100ml to a

1litre infusion), an equivalent volume must first be removed with a syringe and needle.

2.5.7 Inject the medicine into the infusion container through the centre of the injection port, taking care to keep the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least five times to ensure thorough mixing before starting the infusion.

2.5.8 Do not add anything to any infusion container other than a burette when it is hanging on the infusion stand since this makes adequate mixing impossible.

2.5.9 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.

2.5.10 Check the appearance of the final infusion for absence of particles, cloudiness or discolouration.

2.5.11 Label the infusion (see standard 3.3.3).

2.6 Diluting a medicine in a syringe for use in a pump or syringe-driver.

2.6.1 Prepare the medicine in a syringe using one of the methods described above.

2.6.2 Draw the diluent into the syringe to be used for administration by the pump or syringe-driver. Draw in some air (slightly more than the volume of medicine needed) and remove the needle.

2.6.3 Stand the diluent syringe upright. Insert the needle of the syringe containing the medicine into the tip of the diluent (administration) syringe and add the medicine to it. Alternatively, a disposable sterile connector may be used to connect two syringes together directly.

2.6.4 Check that

- the total volume of injection solution in the syringe is as specified in the prescription and that the infusion can be delivered at the prescribed rate by the administration device chosen.
- the rate of administration is set correctly on the administration device and according to the manufacturer's instructions.

2.6.6 Fit a blind hub to the administration syringe and invert several times to mix the contents.

2.6.7 Remove the blind hub. Tap the syringe lightly to aggregate the air bubbles at the needle end. Expel the air and refit the blind hub.

2.6.8 Carefully check the syringe for cracks and leaks and then label it (see standard 3.3.3 , noting especially the requirements specific to syringe drivers)

2.6.9 Check that the rate of administration is set correctly on the device before fitting the syringe, priming the administration set and starting the infusion device.

2.7 Labelling injection and infusion containers

2.7.1 All injections should be labelled immediately after preparation, except for syringes intended for immediate push(bolus) administration by the person who prepared them. Under no circumstances, however, must an operator be in possession of more than one unlabelled syringe at any one time, nor must an unlabelled syringe be fitted to a syringe driver or similar device.

2.7.2 Place the final syringe or infusion and the empty ampoule(s)/vials(s) in a clean plastic tray for transport to the bedside, with the prescription, for administration.

Step 3 Administration of a injectable medicine.

3.1 Before administering any injection

3.1.1 Confirm the patient's identity and re-check *all* the following :

- patient's name
- prescriber's signature
- the approved medicine name
- the dose and frequency of administration
- the date and route of administration.
- the allergy status of the patient

3.1.2 Also check, where relevant :
- brand name and formulation of the medicine
- concentration or total quantity of medicine in the final infusion container or syringe
- name and volume of diluent and/or infusion fluid
- rate *and* duration of administration
- type of rate-control pump or device(s) to be used
- the age and weight of any patient under 16 years of age, where relevant
- date on which treatment should be reviewed

3.1.3 Check that the medicine is due for administration at that time and has not already been given.
3.1.4 Assemble everything you need including any flushing solution(s) needed.
3.1.5 Explain and discuss the procedure with the patient.
3.1.6 Check any infusion already in progress : it should be should be free of haziness, particles and discolouration.
3.1.7 Check that an appropriate access device is in place. Flush it immediately before and after administration of a medicine, and between doses of different medicines administered consecutively, according to local policy. Also check the administration site for signs of leakage, infection or inflammation.

3.2 Administration of injections : general
3.2.1 Check infusions : they should be should be free of haziness, particles and discolouration.
3.2.2 Use aseptic (non-touch) technique at all times.
3.2.3 Spike infusion containers carefully, on a flat surface, using the technique appropriate to the type of container.
3.2.4 Prime the access device according to local policy immediately before starting an infusion.
3.2.5 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.

3.3 After administration
3.3.1 After completion of an intermittent infusion, flush the access device according to local policy.
3.3.2 Ask the patient to report promptly any soreness at the injection site or discomfort of any sort.
3.3.3 Make a detailed record of administration.
- Discard the empty ampoules/vials from which the injection was prepared and any unused medicine in them : ampoules or vials should *never* be used to prepare more than one injection unless labelled by the manufacturer for "multidose" use (see standard 3.2.4).

3.4.5 Re-check the administration site for signs of leakage, infection or inflammation and continue to monitor the patient, contents of the infusion container and the rate of infusion according to local policy.