Patient Safety and Quality Improvement Service

PATIENT SAFETY NOTICE

"A Patient Safety Notice identifies potential patient safety issues requiring risk assessment at the local level to determine appropriate actions".

Distributed to:

- **Hospital and Health Services Boards**
- **Hospital and Health Services Chief Executives**
- **Senior Director Health Services Purchasing and Logistics**

We recommend you also inform:

- Patient Safety Officers
- Clinical Products Advisory Committee (CPAC)
- Materials Management Staff
- QH Distribution Centre Staff
- Hospital and Health Services Safety and Quality Staff

Action required by:

- Hospital and Health Services Boards
- Hospital and Health
- Services Chief Executives

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For Internal Use Only

Persons receiving this Patient Safety Notice should take action if the affected goods are/were supplied to or are/were in use in their hospital and health service.

Subject:	**High Concentration Insulin (UPDATED)**
Issued by:	Medication Services Queensland
Issue Date:	13/03/2017
Approved by:	SIGNED

The purpose of this Patient Safety Notice is to inform clinicians of the safety issues associated with patients requiring high concentration insulin during hospital admission.

*Please note: This notice is an update of the original notice issued in September 2016. The notice has been updated following the discontinuation of Humulin R U-500® **vials**, which have now been replaced by a disposable multi-dose injector device (**Humulin R-500 KwikPen®**).*

Background

Most insulin formulations are presented in a standard concentration of 100 units/mL for use with suitably calibrated insulin syringes or with dedicated injector pens. Currently there are two concentrated insulin products available in Australia:

1. Humulin R U-500® (insulin neutral 500 units/mL): SHORT ACTING

- Only available in a KwikPen® (disposable multi-dose injector device).
- Available under the Special Access Scheme (Not on the Queensland Health List of Approved Medicines).
- Designed for patients requiring more than 200 units of insulin per day.
- Currently in use by approximately 30 people within Queensland.
- Previously only available in a 20 mL vial (which required a dose conversion to be administered via an insulin syringe). *The 20 mL vial is now no longer available outside of the USA as of December 2016.*

2. Toujeo® insulin (insulin glargine 300 units/mL): LONG ACTING

- This medicine is registered by the Therapeutic Goods Administration but not subsidised under the Pharmaceutical Benefits Scheme. Previous Patient Familiarisation Program closed in January 2017.
- Available only as a SoloStar® injector pen (disposable multi-dose injector device).

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Background (Continued)

In 2006, an increase in needle stick injuries prompted the then Centre for Health Care Related Infection Surveillance and Prevention (CHRISP) to release an advisory, stating that clinical staff must administer insulin using a standard 100 unit/mL insulin syringe. The availability of safety engineered (retractable) pen needles led to the withdrawal of this advisory.

Issue/Hazard

Individuals may be prescribed Humulin R U-500® and Toujeo® in order to manage their diabetes more effectively. When patients are using high concentration insulin independently at home, there are usually no issues. However, if admitted to hospital there is a risk of prescribing and administration errors as described below.

Issue 1 - Humulin R U-500® insulin (insulin neutral 500 units/mL)

- The Humulin R U-500 KwikPen® is different from other insulin injector pens. It dials **5 insulin units** with each click of the dose knob. You can give 5 to 300 units in a single injection.
- Insulin should **never** be withdrawn from the Humulin R U-500 KwikPen® with an insulin syringe as 5-fold dose calculation and administration errors may occur.
- As Humulin R U-500® is not registered with the TGA; information within the standard medication texts including MIMS and the Australian Medicines Handbook is absent and is therefore not easily accessed by clinicians.

*Note: Previously only available as a 20 mL vial that required an insulin syringe to administer and subsequent dose conversion—this is no longer necessary with the introduction of the disposable multi-dose injector device (Kwikpen®)—consequently, all insulin inpatient orders should now be in **UNITS.***

Image provided courtesy of Lilly

Issue 2 - Toujeo® insulin (insulin glargine 300 units/mL)

- Insulin should **never** be withdrawn from the Toujeo® disposable injector pen with an insulin syringe as 3-fold dose calculation and administration errors may occur.
- The majority of Toujeo® is prescribed by general practitioners; therefore, hospital clinicians may be unaware of the product and safety issues.

Image provided courtesy of Sanofi

Incident/s

Humulin R U-500® insulin (insulin neutral 500 units/mL)

A number of incidents have been reported related to Humulin R U-500® insulin.

- In all cases, miscalculation of the dose conversion (previously needed to administer the 500 units/mL insulin from the vial via an insulin syringe) has resulted in either a 5-fold overdose or 5-fold under dose.
- In one incident, the patient received a total of 700 units of insulin, instead of the prescribed 140 units. The patient used emergency language to alert staff to the error; however, the 5-fold overdose was administered.

Please note: Now that the vial of Humulin R U-500 is no longer available, these errors are less likely to occur if the insulin is administered directly via the disposable multi-dose injector device (Kwikpen®)

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Toujeo® insulin (insulin glargine 300 units/mL).
The following incident reported in PRIME demonstrates issues related to Toujeo® insulin (insulin glargine 300 units/mL).

- A patient using Toujeo® at home was admitted to a Queensland Health facility and received 3-fold overdoses when insulin was withdrawn from the disposable injector pen using a standard (100 units/mL) insulin syringe.

Recommendations

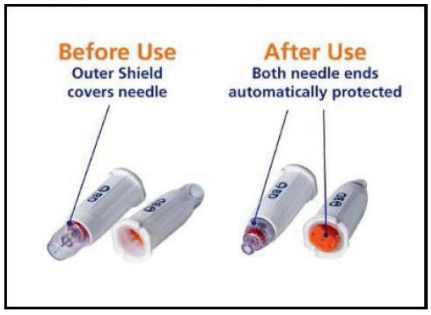
The following strategies may be considered to facilitate the safe prescribing, dispensing and administration of concentrated insulin if patients using high concentration insulin are admitted to your facility:

All high concentration insulin

1. High concentration insulin should NEVER be removed from a disposable injector pen.
2. Patient should be educated to inform doctors, nurses and pharmacists that he/she is using high concentration insulin.
3. Patients who are using high concentration insulin should self-administer insulin doses wherever possible.
4. Containers of insulin (vials, 3 mL cartridges and re-fillable or disposable injector pens) must NOT be used for more than one person.[1]
5. Safety engineered (retractable) pen needles that attach to injector pens have been approved for use by the Communicable Diseases Branch and are now available to use to administer inpatient insulin orders. This change is reflected (under Disposable Multi-Dose Injecting Devices) at: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/infection-prevention/standard-precautions/sharps-safety/needle-stick-injuries.

Standard Pen Needle

BD Autoshield Duo™ Pen Needles



Images Provided Courtesy of BD

6. If retractable pen needles are not available:
   a. The patient may self-administer their insulin with standard pen needles provided they can manage their injection device and remove and dispose of their pen needle safely.
   b. If the patient is unable to self-administer the high concentration insulin, the medical officer must be informed and an alternate medication should be sought.
7. Facilities should undertake a local risk assessment to determine if there is a need to implement retractable pen needles. If implementation is undertaken, strategies to educate clinical staff regarding the correct use of retractable pen needles will be required.
8. If retractable pen needles are implemented in the facility, patients who already use disposable injector pens in conjunction with standard pen needles when they are admitted to hospital will require education on how to use retractable pen needles during their admission. Standard pen needles should be continued on discharge.[1]
9. If retractable pen needles are implemented in a facility, patients who are commenced on insulin in hospital and are discharged on insulin will require education on how to use and how to access supplies of standard pen needles. These patients should be advised that retractable pen needles are only required in hospital to reduce the risk of staff member needle-stick injuries.

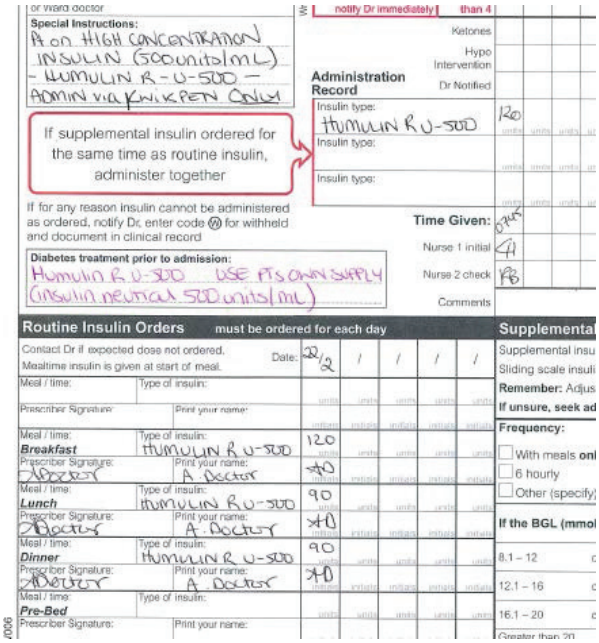
10. The patient has the right to refuse a medication if there is a concern about a medication order. The staff member has the right to refuse to administer a medication if there is a concern about any aspect of preparing, checking or administering a medication. In both instances, the prescriber or another medical officer and the nurse in charge of the shift must be notified and appropriate follow-up taken.
11. Utilise the clinical handover process to communicate that the patient is receiving high concentration insulin.
12. Involve the interdisciplinary team—endocrinologists and physicians, pharmacists, diabetes educators, nurse practitioners and nurse educators to provide education and advice regarding use of high dose insulin and devices.
13. Alerts should be in place on Medical Record folders and electronic systems (e.g. HBCIS, integrated Electronic Medical Record, iPharmacy) when high concentration insulin is prescribed. The following example could be used:

'This patient is using Humulin R U-500 Insulin (500 units/mL). This insulin is FIVE TIMES the concentration of standard insulin (100 units/mL)'

14. The warning posters (included with this Patient Safety Notice) may be displayed in clinical areas. The posters may be edited to incorporate local procedure.

Humulin R U-500® insulin (insulin neutral 500 units/mL)

15. Ensure clinical staff are aware of the availability of Humulin R U-500® insulin and the difference to 100 units/mL insulin
16. Ensure that the order is clearly documented in the Special Instructions area on the Insulin Subcutaneous Order and Blood Glucose Record form to note that the patient uses Humulin R U-500 insulin.



17. Retractable pen needles should be used for patient self-administration and by clinical staff administering Humulin R U-500® insulin for inpatients who are unable to self-administer.
18. If a safety-engineered pen needle is not available, notify the Medical Officer as the insulin regimen will need to be altered.
19. Patients who are using Humulin R U-500® should be provided with and carry 'flash cards' to show clinical staff when they are admitted to hospital and are concerned about a dose of insulin to be administered.

Toujeo® insulin (insulin glargine 300 units/mL)

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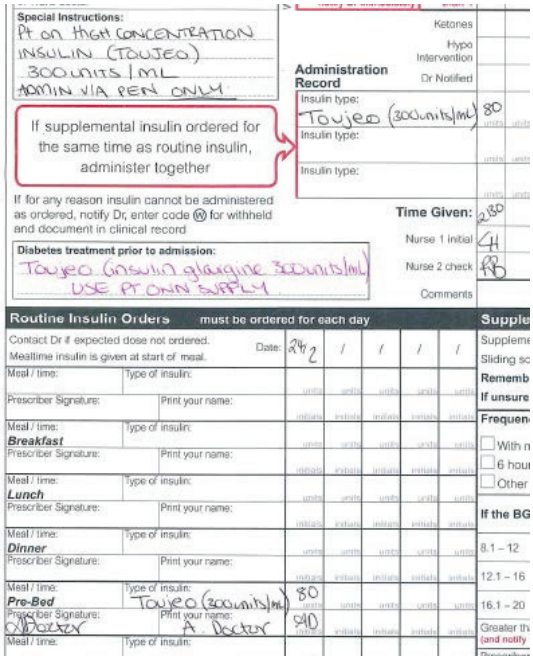
20. Ensure clinical staff are aware of the availability of Toujeo® insulin and the difference to 100 units/mL insulin.
21. Ensure that the order is clearly documented in the Special Instructions area on the Insulin Subcutaneous Order and Blood Glucose Record form to note that the patient uses Toujeo® insulin.



22. Retractable pen needles are used for patient self-administration and by clinical staff administering Toujeo® insulin for inpatients who are unable to self-administer.
23. If a safety-engineered pen needle is not available, a conversion to Lantus® (Glargine 100 units/mL) or another basal insulin may be warranted.
24. If converted to Lantus® a dose reduction of 15-25% may be required, depending on the clinical situation.

Action required by Hospital and Health Services:

1. Disseminate this patient safety notice to relevant clinical and product procurement staff along with additional educational or alert information regarding high concentration insulin (attached).
2. Remove the patient safety notice on high concentration insulin that was released in September 2016 and the Humulin R U-500 poster with the dose conversion information.
3. HHSs undertake a risk assessment to determine if the issues outlined in this Patient Safety Notice exist in your facility.
4. Consider the recommendations listed above and implement as required.

Management Review:

For local risk management.

[1] NHMRC (2010) Australian Guidelines for the Prevention and Control of Infection in Healthcare. Commonwealth of Australia.