

Safety Alert

Risk of Cross-Contamination with Insulin Preparations

Issue

Insulin pens (both disposable prefilled pens and re-useable pens) and insulin cartridges are for Single Patient Use only. During injection, blood and biological matter can regurgitate into the insulin cartridge. Using a cartridge or pen already used for another patient exposes the second patient to any blood-borne pathogens the initial patient may be infected with, e.g. hepatitis B virus (HBV), hepatitis C virus (HCV), and/or the human immunodeficiency virus (HIV).^{1,2} In order to prevent vial contamination and patient exposure which may result from unsafe injection practices, multi-dose insulin vials should also be dedicated to Single Patient Use only.^{3,4}

Evidence of Harm

A study detected squamous and / or epithelial cells in needles and cartridges following an injection from an insulin pen in almost two-thirds of cases.⁵ Another study detected regurgitated blood in 4.1% of cartridges.⁶ There were similar findings in a further analysis of 125 pens where 5.6% tested positive for a variety of cell types or haemoglobin.⁷

In a survey of 5,446 healthcare professionals, 51 professionals reported reusing a syringe to obtain an additional dose from a multi-dose vial and then leaving the vial for use on another patient.⁴ According to the WHO a 'silent epidemic' exists in relation to unsafe injection practice generally and it estimates that such unsafe practices account for a large proportion of new viral infections occurring worldwide annually (42% of HCV infections, 33% of HBV infections and 2% of HIV infections).⁸

How to Reduce the Risks

Safe Administration

- Insulin pens should never be used for more than one person, even when the needle is changed⁹, 'ONE PERSON, ONE PEN'. Changing the cartridge in the pen does not make the device safe for multi-patient use.¹⁰
- Eject the disposable needle from the insulin pen into a sharps bin immediately after use³, 'ONE NEEDLE, ONE TIME'
- Designate multi-dose vials for Single Patient Use only.^{3,4} For standard strength insulin (100 units / ml) use an insulin syringe to withdraw insulin from a multi-dose vial.
- Educate staff on the use of different pen types to reduce the risk that they may resort to withdrawing insulin from the cartridge using a needle and syringe. This practice can result in large air bubbles left behind in the cartridge and in dosing errors or subcutaneous injection of air.¹¹

Supply, Storage and Labelling Issues

- Supply insulin preparations, on a named patient basis where possible, directly from the pharmacy department. Otherwise supply all preparations flag-labelled with space for patient name and unique patient identifier(s) prominently stating 'For single patient use only'.
- Flag-label the body of the pen rather than the cap as caps can be separated from the pen body.¹²
- Restrict stock supplies outside the pharmacy to a limited number of ward areas.
- On ward areas, store in-use insulin preparations at room temperature, ideally in a secure repository at the patient bedside or, if unavailable, in a patient-specific location on the drug trolley. Backup supplies should be refrigerated before first use.
- Keep a stock of needles designed for use with insulin pens on all areas where they may be required.
- If a pen is identified as having been used in more than one patient, promptly notify those exposed and offer follow-up including blood-borne pathogen testing.⁹

Governance

- Ensure awareness/education of clinical staff in relation to the correct use and cross-contamination risks with insulin pens, pen devices and vials.¹³
- Ensure staff have access to technical information about how to administer insulin pens, pen devices and vials.
- Ensure a policy / procedure / guideline is in place regarding the correct use of insulin preparations.¹³ This should cover the following points: labelling, supply, storage, transfer, disposal; supply, use, disposal of needles; management of patients' own pens and pens for patients in isolation; processes for audit and feedback regarding the practices involving insulin preparations; and management of a possible or suspected cross-contamination event.

1. Cross Contamination with Insulin Pens, ISMP Medication Safety Alert Mar 27, 2008.

2. IMB Safety Notice: SN2010 (16), Dec 21, 2010.

3. CDC Injection Safety, Frequently Asked Questions regarding Safe Practices for Medical Injections, <http://www.webcitation.org/6LJxEOTUJ>

4. Preventing infection from the misuse of vials. Sentinel Event Alert, Issue 52, June 16, 2014.

5. Le Floch JP, et al. Biological material in needles and cartridges after insulin injection with a pen in diabetic patients. Diabetes Care 1998; 21:1502-04

6. Sonoki K, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. Diabetes Care 2001; 24:603-04

7. Herdman M, et al. Biological contamination of insulin pens in a hospital setting. AJHP 2013; 70 (14):1244-8

8. Safe Injection Global Network, Advocacy Booklet, WHO 2011.

9. CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person <http://www.webcitation.org/6L658yuQJ>

10. CDC - FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration <http://www.webcitation.org/6LJxEOTUJ>

11. Considering Insulin Pens for Routine Hospital use? Consider this. ISMP Medication Safety Alert May 8, 2008.

12. ISMP Medication Safety Alert, Volume 13, Issue 22, Nov 6, 2008.

13. HSE Briefing Note; Use of Insulin Pens in Clinical Practice. One patient: One pen. Dec 23, 2010.