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Insulin pens; cross-contamination risks

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Insulin Pen Devices

2 basic types: reusable and disposable

Advantages

- fast, simple, accurate administration
- convenient and discrete

Designed for

- Ambulatory care
- Self-administration
- Single person use

However also widely used in institutions by healthcare personnel staff to administer insulin to patients

Cross-Contamination Concern

- Due to potential backflow of a patient's blood into the pen cartridge after injection, using a pen on multiple patients may expose patients to blood-borne pathogens, e.g. HBV, HCV, HIV, if the pen had previously been used on an infected patient.

Insulin Pens

(including the individual components of the cartridge or pen shell)

must never be shared between patients even if new needles are used

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Evidence of Harm

- No documented cases of actual transmission of blood borne pathogens related to the use of insulin pens on multiple patients
- According to the World Health Organization there exists a ‘silent epidemic’ in relation to unsafe injection practice
- Unsafe injection practices account for a large proportion of new viral infections occurring worldwide annually

Evolution of Awareness 1997–2008

1997: Pen devices launched. SPC warning re. sharing.

1998: Biological material in cartridges (Le Floch *et al*)

2001: Regurgitation of blood into cartridges (Sanoki *et al*)

2008:

- March, May, November: ISMP Alerts
  - risk of regurgitation of blood into cartridges
  - improperly using them on multiple patients
  - strategies for labelling of pens
- May: Nassau Medical Centre: 840 patients exposed
- August: FDA alert

Evolution of Awareness 2009–2011

2009

- February:
  - Press release from William Beaumont Medical Army Centre re. pen sharing at two army hospitals
  - ISMP Alert - advises education and continuous monitoring
- March: FDA Alert - warning that pens & cartridges must never be shared

2010

- Irish hospitals inform HIQA, HSE, IMB of concerns
- December 21st: IMB alert 'Safe use of insulin pens'
- December 23rd: HSE briefing note

2011

- March: CDC – 'Guidelines on Infection Prevention during Blood Glucose Monitoring and Insulin Administration'

Evolution of Awareness 2011–2013

2011 August: Dean Clinic, Wisconsin

2012 January: CDC reminder on safe use

August: Hakre *et al.* publish investigation at military hospital

2013

- January:
  - Olean General Hospital, NY
  - ISMP Alert: highlighting practice in Olean General.
- February: ISMP advises hospitals consider transitioning from insulin pens
- March: Medical Center in Salisbury, NC
- May: Report: 'Inappropriate Use of Insulin Pens VA Western New York Healthcare System Buffalo, New York'
- July: Herdman *et al:* 7 of 125 inpatient pens examined tested positive for Hb or cells

Mail Online

More than 700 vets possibly exposed to HIV, hepatitis B and C when veterans hospital mistakenly re-uses insulin pens to deliver medication

- **The hospital only re-used the pens - and not the needles**
- **'I started crying,' says the wife of a Marine Corps. veteran**
- **Doctor says there's 'a very, very low chance,' of transmission for diabetic patients**
- **Of the 716 patients possibly exposed, 570 are still alive**

By DAILY MAIL REPORTER

PUBLISHED: 06:50 GMT, 14 January 2013 | **UPDATED:** 06:50 GMT, 14 January 2013

More than 700 patients at the Buffalo Veterans Administration Center may have been exposed to HIV, hepatitis B or hepatitis C because of accidental reuse of insulin pens, according to a hospital statement and published reports.

Authorities told **The Buffalo News** there is a 'very small risk' for the diabetic patients who may have

CDC & FDA Recommendations I

- Insulin pens should **never** be used for more than one person, even when the needle is changed. Changing only the needle and reusing the cartridge of an insulin pen is a form of syringe re-use.
- Changing the cartridge does not protect against contamination and does not make these devices safe for multi-patient use.
- Medication must never be withdrawn from a cartridge using a syringe and needle.
- A new needle should be attached to the insulin pen before each new injection.

CDC & FDA Recommendations II

- The disposable needle should be ejected from the insulin pen and properly discarded after each injection.
- Pens should be clearly labelled with multiple patient identifiers.
- If re-use is identified, exposed persons should be promptly notified and offered appropriate follow-up including blood-borne pathogen testing.
- Facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.

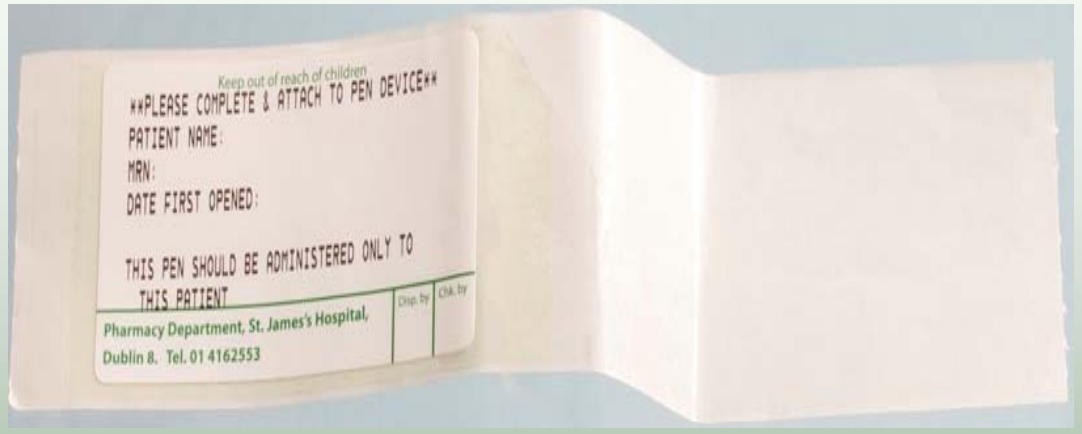
Design Concerns

- No seal on pens to indicate pen has been opened.
- No warning on each individual pens advising that the pen is for ‘individual or single patient use only’

Manufacturers of insulin pens and IMB advised of design issues in 2011 and 2012 by 2 Irish hospitals

Design Work-Arounds: Labelling

Flag Labels



- Flag-label with:
  - patient name
  - unique patient identifier(s)
  - prominent warning ‘For single patient use only’.
- Label the pen body not the cap

Design Work-Arounds: Seals

Concerns with seals applied locally:

- Not fool-proof
- Not validated
- Highly-labour intensive

Insulin: vials or pens ?

Pens

- Lower risk of dosage errors ✦
- Greater risk of cross-contamination
- Greater cost
- Reduced time to prepare dose ✦
- Available for all insulin products ✦
- Greater opportunities for patient education in relation to pen device ✦
- Pen device pre-labelled with the product name & strength ✦

Vials

- Higher risk of dosage errors
- Lower risk of cross-contamination ✦
- Lower cost (unit cost, waste) ✦
- Increased time to prepare dose
- Not available for all insulin products
- Fewer opportunities for patient education in relation to pen device
- No manufacturer labelling: risk of unlabeled syringes

Ensuring safe practice with insulin pens I

- Multidisciplinary risk analysis of local situation
- Document decision-making process in relation to use of vials and pen devices
- Devise implementation plan for rolling out new medical devices
- Reduce/streamline stock of insulin pens at ward level
- Keep stock of needles for pens on all ward areas
- Explore bedside storage options
- Education, training and sign-off procedure, & ongoing support strategy

Ensuring safe practice with insulin pens II

- Develop protocol(s) covering:
  - labelling, supply, storage, transfer, disposal of pens and needles
  - management of patients own pens/pens for patients in isolation
  - management of cross-contamination event
  - how to apply flag labels to pens
  - technical information about how to give the injection
  - audit of practice
  - governance

Conclusion

- Inappropriately using single-patient use insulin pens on multiple patients may potentially expose patients to blood borne pathogens
- This risk has been documented in medical literature since at least 1998, and private and Government patient safety organizations have published alerts on the risk since at least 2008
- It is advisable to undertake a local risk assessment in relation to the risks associated with insulin administration
- If using/planning to use insulin pens implement all necessary safety measures

References

- Note: all internet links were accessed in October 2013.
- All ISMP alerts available at: http://ismp.org/newsletters/acutecare/archives.asp

1. Safe Injection Global Network. Advocacy Booklet. WHO 2011
2. Le Floch JP et al. Biologic material in needles and cartridges after insulin injection with a pen in diabetic patients. Diabetes Care 1998;21(9):1502-1504.
3. Sonoki K, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors.Diabetes Care 2001; 24:603-604. Available at:http://care.diabetesjournals.org/content/24/3/603.full
4. ISMP Medication Safety Alert!, 'Cross Contamination with Insulin Pens'. March 27, 2008.
5. ISMP Medication Safety Alert!, 'Considering Insulin Pens for Routine Hospital Use? Consider this...' May 8, 2008.
6. FDA Patient Safety News. Show # 78, Preventing Medical Errors 'Potential Problems with Insulin Pens in Hospitals'. August 2008.
7. ISMP Medication Safety Alert!, 'Flag insulin pen labels' November 6, 2008
8. Nassau University Medical Center Press Release, May 7, 2008. Available at: http://www.nuhealth.net/pressreleasedetail.asp?ID=340.
9. Nassau Medical Center Extends Warning Over Insulin Pen', Newsday, May 17, 2008. Available at: http://diabeteshealth.com/read/2008/05/22/5765/nassau-medical-center-extends-warning-over-insulin-pens/
10. ISMP Medication Safety Alert!, 'Reuse of Insulin Pen for Multiple Patients Risks Transmission of Blood borne Disease', February 12, 2009.
11. FDA Alert, Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens, March 19, 2009. Available at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm.
12. CDC Injection Safety. FAQs. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. March 2, 2011. Available at: http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

References II

- Note: all internet links were accessed in October 2013.
- All ISMP alerts available at: http://ismp.org/newsletters/acutecare/archives.asp

13. Dean Clinic Patient Safety Notification, August 29, 2011. Available at: http://www.deancare.com/about-dean/news/2011/important-patient-safety-notification/.
14. CDC Clinical Reminder. Insulin Pens Must Never Be Used for More Than One Person. Available at: http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html
15. Hakre S, Upshaw-Combs DR, Sanders-Buell EE, Scoville SL, et al. "An Investigation of Bloodborne Pathogen Transmission Due to Multipatient Sharing on Insulin Pens," *Military Medicine, 2012* 177:8, 930–938.
16. Olean General Hospital Press Release, January 24, 2013. Available at: https://www.ogh.org/programs-and-services/diabetes/Press%20Release-OGH%20Alerts%20Patients%20to%20Possible%20Insulin%20Pen%20Re-use.pdf
17. ISMP Medication Safety Alert!, 'Insulin pens again used on multiple patients'. January 24th 2013.
18. ISMP Medication Safety Alert!, Ongoing concern about insulin pen reuse shows hospitals need to consider transitioning away from the use of insulin pens, February 7, 2013.
19. Statement. W. G. (Bill) Hefner VA Medical Center - Salisbury, NC. March 7th, 2013. Available at: http://www.salisbury.va.gov/pressreleases/Fact_Sheet_for_Insulin_Pens.asp
20. Inappropriate Use of Insulin Pens VA Western New York Healthcare System Buffalo, New York. Report No. 13-01320-200. May 9, 2013. Available at: http://www.va.gov/oig/pubs/VAOIG-13-01320-200.pdf
21. Herdman M, Larck C, Schliesser S, Jelic T. Biological contamination of insulin pens in a hospital setting. AJHP 2013;70(14):1244-1248

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Insulin Pen Contamination Cases Published

Date Discovered/ Communicated	Location	No. of Patients Affected
May 2008	Nassau Medical Centre, New York	840
Feb 2009	William Beaumont Medical Army Centre, Texas and Louisiana	2000 ≤ 15
Aug 2011	Dean Clinic, Wisconsin	> 2300
Jan 2013	Olean General Hospital, New York	1915
March 2013	Salisbury Medical Centre, North Carolina	205
May 2013	VA Western New York Healthcare System Buffalo, New York	716

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