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HEALTHCARE SAFETY INVESTIGATION BRANCH

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Interim bulletin

Prescribing and administering insulin from a pen 'device' in hospital

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Notification of Event and Decision to Investigate

The HSIB was notified by a hospital Trust of an incident whereby a patient received an unintentional overdose with five times the prescribed dose of insulin. The insulin was withdrawn from an insulin pen device and then administered using an insulin syringe. This method is not compatible with safe administration of insulin.
The human body produces the hormone insulin to regulate the body's blood glucose level. Manufactured insulin is used as a medical treatment, mostly, but not exclusively, for diabetes mellitus. Insulin can be administered into the body by:

- insulin syringe (needle attached)
- insulin pen (intended for patient administration) - insulin pens are used with a specific type of needle attachment which is replaced with each use (pen needles)
- insulin pump device (CSII-continuous subcutaneous insulin infusion)

There are over 30 types of insulin available in England, which work at varying speeds to modify blood glucose and can be used to customise treatment according to a patient's needs. Insulins are available in different concentrations, indicated by the units per mL. Insulins with a high concentration (over 100 units per mL) are called high-dose insulins. They are suitable for patients who require a high dosage.

Following the preliminary safety investigation, the Chief Investigator authorised a full investigation as it met with the following criteria:

Outcome Impact: what impact has a safety issue had, or is having, on people and services across the healthcare system?
Deviating from using recommended equipment and techniques to administer insulin (for example

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withdrawing from an insulin pen) can lead to the patient receiving the incorrect amount of insulin. This can result in erratic blood glucose control and avoidable harm: severe physical and/or emotional harm, longer length of stay in hospital, even death. Furthermore, it can contribute to a loss of trust and confidence between patients, their families, and staff.

Systemic Risk – How widespread and how common a safety issue is this across the healthcare system
Aspects of insulin prescribing and administration cross organisational and departmental boundaries and involve multiple healthcare professionals and services. There are a wide variety of insulins, many of which look and sound alike. Although knowledge is generally improving, the risk appears to be persistent and inpatient error rates remain high (NHS Digital, 2018).

The complexity of insulin prescribing and administration is likely to increase as more insulins enter the market to meet the needs of a growing number of patients who require high-dose versions. The increasing complexity and variation will challenge the safety of healthcare systems.

Learning Potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system
Early evidence from the investigation suggests there is potential learning around product design, procurement, operational and clinical processes, the process of transferring information and environment management.

Healthcare Delivery Goals

The safe prescribing and administration of insulin in hospital settings.

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History of the Event

The patient, a 73-year old female had an emergency admission to hospital for investigation of abdominal pain. She had insulin-treated type 2 diabetes and a very high *'body mass index'* (BMI) with subsequently reduced mobility. As a result she used a high-dose insulin (500 units per mL) from an insulin pen device.

Common practice in the hospital concerned was to use a patient's medication if they brought it with them into hospital. The patient had brought her medication, including an unused disposable insulin pen device and approximately six single-use insulin pen needles. The patient was moved to a different ward and her medication was transferred with her. However, her supply of pen needles had been used up on the first ward. The second ward, like the first, did not stock the disposable pen needles for administration of the insulin from her pen.

The nurses improvised by using an insulin syringe to withdraw the insulin from the pen device and administered the insulin to the patient. However, they did not notice that the insulin was one of high concentration - five times the normal strength. The outcome was that the patient received a five times overdose. The patient experienced subsequent hypoglycaemic events (low blood glucose) and required treatment. The patient's blood glucose levels recovered, and the next dosage was administered in the same way.

Later, the patient's husband identified the error when enquiring about the recurrent hypoglycaemic episodes. The patient made a full recovery.

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The preliminary safety investigation revealed there may be additional contributory factors:

- changes were made to the insulin prescription
  - the patient's insulin dose was reduced several times during her stay because she was experiencing episodes of low blood glucose (hypoglycaemia)

  - a number of different professionals with, and without, specialist knowledge of diabetes made changes to the patient's insulin dose

National Context

One in six hospital beds are occupied by someone who has diabetes and in 2017 there were 260,000 people with diabetes in the UK who experienced a medication error. 58,000 people with diabetes experienced a hypoglycaemic event whilst in hospital (Watts and Rayman, 2018). Safety around withdrawing insulin from devices has previously been recognised in the UK as a risk. In November 2016, NHS Improvement (NHSI) released a safety alert about the *'risk of severe harm and death due to withdrawing insulin from pen devices'* (NHSI, 2016). It highlighted that variation in insulin concentration was not always considered increasing the risk of overdose when insulin is extracted from insulin pens.

The former National Patient Safety Agency (NPSA) released a Rapid Response Report *'Safer administration of insulin'* (2010) identifying administration errors, including errors due to the mis-operation of insulin pens or lack of training. They further noted that licensed insulin products were standardised at 100 units per mL, with exceptional patient-specific cases of 500 units per mL (they are also available in 200 and 300 units per mL). The report identified international concern about the use of 500 unit per mL insulin, which had led to significant patient harm. NHS Diabetes recommended 500 unit per mL insulin products must be:

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- kept separate from all other insulins,
- clearly labelled
- only be administered by staff who have specific training in its use.

In 2018, National Health Service Improvement (NHSI) released a new version of the Never Event list (NHSI, 2018) confirming that an overdose of insulin due to confusion from abbreviations or use of an incorrect device is a Never Event. This includes when a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers it using a syringe and needle.

In 2018 Diabetes UK (Watts and Rayman, 2018) published their report *'making hospitals safer for people with diabetes'*, in which they proposed 6 areas for improvement:

- multidisciplinary diabetes inpatient teams in all hospitals
- strong clinical leadership from diabetes teams
- knowledgeable healthcare professionals who understand diabetes
- better support in hospitals for people to take ownership of their diabetes
- better access to systems and technology
- more support to help hospitals learn from mistakes.

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Identified Safety Issues

The following safety issues were identified by HSIB and will be explored during the National Investigation:

High Risk Medications

- Use of and knowledge of concentrated insulin which is not licensed for use in England
- Perceived and actual barriers to self-administration using a pen device in hospital

Devices

- Design and usability of pen device and pen needles.

Procurement & Storage

- Procurement processes across the NHS specifically around the various pen needles for insulin pen devices.
- Design of environments in which insulin pens and needles are stored in hospitals.

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Next Steps

The HSIB will investigate the safety risks and welcomes further information which may be relevant, regardless of source.

The HSIB will report any significant developments as the investigation progresses.

References

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