Irish Medication Safety Network

Best Practice Guidelines for the Safe Use of Insulin in Irish Hospitals

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Prepared by

Version 1 (May 2010): Eileen Relihan[a]

Version 2 (March – July 2019, final edits March 2020): Eileen Relihan[a]; Jennifer Hayde[b]

on behalf of the Irish Medication Safety Network in consultation with Irish Medication Safety Network members.

[a]Medication Safety Facilitator, St. James's Hospital, Dublin

[b]Medication Safety Manager, Tallaght University Hospital, Dublin

About the IMSN

The Irish Medication Safety Network (IMSN) is a voluntary, independent group, comprising hospital pharmacy based specialists actively involved in medication safety and Medication Safety Facilitators/Coordinators which aims to promote patient safety and safe medication practices through collaboration and shared learning within the network and with the wider community.

Website: **www.imsn.ie** Email: **enquiries@imsn.ie**

Background and Evidence of Harm

Insulin as a High-Alert Medication

Insulin is widely considered by safety agencies internationally to be a 'high-alert' medication, i.e. a medication that bears a heightened risk of causing significant patient harm when used in error.[1-4] Recent data from England and Wales show that 40 per cent of people with Type 1 diabetes and 37 per cent of people with Type 2 diabetes treated with insulin had an insulin error while in hospital.[5] Research from the US has indicated that 33% of the medical errors that cause death within 48 hours of the error, involved insulin therapy in the care of a hospitalised patient.[6] The most common types of insulin errors are errors of omission (leading to hyperglycaemia) and inaccurate doses (leading to both hyperglycaemia and hypoglycaemia).[7]

Although very limited Irish data is available, anecdotal evidence from hospitals suggests that insulin, as an individual medication, accounts for a substantial percentage of the total number of medication errors reported in organisations.[8] Data published by the State Claims Agency in 2017 shows that insulin was amongst the top ten medication classes reported through the National Incident Management System (NIMS).[9]

Best Practice Guidance

Very comprehensive guidance relating to the safe use of insulin in the inpatient setting has previously been published by the American Society of Health-System Pharmacists (ASHP).[10, 11]

For this document, the IMSN has decided to highlight five best practice guidelines from published recommendations. Our selection was based on practices which are relatively simple to implement, but which nonetheless would have a significant impact on insulin safety if complied with in individual organisations (Table 1).

Key Recommendations

Table 1: Safe Use of Insulin: Recommendations

1. The word 'units' must be written in full.[6,11] The abbreviation 'u' or 'iu' must not be used for units.
2. All insulins should be measured in insulin pens or in appropriately-sized insulin syringes marked in units. Tuberculin and other 1 mL or 2 mL syringes should **NOT** be used.[12,11]
3. All staff, medical and nursing, involved in administration of insulin should receive training and be educated in the concentrations of insulin available.[12] (See IMSN Alert 'Risks Associated with High Strength Insulin Preparations' in Appendix 1.)
4. A second practitioner, either medical or nursing, should perform an independent second check of insulin doses.[12],[11]

   This second check must:

   - include all aspects of administration irrespective of route or administration method
   - be conducted from preparation through to administration and documentation of administration
   - include the use of any devices and calculations.

   Note: The IMSN supports the self-administration of insulin, when it is safe to do so, and when undertaken in the manner specified in local hospital policy.
5. Insulin pens (both disposable pre-filled pens and re-useable pens) and insulin cartridges are for Single Patient Use only (see IMSN Alert 'Risk of Cross-Contamination with Insulin Preparations' in Appendix 2).

Case Study

The IMSN has collated and reviewed several examples of errors involving insulin, which have occurred in Irish hospitals. Generally these errors have multiple contributory factors and more than one best practice recommendation is applicable in terms of reducing the risk of reoccurrence. This is typical of the multifactorial nature of harmful medication errors and the complexity of the response required to address them. A case study of an error is provided below which illustrates the importance of guidance points 2, 3 and 4 as outlined in Table 1 above.

Sample Insulin Error

Patient was prescribed the following treatment for hyperkalaemia: 10 mLs of 10% calcium gluconate and 50 mLs glucose 50% with 10 units of Actrapid® insulin. In error, the intern administered an infusion of glucose containing 100 units of Actrapid® instead of 10 units. Approximately three hours later, the patient was discovered unresponsive, cold and clammy to touch, by nursing staff. On measurement, the patient's blood

glucose level was found to be 0.7 mmol/L. The hypoglycaemic episode was successfully reversed with 100 mLs of glucose 50%, followed by a 10% glucose infusion.

Contributory Factors

- The doctor was unfamiliar with insulin preparations and their administration; he therefore was unaware that the standard insulin concentration available at the time was 100 units/mL (since the time of this error additional higher concentrations of insulin have become available on the Irish market).
- At the time of the event the product label for Actrapid® only specified the concentration (as 100 units/mL) and not the total number of units in the entire vial (i.e. 1,000 units)* This type of labelling can predispose users to misinterpret the concentration as the total quantity of drug in a product, e.g. in this case to mistakenly believe that there was 100 units as opposed to 1,000 units in the 10 mL vial.

  *[*Note: following the reporting of concerns regarding the labeling of Actrapid® the manufacturer addressed this risk by amending the label to include the total number of units in the vial, as well as the concentration.]*
- A regular syringe with millilitre gradations, rather than an insulin syringe with insulin unit gradations was used to draw up the dose of Actrapid®; reducing the chance of detecting the error prior to administration.
- The doctor did not seek any second person check on the insulin preparation or its administration. There was therefore no opportunity for a second staff member to detect the dosing error and intervene.

Implementation of Recommendations

Individual healthcare organisations can undertake a simple gap analysis in relation to insulin safety by comparing local practices with the recommendations in Table 1. The aim is to identify any system weaknesses which might be addressed by implementing new safety initiatives or strengthening existing ones.

The following insulin safety strategies address the four key recommendations and have previously been successfully employed by Irish hospitals:

- Consider designing a drug chart solely for insulin prescribing and administration. This drug chart may incorporate the following safety features:
  - The word ‘units’ pre-printed wherever a dose of insulin has to be completed by the prescriber.

- A reference list of the insulins most commonly prescribed in the hospital, classified by their different formulations, i.e. rapid/short/intermediate/long-acting and pre-mixed biphasic insulins, together with the brand names and concentrations available for each product.
- Pre-printed proformas for various regimens and management options, e.g. 'basal bolus' regimen, carbohydrate counting and insulin pumps, accompanied by a brief description of the components of the regimens and/or the rationale for their use.
- Pre-printed proformas for the management of conditions such as diabetic ketoacidosis and hyperosmolar hyperglycaemic state.
- Provision of space for double signatures on the drug chart to prompt staff to seek a second person check on insulin doses.
- A warning regarding the concentration of insulin, i.e. that the vast majority of insulin has a standard concentration of 100 units/mL, but a variety of higher concentration insulins are now available on the market, e.g. Tresiba® and Humalog® which are available in concentrations of 200 units/mL as well as 100 units/mL, and Toujeo®, which is available as 300 units/mL

- Review of wards to ensure all areas have insulin syringes in stock and that staff are aware of their availability.
- Development of an insulin education programme for both doctors and nurses, which incorporates training on practical points such as drawing up insulin from a vial using an insulin syringe and how to use insulin pen devices. This education programme can be incorporated into the orientation training for each new intake of doctors.
- Active promotion of key recommendations (Table 1) at suitable educational opportunities e.g. diabetes study days, nursing in-services, intern orientation, junior doctor education sessions.
- Passive promotion of recommendations by means of in-house publications, e.g. Prescribers' Guides, medications safety bulletins, medication safety intranet sites.
- Use of in-house examples of insulin errors as opportunities for shared learning, by linking contributory factors identified for the errors to best practice recommendations that may prevent the incident arising.
- Addition of guidance to Prescriber's Guides regarding the typical dose range (in units/kg) of insulin that might be expected for patients with diabetes.

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Appendices 1 and 2

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Appendix 1: **Safety Alert: Risks associated with High-Strength Insulin Preparations**

Issue:

Insulin is a high risk drug which has the potential to cause serious harm if it is not used correctly.[1] Until recently, all insulin available on the European market contained 100 units / mL. A high-strength insulin is one which contains insulin at a concentration of more than the standard 100 units / mL.[2] These high-strength insulin products may contain, for example, **200 units / mL** or **300 units / mL.** There is a potential for harm if these products are not prescribed, dispensed, and administered properly.

Brand Name	Insulin Type	Strength	Dose counter	Range of units per injection
Tresiba® (100)	*Insulin Degludec*- long acting	100 units / mL	1 unit increments	1 – 80 units
Tresiba® (200)	*Insulin Degludec*- long acting	200 units / mL	2 unit increments	2 – 160 units
Toujeo®	*Insulin Glargine*- long acting	300 units / mL	1 unit increments	1 – 80 units
Caution: While both Lantus® and Toujeo® contain insulin glargine, they are not bioequivalent and are not interchangeable. If switching between these brands, consult the product literature for advice.[3]				
Humalog® (100)	*Insulin Lispro*- short/ rapid acting	100 units / mL	1 unit increments	1-60 units
Humalog® (200)	*Insulin Lispro*- short/ rapid acting	200 units / mL	1 unit increments	1-60 units
Caution: Do not confuse with other Humalog® preparations which are not High-Strength insulins, such as Humalog® Mix 25 and Humalog® Mix 50.				

Evidence of Harm:

There is a risk of accidental mix-up with a variety of concentrations of insulin, and multiple branded products containing the same insulin[4]. It is not possible to accurately prescribe, dispense or administer these products solely with the name of the active substance (e.g. insulin lispro, insulin glargine, insulin degludec). It has also been identified that some patients and health care professionals have extracted insulin from pen devices using an insulin syringe and needle which can, in the case of high-strength insulin, lead to the administration of an insulin overdose because insulin syringes are calibrated for 100 units / mL insulin only.[2,5,6] This practice must be avoided with all insulin pens as it can lead to dosing errors in general and if a pen is used to provide insulin to more than one patient it can lead to transmission of blood borne viruses.

How to Reduce the Risks:

Safe Prescribing

- Always prescribe these insulins by brand name, and strength in cases where multiple strengths of same brand exist.
- The word 'units' must be written in full. The abbreviation 'u' or 'iu' must never be used for units[7].
- Circle the strength of the high-strength insulin when prescribing e.g. Tresiba® (100) or Tresiba® (200).

Safe Supply, Storage, and Labelling

- Supply on a named patient basis: where possible, directly from the Pharmacy Department.
- Select and check the correct product by (1) brand name, and (2) strength where multiple strengths exist.
- In order to prevent missed doses, ensure sufficient supply (check total volume of pen and consider total units)

Safe Administration

- Check the brand and the strength against the insulin prescription
- Only administer using the pen device with appropriate needle attached. Never extract insulin from a pen device with a needle and syringe.
- Visually verify the dialled units on the dose counter of the pen, against the units prescribed.

Patient Factors

- Tresiba®: In order to self-inject, patients must be able to read the dose counter on the pen. Tresiba® (200) dials up in 2 unit increments so there is a danger of overdose if the visual verification step is skipped.

Governance

- Ensure awareness/education of clinical staff on the correct use of all insulin including high-strength insulin.[2]
- Ensure staff have access to technical information about how to administer insulin using pens, pen devices and vials.[5]
- Ensure a policy / procedure / guideline is in place regarding the correct use of insulin preparations. This should include information on the safe use of high-strength insulin.

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Prepared by: Jennifer Hayde, Tallaght Hospital; Deirdre Lenehan, Mater Misericordiae University Hospital, on behalf of the IMSN.

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Appendix 2: **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 changed[9], '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 use[3], '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.

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Prepared by: Eileen Relihan, St. James's Hospital; Ciara Kirke, Tallaght Hospital; Maria Creed, Mater Misericordiae Hospital, on behalf of the IMSN.
Updated by: Deirdre Lenehan, Mater Misericordiae University Hospital, on behalf of the IMSN.