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Safety Notice 009/17

High Concentration Insulin Products

5 September 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Associate Director, Private Health Care

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Drug and Therapeutics Committees
- Diabetes Clinics
- Endocrinologists
- Diabetes Educators
- Directors of Medical Services
- Directors of Nursing
- Directors of Pharmacy

Expert Reference Group

Content reviewed by:

- Medication Safety Expert Advisory Committee
- ACI Endocrinology Network

Clinical Excellence Commission

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Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

September 2019

Insulin is a high-risk medicine which can cause harm if misused or used in error.¹ In NSW hospitals, insulin is the third most common medicine involved in medication incidents.

Most insulin formulations are presented in a standard concentration of **100 units/mL** and are administered using a 100 units/mL insulin syringe, or a dedicated injector pen. The introduction of high concentration insulin products has increased the potential for errors and serious harm to patients.

Currently, there are two high concentration insulin products available in Australia, with more expected to become available in the future:

- Humulin® R U-500 (insulin neutral) **500 units/mL** is available as a disposable injector pen through the Special Access Scheme and is **five** times more concentrated than standard insulin products.



Image provided courtesy of Lilly

- Toujeo® (insulin glargine) **300 units/mL** is available as a disposable injector pen through private prescription and is **three** times more concentrated than standard insulin products.



Image provided courtesy of Sanofi

High concentration insulin may be used by some people with diabetes, for example in order to decrease the daily injection volume in those with severe insulin resistance requiring high doses of insulin, or for a range of other clinical reasons. These products are usually safely self-administered by patients at home. However, the lack of staff familiarity with these products can result in **3- to 5-fold** dosing errors when these patients are admitted to hospital.

In Australia, a number of actual and near miss incidents have been reported where inpatients have received incorrect doses of high concentration insulin.

Suggested actions by Local Health Districts/Speciality Networks

1. Forward information to relevant clinicians, clinical departments/units, and Drug and Therapeutics Committees (or similar) for action.
2. Conduct a local risk assessment on the use of high concentration insulin products in each area where they are stored, or may potentially be used, and implement strategies to reduce errors. Strategies could include:
 - Increase staff awareness of the high concentration insulin products.
 - Ensure the treating team consults the local Endocrinology team and/or the Endocrinologist who normally manages the patient's high concentration insulin as soon as possible.
 - Ensure medication orders for high concentration insulin products include the full brand name.
 - Ensure that the insulin dose is clear to all staff involved in the handling of the high concentration insulin.

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Suggested actions by Local Health Districts/Speciality Networks

- Hospital supply of high concentration insulin products should only be through individual patient dispensing.
 - Dispensing labels for high concentration insulin products should be affixed to the body of the pen (not the removable cap).
 - **A syringe should never be used to withdraw insulin from these pen devices due to the high potential for dosing errors.**
 - **Do not perform dose conversions** as the pen device automatically does this function.
 - Whenever possible, patients should **self-administer** their high concentration insulin under supervision in accordance with NSW Health Policy on Medication Handling in NSW Public Health Facilities.² Refer to the 'Safe administration' section below for more detail on how to safely administer insulin from these products.
 - Use of reminders that specify the mandatory requirement for an independent double check when administering insulin.
 - Place an alert on the patient's electronic medical record and any relevant paper charts to indicate that they are using a high concentration insulin.
 - Ensure the separate storage of high concentration insulin from standard insulin products.
 - Use warning labels on high concentration insulin product packaging and shelving areas.
 - Ensure appropriate clinical support is available after-hours for managing the use of high concentration insulin products.
3. Monitor and document adverse outcomes associated with the use of high concentration insulin.
 4. Ensure a system is in place to document and review actions taken.

Safe administration

Patients should administer their high concentration insulin using a standard pen needle, they must be able to manage the pen device and dispose of their pen needle safely. If it is necessary for staff to administer a dose of high concentration insulin then a safety pen needle must be used.

- It is important that the safety pen needle shields both ends of the device after use to prevent needle stick injury (e.g. BD AutoShield Duo™).
- Before facilities make these devices available, strategies to educate nursing staff regarding the correct use of the safety pen needles are required.³

Standard Pen Needle



BD AutoShield Duo™ Safety Pen Needle



Images provided courtesy of BD

References

1. [NSW Health Policy Directive PD2015_029 High-Risk Medicines Management Policy](#)
2. [NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities](#)
3. [BD AutoShield Duo™ Safety Pen Needle Instructions for Use](#)