The Manitoba Pharmaceutical Association

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Guidelines for the Pre-filling of Insulin Syringes

Pharmacists today are increasingly involved in providing patient-specific services to facilitate compliance with drug therapy regimens and are often asked to pre-fill insulin syringes for patients living with diabetes. Pre-filling syringes is an important service for patients lacking the manual dexterity to fill syringes, who are visually impaired or dependent on others for drawing their insulin. For specific patients, the pharmacist may be the only caregiver who can provide this valuable service.

Notwithstanding pre-filled insulin pen-like devices and insulin-containing cartridges are commercially available that deliver insulin subcutaneously through a needle. Patients should be encouraged to use these insulin delivery devices whenever possible to lessen the potential for contamination possible when syringes are prepared in pharmacies. In those selected patients, who are visually and/or neurologically impaired and those using multiple daily injection regimens, these devices may improve accuracy of insulin administration and/or be more convenient.

These guidelines are directed towards the community pharmacy practice setting. The goal is to provide pharmacists, patients and caregivers with guidelines in order to ensure provision of pre-filled insulin syringes of consistent potency and sterility.

1.0 All preparation of insulin pre-filled syringes should be conducted by the pharmacist or under the direction of a pharmacist using technical personnel who have received proper training in aseptic technique.

Area

2.0 Pharmacists engaged in preparation of pre-filled insulin syringes should have a specific designated area for the orderly placement of equipment and materials used. The preparation area should be a separate and distinct area with limited access, secluded from general traffic, with reduced activity and staff interruptions to minimize air turbulence.

3.0 The area shall be maintained in a clean, sanitary condition and good state of repair to minimize the potential for contamination of the insulin and syringes or addition of any extraneous material. Counter tops should be cleaned with antibacterial soap, rinsed with clean water and dried and disinfected using 70% isopropyl alcohol. The antibacterial soap and the alcohol provide dual and complementary assurance that all bacteria and viruses are killed in order to provide a sterile work environment.

Policies and procedures

4.0 Policies and procedures should be developed in regards to the training of pharmacists and technical pharmacy personnel in aseptic technique, and procedures to minimize the potential for contamination and addition of extraneous material in the preparation of pre-filled syringes.

Preparation

5.0 Personnel preparing the syringes should remove wristwatches and jewellery and wash their hands and arms thoroughly with an antibacterial soap. Jewellery often has rough surfaces that may be susceptible to the collection of bacteria. These rough surfaces can be difficult to cleanse and disinfect.

6.0 Gloves should be worn and disinfected by wiping them with gauze soaked in 70% isopropyl alcohol. Gloved hands should be rubbed together until the alcohol evaporates and changed after each session or when their integrity has been compromised.

7.0 The insulin vial should be checked for particulate matter, cracks, leaks and expiry date. If the vial appears to be intact and free of particulate matter, swab the entire vial with 70% isopropyl alcohol and place it in the disinfected area on the counter.

8.0 The insulin syringes should be removed from their outer packaging and placed in the disinfected surface. **Do not remove the cap from the needle at this time.** Discard the outer packaging in an appropriate garbage container.

Procedure

9.0 Wipe the gloves again with gauze soaked in alcohol and rub the gloved hands together until the alcohol evaporates. Swab the rubber stopper in the insulin vial and again allow the alcohol to evaporate.

10.0 Keeping the needle capped, withdraw a volume of air from the insulin syringe, by pulling back the plunger, equivalent to the insulin solution to be withdrawn.. When pulling back on the plunger, your fingers should not come into contact with any part of the plunger except the flat lip at the end. **Do not touch the body of the plunger.**

11.0 The cap should then be removed from the needle and place on an alcohol swab in the disinfected area on the counter so it can be used to re-cap the needle. Alternately, place the cap between the fourth and fifth fingers of your non-dominant hand. By keeping the cap between the fourth and fifty fingers until the procedure is completed, you are protecting it from contamination until the needle is re-capped.

12.0 Holding the syringe like a pencil, place the needle on the disinfected rubber stopper. The needle should be placed with the tip up and at a 45-degree angle with the bevelled edge facing upward.

13.0 The needle should be inserted using a slight downward pressure to allow the tip and the heel of the bevel to penetrate at the same point. This will reduce coring of the rubber stopper. When the needle has penetrated the closure, quickly move the needle and syringe to the vertical position and completely puncture the stopper.

14.0 Invert the vial and syringe and gradually inject the air into the vial. The injected air will displace the solution in the vial so that it can be drawn up into the syringe. Be careful not to use too much pressure and avoid injecting air into the solution. This will help prevent foaming or bubbling.

15.0 If additional solution is needed, lower the needle tip into the solution and gradually pull the plunger out of the syringe, keeping the bevel below the level of the solution until you get the desired volume.

16.0 When the required amount of solution is in the syringe, push the needle into the vial so that the bevel of the needle is above the level of the remaining solution.

17.0 To remove air bubbles, while the needle is still in the vial, put the bevel of the needle above the level of the solution in the vial and draw air into the syringe. When the needle is not long enough for the bevel of the syringe to extend above the level of the solution placing the vial at an angle, the bevel of the syringe will usually be able to extend above the solution. Gently tap on the syringe barrel to free any air bubbles. Expel the air in the syringe back into the vial.

18.0 Leaving the needle in the vial, adjust the solution in the syringe to the desired volume, if required.

19.0 When the desired volume of insulin in the syringe is reached, return the vial to the upright position and pull the needle straight out. Re-cap the needle on the syringe and check the syringe for particulate matter, stopper cores etc.

20.0 Place the gloves and other waste into an appropriate garbage container. Pharmacist should be aware that insulins can be absorbed onto plastic surfaces and cleaning the counter area with soap and water and an appropriate disinfectant, so that it is ready for other dispensing activities, is recommended.

Labelling

21.0 Only after the pharmacist or technician feels confident of the syringe's integrity, should it be labelled. Each order for pre-filled syringes must be patient specific and each syringe leaving the pharmacy must be labelled. The minimum information that must appear on the syringe label is:

a) Patient's name,
b) Type of insulin
c) Number of units

22.0 Labelled syringes should be placed on the disinfected area of the counter and dispensed in a resealable plastic bag or larger container bearing a label with all the required information in accordance with Section 19 of the Regulations to the Pharmaceutical Act.

Expiry Date and Storage

23.0 Although insulin vials can be kept out of the refrigerator for 28 days, pre-filled syringes should be stored in the refrigerator because preservative concentration decreases more during storage at room temperature than when refrigerated. The "**Refrigerate"** auxiliary label place should be placed on the outer container as well as lot number and expiry date. Pre-filled syringes are stable for up to 30 days when refrigerated.

24.0 Patients should be counselled to roll the pre-drawn syringe between the hands before administration to warm the insulin to room temperature before injecting.

25.0 Pre-filled syringes should be stored vertically with the needle pointing up since insulin crystals settling out of suspension could settle towards the plunger and clog the needle. If syringes are stored horizontally the needle should not be below the syringe. This will ensure crystals settle towards the side of the syringe rather than toward the needle.

Mixing Insulins

26.0 Pre-filling syringes with insulin mixtures should be discouraged due to the potential variability in response depending on the time after admixture the injection is given, and the availability of stable insulin combinations on the market.

27.0 Mixing two insulins in the same syringe, could potentially convert short-acting insulin (regular/clear) into intermediate or longer acting insulin (lente, NPH/suspensions), depending on which insulins are being mixed. Mixing these two types of insulin is not recommended except for patients already adequately controlled on such a mixture. Upon mixing, Zn^{2+} present in the lente insulins will bind with the short-acting insulin and delay its onset of action. The degree and rate of binding varies with the ratio and species of the two insulins and binding equilibrium may not be reached for 24hrs. The result would be inconsistent readings, making good glycemic control difficult. If using this mixture is unavoidable patient should standardize the interval between mixing and injections.

28.0 If glycemic control is still compromised or difficult to obtain with this combination, a mixture of regular and NPH may be substituted for the regular and lente combination after consultation with the prescriber. For regular and ultralente combinations a substitution to regular and NPH could be made with necessary changes in the insulin regimen due to differences in the time-action profile.

29.0 Insulins mixtures such as NPH and Lente must be mixed by rotating the vial between the hands prior to withdrawing the insulin dose. It stands to reason, if the patient is using pre-filled syringes containing an insulin suspension (NPH, lente), the insulin preparation must be adequately re-suspended by shaking or rolling the syringe prior to injection. Proper mixing of the insulin before withdrawal and injection would result in fewer hypoglycemic episodes.

30.0 When mixing short-acting (regular/clear) insulin with intermediate-acting insulin (suspensions), draw regular insulin into the syringe first. If the intermediate acting insulin is drawn first, the regular insulin may become cloudy as it is added to the syringe. In addition, the action of the regular insulin may be altered. As a result, patient would not know if the regular insulin was cloudy from the introduction of the insulin suspension, or if a problem has developed with the regular insulin.

31.0 Patient using pre-filled syringes with mixtures of Iletin (beef/pork) or Iletin II (pure pork) regular insulin and Lente, the most consistent effect will be obtained if only syringes that have been filled at least 24 hours previously are used for injection. For example, in the case of a home care nurse who visits once a week. On the day of the visit, the patient should use a syringe that has been filled on the previous visit of the nurse, not a freshly mixed syringe.

32.0 Phosphate-buffered insulins (NPH) should not be mixed with lente insulins. Zinc phosphate may precipitate, and the longer-acting insulin will convert to short-acting insulin to an unpredictable extent.

33.0 Insulin formulations may change; therefore, the manufacturer should be consulted in cases where its recommendations appear to conflict with these guidelines.

Monitoring

34.0 The effects of pre-filling insulin syringes on glycemic control should be assessed regularly. When premixing is required, consistency of technique and careful blood glucose monitoring are especially important.

35.0 As part of providing this service, pharmacists must discuss infections at the injection site with the patient and monitor the incidence of infection as part of a quality assurance program.

* In compiling this document, standards and guidelines developed by various health care organizations and groups have been utilized. In many cases the language and material is directly transposed from the original documents.

Mar/01