



# Safe Delivery of Insulin: Summary Report and Recommendations

# Roundtable Meeting held February 27, 2014, Toronto, ON

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CSHP – Ontario Branch ISMP Canada

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**The Canadian Society of Hospital Pharmacists Ontario Branch (CSHP Ontario Branch)** is a provincial branch of CSHP. CSHP is the national voluntary organization of pharmacists committed to patient care through the advancement in safe, effective medication use in hospitals and other collaborative healthcare settings.

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# Safe Delivery of Insulin Roundtable: Summary Report and Recommendations

# 1. Background

Insulin pens, originally intended for use in the home environment by patients or their caregivers, are increasingly being used in hospital settings. Some hospitals have replaced the traditional multi-dose vials and syringes with insulin pens for subcutaneous administration of insulin. The impetus behind the transition to pens was a belief that insulin pens were inherently safer than multi-dose vials (i.e., the insulin pens would prevent dosing errors), were a more convenient method to deliver insulin and would offer a cost savings to hospitals (1).

However, it has come to light that insulin pens, when used incorrectly, can pose a serious patient safety risk in the hospital setting. There have been reports in both Canada and the United States of cross-patient use of insulin pens, i.e., the same insulin pen was used on multiple patients (2-5). There is a misconception by some healthcare providers administering insulin that the insulin cartridge remains sterile after injection. In fact, during the injection process, a minute amount of biological fluid from the patient may backfill into the cartridge within the pen (6,7). As a result the cartridge is no longer sterile and should not be used on any other patient due to the potential transmission of blood borne pathogens such as human immunodeficiency virus (HIV), and hepatitis B and C. The Centre for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in the US have both issued statements advising against sharing insulin pens amongst patients and have provided resources outlining the risks associated with this unapproved practice (8-10).

The Institute for Safe Medication Practices (ISMP), in the US issued a statement encouraging hospitals to reconsider use of insulin pens for routine administration of insulin to inpatients because of ongoing concerns about the identified risks (4). ISMP issued this statement after it was discovered that several hospitals in the US had inadvertently placed hundreds of patients at risk due to this unsafe practice and they felt education and monitoring alone were insufficient tactics to mitigate this risk.

Since the release of the ISMP alert in the US, ISMP Canada has received many requests from hospitals in Canada for guidance in this area. In response, ISMP Canada released a bulletin that reiterated the risks associated with insulin pens, confirmed the risk is relevant in Canada as well and provided recommendations on the safe management of insulin pens (5). In addition, with support from the Ontario Ministry of Health and Long-Term Care (MOHLTC), ISMP Canada developed an e-learning module for hospitals to use to educate all staff involved with subcutaneous insulin administration on best practices and potential risks associated with insulin pens.

The need for a stakeholder forum to further address infection control issues was identified. It was also identified that medication safety issues needed to be addressed to fully appreciate safety concerns with subcutaneous insulin delivery in hospitals; as insulin has been repeatedly associated with medication incidents resulting in harm in hospitals at all stages of the medication use cycle (11, 12). In response the Canadian Society of Hospital Pharmacists Ontario Branch and ISMP Canada hosted a roundtable discussion in Toronto on February 27<sup>th</sup>, 2014 to further explore safety considerations with both insulin pens and multi-dose vials and syringes and to provide strategies to promote the safe use of subcutaneous insulin administration in hospital settings.

# 2. Purpose

To convene a roundtable discussion with expert representatives from internal medicine, infectious diseases, nursing and pharmacy to provide guidance to practitioners in hospitals with the goals of:

- Identifying medication safety considerations for insulin pens and multi-dose vials and syringes;
- Assessing infection control risks associated with insulin pens and multi-dose vials and syringes; and
- Proposing recommended strategies to promote safe administration of insulin in acute care settings

# 3. Approach

### **Environmental scan**

A review of the literature was completed to identify published recommendations on best practices and infection control and medication safety concerns associated with subcutaneous insulin administration. An informal scan of Ontario hospitals was completed to determine the current level of use of insulin pens in Ontario hospitals. Hospitals reporting use of insulin pens were asked to describe current infection control practices for the devices.

### **Participant selection**

Participants were selected who had expertise in medication safety, infection control, medication dispensing processes and/or administration of subcutaneous insulin in inpatient settings. Participants were selected from hospitals that primarily use multi-dose vials and syringes for insulin delivery and from those that primarily use insulin pens.

### **Roundtable discussion**

A three hour meeting was held on February 27<sup>th</sup>, 2014 in Toronto, Ontario.

To ensure there was a common understanding of the issues to be discussed, participants were provided with a review of the purpose of the roundtable discussion and a brief overview of medication safety and infection control considerations with insulin pens and vials and syringes. (Refer to Appendix 1).

The participants were divided into 4 groups to facilitate detailed discussions. An attempt was made to have all disciplines represented in each of the groups and to avoid having people from the same organization in the same group. The groups were provided with three worksheets to help facilitate their discussions (Refer to Appendix 2). The first worksheet prompted the groups to assess the level of risk (minor, moderate, or high) for a number of issues associated with both insulin pens and multi-dose vials and syringes that were pre-identified through the environmental scan. The second worksheet prompted the groups to discuss potential strategies to mitigate these risks, and to consider if these strategies were feasible to implement in most acute care settings, beneficial in reducing potential harm or risk from either multi-dose vials or insulin pens and impactful in positively influencing patient outcomes. The third worksheet asked the groups to choose one solution that they felt most strongly should be implemented and identify the key characteristics

of that solution that led the group to select it. The participants reconvened as a larger group to review the findings from each group and other relevant issues emerging from the discussion.

# 4. Discussion Summary

### **Small Group Discussions**

### Potential Risks Associated with Insulin Multi-Dose Vials and Insulin Pens

The likelihood of cross-patient use of multi-dose insulin vials compared to insulin pens was discussed. The likelihood of cross-patient use was thought to be higher with multi-dose vials than with insulin pens. Although not considered best practice, it is common for hospitals to use multi-dose vials of insulin for more than one patient and to have multi-dose vials of insulin available on nursing units as ward stock. Some hospital pharmacies do dispense multi-dose insulin vials with patient-specific labels; however because of the familiar practice of using multi-dose vials for more than one patient there is concern that the practice of 'borrowing' between patient supplies may still exist.

Although most participants felt that insulin pens carried a moderate degree of risk of cross-patient use, it was thought by some that this risk could be minimized with appropriate education and appropriately placed patient specific labels. A few participants were of the opinion that education and labeling alone wouldn't overcome the false sense of security that might be provided by changing the needle on the pen between uses and that some individuals might interpret this as maintaining sterility of the cartridge inside in the pen. Concern was also expressed that it would be difficult to break the habit of using the same insulin product for multiple patients.

In discussions on the level of risk to the patient if cross-patient use occurred, it was felt that the infection control risk of multi-dose vials is minor, provided that a clean needle and syringe is used each time a needle is inserted into the vial. If a used needle is inserted into the vial or if a used syringe is used with a new needle then the risk to the patient substantially increases. However insulin administration rarely requires more than one syringe draw and it is ingrained into practice to immediately dispose of a syringe and needle after medication administration.

It was noted that if multi-dose vials are not used exclusively in medication rooms, but taken from one patient room to another, then other infection control concerns arise (i.e., spread of disease through inanimate objects). These same concerns are also applicable to insulin pens. For this reason it was recommended to dispose of a refillable insulin pens when empty and have pharmacy dispense a new pen and cartridge. Insulin pens in general were thought to have a higher level of infection control risk associated with them since the insulin cartridge inside the insulin pen is considered contaminated immediately after the first administration to the patient.

A medication safety concern that was discussed was the potential for inadvertent insulin administration. Multi-dose insulin vials and insulin pens that do not have patient-specific labels were considered as factors that could contribute to the wrong patient receiving a dose of insulin. The process of drawing up insulin in an unlabeled syringe at a location remote to the bedside was considered by the participants to carry the highest risk due to the lack of patient and medication specific information on the syringe.

Dosing errors were thought to be more likely when using multi-dose vials and syringes. Dose miscalculations, choosing the wrong syringe and difficulty interpreting the markings on syringes were all brought up as issues that could lead to dosing errors. Conversely it was felt that the dialing feature of the pen allows for more accuracy with determining the appropriate dose to be administered. For both delivery methods, the use of safety-engineered needles decreases the potential for needle-stick injuries. The participants recognized that despite attempts by manufacturers to make their products more distinct the look-alike nature of all insulin products continues to introduce risk during product selection. For example, it was noted that the colour code identifiers used on multi-dose vials are lost when the cap is removed from the vial. This risk was thought to be more apparent during selection of multi-dose insulin vials and refillable insulin cartridges that are available as ward stock, especially when the products are removed from the outer packaging. It was suggested that these products should be dispensed from pharmacy with patient-specific labels to lessen the risk. In addition, cartridges should be dispensed already inserted into the pen for refillable pens. It was also thought that pre-filled insulin pens may have an advantage because the cartridge is already inserted in insulin pens, removing one error-prone step of product selection. In addition, pre-filled insulin pens have product labelling on the outer pen, not just on the cartridge as with refillable pens.

The ease with which patients are able to transition in and out of hospital was also considered against which insulin delivery method is used in hospitals. The participants were in agreement that smoother transitions occur for patients who are continued on the same insulin delivery method in hospital as they use in their home environments. During the patient's hospital stay, teaching or reinforcement of correct administration technique can occur at each dose administration time. The participants that also work in outpatient settings felt that most patients use insulin pens at home.

Discussion also occurred on the use of insulin cartridges as multi-dose insulin vials in hospitals. Cartridges were not designed with this intent in mind. Inserting a needle into the cartridge to withdraw insulin has resulted in the cartridge breaking and/or the stopper popping off. Although this practice is not recommended, hospitals that do not stock insulin pens have adopted this practice for particular insulins that are not available in a multi-dose vial format. The participants agreed that this practice was unsafe and should be abandoned.

### Potential Risk Mitigation Strategies

There was consensus that dispensing insulin pens or multi-dose vials with pharmacy generated patientspecific labels is the most appropriate labeling strategy to mitigate risk. For insulin pens, the label should be placed on the barrel of the pen and not on the cap of the pen as the pen caps can easily be inadvertently placed on the wrong insulin pen. The participants thought that patient-specific labels on both insulin pens and multi-dose vials would help to reinforce the importance of using a product for single patient use only. Labeling should be the responsibility of pharmacy staff and the increase in workload for pharmacy would be outweighed by the risk of having nurses rely on memory to generate and place patient-specific labels on the products. There was also consensus that having pharmacy dispense patient-specific doses of insulin in syringes while beneficial is not a feasible strategy due to the volume of insulin doses administered coupled with the frequency with which insulin doses are adjusted.

The value of mandatory completion of an independent double check before each dose of subcutaneous insulin is administered was discussed. There was agreement that when all the steps of an independent double check are performed correctly it has the potential to be an effective risk-reduction strategy. However, due to the volume of subcutaneous doses of insulin administered on a typical nursing unit,

requiring an independent double check for all subcutaneous insulin doses may not be feasible. Concerns were expressed that in busy and stressful environments 'true' independent double checks were not occurring and that shortcuts were being taken. A number of participants stated that in their hospitals independent double checks were reserved for insulin infusions and not encouraged for routine subcutaneous insulin doses.

Staff education on best practices and potential risks associated with subcutaneous insulin administration as a risk mitigation strategy was considered. There was agreement that while education is an essential component of any risk mitigation strategy, it cannot be the sole strategy used to reduce risk. Education is more effective when bundled with high-leverage system strategies (e.g., automation or forcing functions) that reduce reliance on memory and vigilance for an individual (Refer to Appendix 3). Concerns were expressed that ensuring all staff receive initial and ongoing repeated education can be challenging due to high staff turnover, use of casual staff, competing educational priorities and high workloads.

Barcoding was identified by the groups to be a high-leverage risk mitigation strategy that has the potential to have positive impact on medication systems. However, most participants expressed concern that barcode implementation is still many years away from implementation in their hospitals and reliance on this risk mitigation strategy is not practical at this point. It was also recognized that while barcoding will assist with selecting the correct insulin for the correct patient, the potential for dosing errors will still exist.

All of the groups selected insulin pens as the solution they felt most strongly should be implemented in their hospitals. The participants stated that they felt with correct placement of appropriate pharmacy generated patient-specific labels and ongoing staff education on the safe use of insulin pens, the risks associated with insulin pens could be controlled. The potential decrease in dosing errors with insulin pens and the opportunity for smooth patient transitions from hospital to home also influenced selection of the insulin pen as the more advantageous choice.

### Large Group Discussion

### Cross-patient Use

The issue of cross-patient use and strategies to mitigate this risk were a large focus of this phase of the roundtable discussion. The conversation centered on the cultural shift that would be necessary to have those administering subcutaneous insulin change the misperception and widely accepted practice that multi-dose vials are appropriate and safe to be used on multiple patients. In addition to the risk of transmission of blood-borne pathogens that can occur if a previously used needle is inserted into a multidose vial, there are other infection control concerns as well. If proper aseptic technique is not followed when preparing and administering insulin injections (e.g., gloves are not changed/ hands are not washed between patients, multi-dose vials are not exclusively used in designated clean medication areas) there is a potential for transmission of other bacteria and viruses. Some participants felt very strongly that it was critical to first address the inappropriate use of multi-dose vials for multiple patients before switching to the routine use of insulin pens in acute care settings. An initial change to pharmacy generated patient-specific labels for multi-dose vials, where this is not already in place, would help to combat the general acceptance of the use of multi-dose insulin products for multiple patients. This would reinforce the message of 'one insulin product for one patient' before switching over to insulin pens. Concern was also expressed that the inappropriate practice of using insulin cartridges as multi-dose vials may contribute to the misperception that cartridges within pens can be used on multiple patients.

### Potential Risk Mitigation Strategies

In conjunction with this conversation there was discussion on effective risk mitigation strategies. Everyone was in agreement that seemingly most hospitals in Ontario and beyond will be using insulin pens with increasing frequency, whether multi-dose insulin vials are fully replaced or not, and that effective risk mitigation strategies beyond ongoing education are needed. Requiring pharmacy generated patient-specific labels for insulin pens was a strategy everyone agreed upon and suggestions were put forth on how best to capitalize on this strategy. A strategy implemented by one hospital included placing patient specific labels on the barrel of the pen with patient information clearly typed on one side of the label. On the other side of the label was a reminder that insulin pens should not be used for more than one patient and cross-contamination will occur even if the needle is changed.

Several participants who had been involved with insulin pen implementations in their hospitals provided insights on auxiliary processes that were put in place to support pharmacy generated patient-specific labels. Insulin pens were stocked in the night cupboard to ensure availability when pharmacies were closed, however it became apparent that processes needed to be in place to ensure nurses applied patient-specific labels to the barrel of the pen on removal from the night cupboard. One site applied blank patient-specific labels on insulin pens that were stocked in night cupboards for nurses to fill out to assist with this. It was suggested that audits of this process should be done as insulin pens were discovered in medication rooms with blank labels. One participant suggested placing tamper-proof seals on the pens. If an insulin pen is found with the seal broken and the patient-specific label has not been filled out, the pen should be disposed of immediately. In addition, proximity of the night cupboard to the nursing unit requiring the insulin pen was noted to be a factor in the potential for borrowing from another patient's medication supply. The practice of borrowing, when applied to insulin pens, has significantly more risk associated with it then with other types of medications. This problem was overcome at one hospital by employing a porter to access the night cupboard on the nurses' behalf.

Another potential risk mitigation strategy suggested was targeted at insulin pen manufacturers and included supplying insulin in single-dose pens in standard dosing sizes, e.g., 10 units, 50 units, 100 units. It was suggested that the pens could be configured in such a way that after the first depression the pen would lock, rendering it incapable of delivering another dose. For example, if a dose of 6 units was required then a 10 unit size pen would be selected. A dose of 6 units would be dialed and administered. The pen with the remaining 4 units of insulin would be disposed. It was thought this could ensure that only one pen could be used on one patient.

### Environmental concerns

Environmental concerns were also brought forth as a factor that encourages some healthcare providers to re-use insulin pens. Uneasiness with 'wasting' insulin pens that had still had insulin remaining in the pen was cited as the reason. Participants who had previous experience with this concern suggested addressing it early on in the training phase by putting into context the environmental concerns versus the concerns with exposure to HIV, hepatitis B or C. In an effort to dispel increased environmental concerns with insulin pens at one hospital a visual representation of 25 doses of insulin using pens and needles was shown as compared to 25 doses of insulin using syringes a vial, (Refer to Appendix 4).

### Audits

Audits were used by one hospital to determine adherence with best practice techniques for insulin administration and was used as a method to identify and mitigate risk at one hospital. The hospital trained pharmacy students on best practices and had them observe insulin administration by nurses at key dosing times. Any deviations from best practice were addressed. There was agreement that regular auditing should occur frequently during the early stages of insulin pen implementation and then at regular intervals on an ongoing basis. Discussion also occurred about the use of measures such as the number of hypoglycemia incidents or the number of medication incident reports generated and if these would be an accurate reflection of a successful implementation of a new insulin delivery method. The general trend of underreporting of medication incidents, the number of possible confounding factors that can contribute to a hypoglycemic event and the notion that a person cannot report an error that they are unaware they are making were deemed to make these markers unreliable measures.

# 5. Recommendations

The roundtable discussion generated the following specific recommendations:

Multi-dose vials:

• Dispense multi-dose vials of insulin with pharmacy generated patient-specific labels, for single patient use only.

Insulin pens:

- Dispense insulin pens with cartridges in place with pharmacy generated patient-specific labels, for single patient use only.
- Place patient-specific labels only on the barrel of the insulin pen; never on the cap.
- Do not replace cartridges in refillable insulin pens in hospital; dispose of the pen when the cartridge is empty.
- Use insulin cartridges only with an insulin pen. Do not withdraw insulin from cartridges with a needle and syringe.
- Educate all healthcare providers who are expected to use insulin pens on best practice techniques and potential risks associated with insulin pens prior to insulin pen implementation, at orientation for new staff and repeat this education on a regular basis.

Multi-dose vials and insulin pens:

- Perform regular audits to assess compliance with best practice administration techniques and appropriate labeling practices for both insulin pens and multi-dose vials.
- Develop a long-term medication safety plan that incorporates high leverage risk reduction strategies to ensure subcutaneous insulin products are not used on multiple patients, e.g., barcoding technology.

- Consider conducting a Failure Mode Effects Analysis (FMEA) on insulin administration processes for both multi-dose vials and syringes and insulin pens.
- Encourage the reporting of medication incidents to identify ongoing system issues related to the administration of insulin.

# 6. Conclusion

This roundtable discussion provided opportunity for a practitioner group with expertise in medical management of insulin dependent diabetes, medication safety, infection control, medication dispensing processes and administration of subcutaneous insulin in inpatient settings to come together to identify medication safety considerations for insulin pens, vials and pre-filled syringes, assess the relative infection control risks associated with the various delivery options and propose recommended strategies to promote the safe administration of insulin in hospital settings. The recommendations generated are anticipated to provide needed guidance for hospitals. The dissemination plan for the recommendations includes webposting of this report, development of an ISMP Canada Safety Bulletin as well as educational presentations to practitioners.

ISMP Canada is not advocating for use of one insulin delivery method over the other, but advocating that hospitals determine which method offers the least amount of risk and best suits the culture of their unique settings. Utmost attention should be applied to implementing recommended safety strategies with the selected subcutaneous insulin delivery method.

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# Appendix One: Presentation Delivered at Roundtable Meeting













Possible HIV	exposure at Buffalo VA	hospital
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### Other Infection Risks for Diabetic Patients - CDC

- Using finger stick devices for more than one patient
- Using blood glucose meter for more than one person without cleaning and disinfecting between uses
- Failing change gloves and perform hand hygiene between finger stick procedures

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# Appendix Two: Worksheets for Small Group Discussions

Issue	Vials (minor / moderate / high)	Pens (minor / moderate / high)
Likelihood of cross-patient use		
Risk when cross-patient use occurs		
Dosing errors		
Unlabeled syringes / pens		
Look-alike products		
Transition points / continuity of care		
Withdrawing from 3 mL cartridges		
Needle stick injury		

### Potential Risk Associated with Insulin Vials and Pens

### Strategies to Mitigate Risk

Strategy	Vials (feasible / beneficial / impactful)	Pens (feasible / beneficial / impactful)
Dispense insulin pen with pharmacy generated patient-specific labels		
Dispense multi-dose vial with pharmacy generated patient-specific labels		
For insulin vials dispense patient-specific insulin doses in insulin syringes		
Enforce independent double checks before each dose of insulin is administered		
Staff education and sustainability plan		
Bar coding		

Feasible – can it be done in most acute care settings in Ontario Beneficial – will it actually reduce potential harm / risk Impactful – will this positively influence patient outcomes



Small Group Summary Sheet

1. Is there one solution your group felt most strongly should be implemented?

2. What were the key characteristic of this solution that led the group to decide it should be implemented over the other solutions?

3. Is there one solution your group felt most strongly would not be helpful in ensuring the safe delivery of insulin? Why?

# Appendix Three: Hierarchy of Effectiveness



Reference: Designing Effective Recommendations. Ontario Critical Incident Learning. 2013;(4):1-2.

# Appendix Four: Wastage Comparison Between Insulin Pens and Vials and Syringes



Courtesy of Peterborough Regional Health Centre - J. Murdock, Clinical Nurse Educator