



Health Services Safety
Investigations Body

Investigation report

Investigation report: Administering high-strength insulin from a pen device in hospital

Date Published:

08/07/2022

Theme:

Medication, Checking

This PDF was downloaded from the Health Services Safety Investigations Body (HSSIB) website. To make sure you are reading the latest version, and for accessible reports, please visit <https://www.hssib.org.uk>

Contents

[Show subheadings](#)

[A note of acknowledgements](#)

[About Kathleen](#)

[About this report](#)

[Executive Summary](#)

[1 Background and context](#)

[2 The reference event](#)

[3 Involvement of the Healthcare Safety Investigation Branch](#)

[4 Analysis and findings – the reference event](#)

[5 Analysis and findings – the wider investigation](#)

[6 Summary of findings, safety observations and safety action](#)

[7 References](#)

A note of acknowledgements

We are grateful to Kathleen (the Patient) and her Husband, whose experiences were central to this investigation. They wanted to participate so they could help to improve the experiences of other people with diabetes when they too are in hospital.

We would also like to thank the NHS staff who engaged with this investigation for their time, professionalism and enthusiasm for understanding what had happened and why they should support improvements in this area.

About Kathleen

At the time of the investigation, Kathleen had been married to Bob for 52 years. Together they have five children, nine grandchildren and two great-grandchildren. Kathleen is described as “always having a smile on her face” and “loves helping people”. Before she retired, Kathleen had been a hairdresser; in her spare time she loves to draw. Kathleen still enjoys watching a horror movie when not chatting with her family.

About this report

The aim of this report is to help improve patient safety in relation to administering high-strength insulin from a pen device to patients with diabetes in a hospital setting. This report is intended for healthcare organisations, policymakers and the public. For readers less familiar with this area of healthcare, medical terms are explained within the text of the report.

Executive Summary

Background

The aim of this investigation was to explore the factors that challenge the safe administration of high-strength insulin (a hormone that helps control blood sugar) to patients with diabetes by hospital staff using an insulin pen device (an injection device that is used to deliver insulin to the body).

Diabetes occurs when a person's body does not naturally regulate its blood glucose (sugar) levels because it cannot make insulin (type 1 diabetes) or does not produce enough insulin or does not respond to insulin (type 2 diabetes). Blood glucose levels then become too high. Some people who have diabetes need to receive insulin from outside sources (that is, as a medication) to regulate their blood glucose levels. There are different types of insulin and different ways to get it into the body. If too much insulin is given then a person can experience hypoglycaemia, where their blood glucose level becomes too low. This can be dangerous if not treated quickly.

Kathleen has type 2 diabetes and was using a high-strength insulin administered from an insulin pen device to manage her condition. When Kathleen was admitted to hospital for a reason other than her diabetes, insulin was withdrawn from her pen device using an insulin syringe and needle and given to her as an injection, instead of using her insulin pen device. This resulted in Kathleen receiving more than her prescribed dose of insulin, and she experienced hypoglycaemia on at least two occasions.

This investigation's findings and safety observations aim to prevent future occurrences of hypoglycaemia as a result of an insulin overdose among hospitalised patients receiving insulin from a pen device.

The reference event

Kathleen, a 73 year old woman with type 2 diabetes, used Humulin R U-500 insulin, which is five times the strength of most insulins. Most people are prescribed Humulin R U-500 insulin from a pre-filled insulin pen device (KwikPen), which is designed to prevent dosing errors with high-strength insulin.

This medication is not licensed by the medication regulatory body for use in the UK and is imported from the USA. It is used when an individual needs a lot of insulin, as it allows the dose to be given in a smaller volume.

When Kathleen was staying in hospital for a reason unrelated to her diabetes, she was prescribed 48 units of 500 units/ml insulin. Nurses administered 48 units of insulin as measured with an insulin syringe, rather than via her insulin pen device. Insulin syringes are intended for use with standard insulin strength of 100 units/ml, meaning that when a syringe was used to withdraw the insulin dose from the pen device, this was five times the dose of insulin that Kathleen had been prescribed.

Kathleen received two recognised overdoses of insulin in this way while she was in hospital. On both occasions she became hypoglycaemic, received medical treatment and recovered.

The national investigation

The national investigation explores the systemic risks associated with administering high-strength insulin from a pen device to people in hospital, and the barriers in place to mitigate against these risks.

The risk of people with diabetes becoming unwell or harmed while they are in hospital is nationally recognised. Administering insulin by extracting it from a pen device with a syringe is classed as a 'Never Event' – meaning that it should never happen.

High-strength insulin preparations have been introduced to healthcare to cater for people with diabetes who require a high dose of insulin, and are increasingly being prescribed within England. It is widely recognised that high-strength insulins need careful management to minimise the risk of medication errors. Safety measures include ensuring that high-strength insulins are only supplied in a pre-filled pen device, and that the insulin is only administered using that device. For these measures to be effective, however, staff caring for people on high-dose insulin must: (1) be aware that high-strength insulin exists; (2) have access to the relevant equipment for delivering high-dose insulin; and (3) have the relevant competencies.

Findings

The investigation's findings are summarised below.

Use of high-strength insulin

- Trusts vary in their use of high-strength insulin and the number of patients on these medications.
- Healthcare staff in any speciality may be required to care for hospital patients prescribed high-strength insulin.
- Restrictions on promoting the use of an unlicensed medication have made it difficult to communicate the risks associated with the 'semi-routine' use of Humulin R U-500 insulin.

Staff knowledge and skills

- Nursing staff were not always familiar with the range of different high-strength insulins and associated pen devices.
- Variation was seen in the training and competency assessment of healthcare professionals with respect to the administration of insulin.
- National safeguards are inadequate to support the safe use of high-strength insulin by healthcare professionals.
- There is a lack of standardisation in the role and training of diabetes specialist nurses.
- Inconsistent numbers of diabetes specialist nurses are employed across trusts to support the upskilling of ward staff in relation to diabetes management, including on the use of high-strength insulin.

Equipment

- Administering insulin via a pen device is a complex task that requires co-ordination across and between different departments to ensure that the insulin and associated equipment required are readily available in the clinical area when they are needed. The consequences of not using the insulin pen administration device as intended can be significant, particularly with high-strength insulins.
- The equipment for administering insulin via a pen device would usually be obtained through NHS Supply Chain.
- Contract changes meant that a safety needle in widespread use across England disappeared from the catalogue.
- NHS Supply Chain has confirmed it has systems and processes in place to support trusts with an alternative where a previously available product is no longer listed.

HSIB makes the following safety observation

The intention of this safety observation is to ensure that there is a nationally agreed approach to how high-strength insulins should be safely used.

Safety observation O/2022/175:

It may be beneficial for insulin training to be competency based and specific to the healthcare practitioner's role, in line with the 'Diabetes: getting it right first time' national specialty report.

The intention of this safety observation is to ensure that the workforce has the necessary knowledge and skills to care for patients on insulin.

Safety observation O/2022/176:

It may be beneficial if national work was undertaken to review the robustness of the strategies to prevent administration errors with high-strength insulin and update accordingly.

The intention of this safety observation is to ensure that the medication regulator becomes aware of when an unlicensed medication is being widely used.

Safety observation O/2022/177:

It may be beneficial for systems to support regulators in identifying when large volumes of unlicensed medication are regularly being prescribed to patients. Regulators can then engage in dialogue with the manufacturer about applying for a UK product licence.

The intention of this safety observation is to ensure there is clarity and consistency in the role and competencies of the diabetes nurse specialist.

Safety observation O/2022/178:

It may be beneficial to conduct work to standardise the role, qualifications, training and competency of diabetes nurse specialists, as recommended in the Diabetes UK Position Statement.

HSIB notes the following safety action

Safety action A/2022/052:

The British National Formulary has been updated to provide information to healthcare practitioners on Humulin R U-500 insulin.

1 Background and context

1.1 Diabetes mellitus

1.1.1 The human body produces the hormone insulin to regulate the body's blood glucose (sugar) levels. Insulin helps the body use glucose for energy. Diabetes mellitus (diabetes) is a long-term condition that occurs when the body is unable to produce insulin or where insulin is less effective. This causes a person's blood glucose levels to rise. Treatment aims to prevent health problems that arise from high blood glucose levels.

1.1.2 Diabetes can occur in two main forms (NHS, 2019):

- Type 1 – where the body attacks cells in the pancreas (a gland behind the stomach), which means it cannot make insulin.
- Type 2 – where the body is unable to make enough insulin or the body's cells do not react to the insulin.

1.1.3 Type 2 diabetes is more common than type 1; about 90% of adults with diabetes in the UK have type 2 diabetes (NHS, 2019). Excess body weight is the single greatest risk factor for developing type 2 diabetes. Therefore, with the increase in the rates of obesity, more people than ever are living with type 2 diabetes (Diabetes UK, 2019a).

1.2 Treatment and management of diabetes

1.2.1 Treatment for diabetes differs depending on the type:

- Type 1 diabetes is treated with insulin.
- Type 2 diabetes may be managed through a combination of lifestyle changes and medications. This may include the need to inject insulin to control blood glucose levels.

1.2.2 Healthcare teams may set customised target ranges for a patient's blood glucose levels according to that person's needs. A patient's blood glucose levels may need to be regularly monitored by the patient, a carer or healthcare professionals to make sure they keep within that target range. How often this needs to happen depends on the type of diabetes and whether the person is unwell. This helps to identify when the person may need changes to their treatment.

1.3 Insulin pens and insulin pen needles

1.3.1 Insulin pen devices are tools to administer insulin; they are typically designed for use by the patient. They resemble a fountain pen, with a main body and cap (see figure 1). The pen body includes a dose-adjustment dial, which is turned until the correct dose is shown in the dose window, and an injection button to press to administer the insulin dose.



Figure 1 Example reusable insulin pen device

1.3.2 Some pens are designed to be reusable. In reusable pens, a pre-filled insulin cartridge is inserted into the body of the pen. When the insulin has been used up, the cartridge can be removed, disposed of and replaced.

1.3.3 Other pens are designed to be disposable. Disposable insulin pens incorporate an insulin reservoir in the body of the pen. When the insulin has been used up, the whole pen is thrown away.

1.3.4 Regardless of whether an insulin pen is disposable or reusable, a single-use needle is required for administration. Pen needles screw onto the pen body and are needed to inject the insulin from the pen into a person's body. A new needle should be used for each injection.

1.3.5 There are standard and safety needle types. Standard needles are used by patients. Safety needles are used by those helping a person to inject their insulin to protect against needlestick injuries (that is, when the needle punctures the caregiver's skin unintendedly).

1.4 Insulin syringes

1.4.1 Insulin syringes, known as U-100 syringes, are designed for use with insulin preparations where the insulin concentration is 100 units per millilitre (units/ml) (see figure 2). This contrasts with other syringes that measure liquid volumes in millilitres. The U-100 insulin syringe is the only type approved for use in healthcare in the UK.



Figure 2 U-100 insulin syringe with integral needle

Image courtesy of BD Advancing the world of health

1.5 Insulin

1.5.1 Numerous different types of insulin are available, and they differ in how quickly the insulin acts (its speed of onset) and how long the effect lasts before it wears off (duration). Insulins are provided in different preparations, including the pre-filled pen device. At the start of June 2022, there were 30 different types of insulin marketed in the UK, of which 11 were available in a total of 27 disposable pre-filled insulin pen devices (MIMS, 2021, 2022). Information on what insulin doses can be delivered by which pen device is given on the patient information leaflet provided by the manufacturer with the insulin.

1.5.2 Since 2013, insulins have become available in different concentrations in the UK, indicated by the number of units per millilitre. Insulins with a high concentration (over 100 units/ml) are called 'high-strength' insulins. High-strength insulins need less liquid to deliver the same dose of insulin compared with lower-strength formulations, and are preferable for patients who require high insulin doses.

1.6 Regulation of insulin

1.6.1 Disposable insulin pens and insulin pen cartridges are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) as medications. Reusable pen devices are regulated by the MHRA as medical devices.

1.6.2 A 'licensed medicine' is one that has a marketing authorisation from the MHRA or the European Medicines Agency. The marketing authorisation is an indication that the medication has been appropriately tested in clinical trials to ensure that it works, is safe and is of an appropriate quality. An 'unlicensed medicine' does not have a marketing authorisation for the UK. It might, however, be licensed as a medication in a different country. An unlicensed medication may only be supplied to meet the special needs of an individual patient (Medicines and Healthcare products Regulatory Agency, 2014).

1.6.3 The European Medicines Agency has issued good practice guidance on minimising risk and preventing medication errors (European Medicines Agency, 2015a), with separate guidance for users specific to high-strength insulins (European Medicines Agency, 2015b).

1.7 Monitoring blood glucose

1.7.1 In hospital, people with diabetes require frequent blood glucose checks. For the majority of those on insulin, this is done using a capillary blood ('finger-prick') test at the bedside, measured before each meal and at bedtime. The ideal blood glucose range varies according to the individual's frailty (see table 1) (University Hospitals of Leicester, 2019). The blood glucose level indicates whether the patient's insulin dose needs to change, and by how much.

Table 1 Adult inpatient blood glucose targets

Characteristics of the person	Target blood glucose level (mmol/litre)
Standard	6–10 (4–12 is acceptable)
Older adult/frail	7.8–10
Moderate to severe frailty/end of life	7.8–15 (individualised to avoid hypoglycaemia)

1.8 Hypoglycaemia

1.8.1 When a person's blood glucose level becomes too low, this is called hypoglycaemia. People suffering from hypoglycaemia may feel dizzy, tired and sweaty. They may also be confused, pale, weak and hungry, and have a fast heart rate and blurred vision. People with hypoglycaemia can lose consciousness and convulse and, in extreme cases, become comatose or die. Some people will experience warning signs that hypoglycaemia is coming on, while for others it can be sudden.

1.8.2 Hypoglycaemia can happen for a variety of reasons, including exercising more than usual, eating less than usual, drinking alcohol or receiving too high a dose of insulin. Hypoglycaemia is the main side effect of insulin treatment.

1.8.3 It is recommended that all non-pregnant adults with diabetes in hospital who have a blood glucose level of less than 4 millimoles/litre (mmol/litre), whether or not they have symptoms of hypoglycaemia, should be treated for hypoglycaemia (Joint British Diabetes Societies for Inpatient Care, 2022).

1.9 Insulin administration

1.9.1 At home, many people with diabetes administer their own insulin or are supported by friends, relatives or carers. When people with diabetes are admitted to hospital, it is common practice for healthcare professionals to take over their insulin administration. Therefore, staff in clinical areas who may care for people with diabetes need timely access to equipment for monitoring blood glucose levels and administering insulin, and the skills to do this safely.

1.10 Never Events

1.10.1 The NHS Never Events policy and framework defines Never Events as: 'Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers' (NHS Improvement, 2018).

1.10.2 An 'overdose of insulin due to abbreviations or incorrect device' is categorised by NHS Improvement (2021) as a Never Event. In this context, 'overdose refers to when:

- a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system.' (for example, abbreviating to 1IU may look like 110 or 11 units)
- 'a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin.

- a healthcare professional withdraws insulin from an insulin pen or pen refill [cartridge] and then administers this using a syringe and needle’.

1.10.3 The Healthcare Safety Investigation Branch has conducted a number of investigations into Never Events, and recently published a national learning report summarising these investigations (**Healthcare Safety Investigation Branch, 2021**). This report highlights that many incidents considered to be Never Events do not have strong or systemic barriers to prevent their occurrence, and are therefore not wholly preventable.

1.10.4 The withdrawal of insulin from a pen device falls into this category. In 2016, NHS Improvement issued a national patient safety alert about the ‘Risk of severe harm and death due to withdrawing insulin from pen devices’ (NHS Improvement, 2016). Several recommendations were made.

- Staff should be warned that extracting insulin from pen devices or cartridges is dangerous and should not happen.
- Organisations should ensure that staff are trained and competent in using insulin pens; relevant training should be available.
- Staff should be routinely provided with safety needles and equipment to safely remove and dispose of used insulin pen needles.
- Staff should be trained in correctly using safety needles.

2 The reference event

This investigation used the following patient safety incident, referred to as ‘the reference event’, to consider:

- the systemic risks associated with administering high-strength insulin from a pen device to people in hospital
- the barriers that exist to mitigate against these risks.

2.1 About the patient

2.1.1 Kathleen was 73 years old at the time of the reference event. She had type 2 diabetes as well as a range of other medical conditions, including chronic obstructive pulmonary disease, hypertension (high blood pressure), chronic kidney disease (a long-term condition with loss of kidney function) and lymphoedema (another long-term condition that causes swelling in a person’s body’s tissues).

2.1.2 At home, Kathleen's Husband managed all aspects of her care and medication. This included monitoring her blood glucose levels and adjusting her insulin dose accordingly. He also co-ordinated her health appointments and liaised with care professionals on her behalf.

2.2 Prescribing history

2.2.1 In 2015, Kathleen was prescribed Humulin R U-500 insulin to manage her diabetes. At this time the insulin was supplied as a multidose vial, which is a glass container with a rubber top that contains more than one dose of the medication. This medication is five times the strength of the standard licensed insulins available in the UK, at 500 units/ml versus the standard 100 units/ml. The decision to use high-strength insulin was based on the need to improve Kathleen's blood glucose levels while reducing the volume of insulin she had to inject.

2.2.2 The high-strength preparation meant that Kathleen was injected with one fifth of the usual volume of insulin, while receiving the same dose of insulin to treat her diabetes. When high volumes of insulin are injected subcutaneously, there is a risk that the insulin pools under the person's skin and is not properly absorbed. It can also be uncomfortable for the individual.

2.2.3 In 2018, the manufacturers of Humulin R U-500 insulin launched a pre-filled disposable pen device, called a KwikPen (see figure 3), in addition to the vial presentation. Kathleen was prescribed the Humulin R U-500 KwikPen insulin device, and she and her Husband were trained on how to use it.

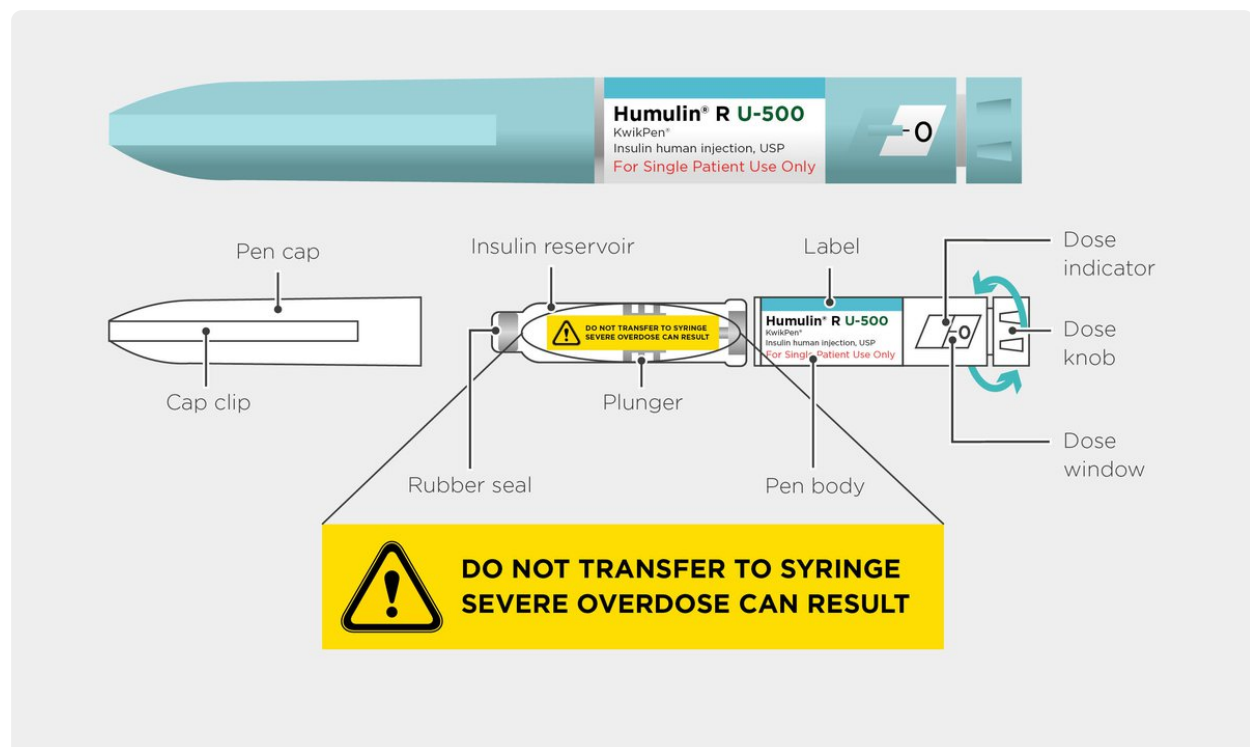


Figure 3 Humulin R U-500 KwikPen

2.3 Kathleen's admission to hospital in 2019

2.3.1 While at home, Kathleen experienced chest pain and breathlessness. Kathleen's family called an ambulance, and her Husband prepared a bag of her medication, including a new insulin pen and approximately six or seven insulin pen needles. Kathleen usually used two insulin pen needles each day.

2.3.2 The ambulance service transported Kathleen to the local emergency department, where she was admitted to hospital with pain due to gallstones.

2.3.3 The next day (day 2), Kathleen was transferred from the emergency department to a surgical ward for further assessment. Her Husband told staff on the surgical ward about Kathleen's medication, including that her insulin (Humulin R U-500) was five times stronger than standard insulin. Staff took over the management of Kathleen's diabetes while she was on the ward.

2.3.4 On day 3, Kathleen was reviewed by a diabetes specialist nurse (DSN), who noted that Kathleen's usual insulin dose was 140 units twice a day from her insulin pen device. As Kathleen was not eating as much as usual, the DSN recommended that her insulin dose be reduced to 60 units twice a day, with a target blood glucose level of 5–10mmol/litre.

2.3.5 On day 5, Kathleen was transferred to a surgical ward at a different hospital within the same Trust. On this surgical ward, patient care was led by nurse practitioners (NPs) and overseen by a surgical consultant.

2.3.6 On day 6, the consultant requested that a DSN review Kathleen. At 14:55 hours, a second DSN visited Kathleen and recorded in the medical notes that Kathleen was currently receiving 60 units Humulin R U-500 twice a day. They suggested reducing the evening dose by 20% (12 units). The morning dose remained at 60 units.

2.3.7 The DSN discussed their recommendation to reduce the evening dose by 20%, to 48 units, with the NP on the ward. The NP then altered the evening prescription from 60 to 48 units of Humulin R U-500, as per the recommendation from the DSN.

2.3.8 At approximately 16:45 hours, Kathleen's blood glucose level was 4mmol/litre, which was below her target of 5–10mmol/litre. The nurse caring for Kathleen was concerned that administering further insulin would make Kathleen hypoglycaemic and checked the Trust guidance. The guidance advised staff to treat the hypoglycaemic event and then give insulin as prescribed.

2.3.9 At 17:46 hours, the nurse took Kathleen's pre-filled disposable insulin pen device from the ward fridge in the treatment room. The nurse used a hand-held device to access the Kathleen's electronic medication chart on the electronic prescribing and medicines administration system. They noted that the NP had amended the prescription from 60 to 48 units of Humulin R U-500 insulin.

2.3.10 There were no available pen needles to attach to Kathleen's insulin pen device, so the nurse used a U-100 insulin syringe with integral needle to withdraw 48 units of insulin from the U-500 pre-filled insulin pen device. They then asked another nurse on duty to "double check". The nurse then administered Kathleen with 48 units, as measured in the U-100 insulin syringe, of Humulin R U-500 insulin. At five times the usual insulin strength, this dose was equivalent to 240 units of insulin – five times the prescribed dose Kathleen should have received. Kathleen became hypoglycaemic and was treated with glucose drinks to correct her low blood glucose.

2.3.11 On day 7, in response to Kathleen's hypoglycaemia the previous night, Kathleen's morning insulin dose was reduced by 20%. This brought it in line with the prescribed evening dose, at 48 units.

2.3.12 At 10:33 hours, another nurse attempted to administer Kathleen's prescribed dose of 48 units of insulin. They noticed the insulin pen device would only measure insulin in increments of 5 units, which meant that 48 units could not be administered. This nurse asked colleagues how the previous evening's dose had been administered. They explained that the insulin had been withdrawn into an insulin syringe because the ward did not have any pen needles to administer from the pen. The nurse also gave Kathleen her insulin with an insulin syringe.

2.3.13 At 11:30 hours, Kathleen had a second hypoglycaemic event and her low blood glucose was again treated. The DSN team was informed, and they advised that Kathleen's evening dose should be reduced by a further 20% to 38 units. The advice was passed to the NP, who amended the prescription.

2.3.14 At 14:50 hours, Kathleen's Husband spoke with the NP about the hypoglycaemic events. The NP attempted to reassure him by telling him that the evening dose would be reduced to 38 units. He queried how 38 units could be administered from a pen device that measures in increments of 5 units. The NP asked the nurse how the previous 48 units of insulin had been administered if the insulin pen device measures in increments of 5 units. The NP then became aware that on at least two occasions, Kathleen had been administered insulin using an insulin syringe with the dose withdrawn from the insulin pen device.

2.3.15 The prescription was then changed to 35 units and Kathleen received further doses of insulin from the pre-filled insulin pen device via a safety pen needle. Kathleen made a full recovery from the hypoglycaemic events.

2.3.16 Kathleen required more than one treatment to correct her blood glucose levels, as effect of the Humulin R insulin continued for about 12 hours after being given.

3 Involvement of the Healthcare Safety Investigation Branch

This section of the report outlines how the Healthcare Safety Investigation Branch (HSIB) identified issues around the safeguards in place to prevent high strength insulin being withdrawn from the pen device by hospital staff. It also describes the criteria HSIB used to decide whether to go ahead with the investigation, and the methods and evidence used in the investigation process.

3.1 Notification of the reference event

3.1.1 The reference event was referred to the HSIB by the Medical Director of the Trust where the event occurred. The safety risks associated with the use of high-strength insulin administered from a pen device in hospital were identified by HSIB as a patient safety risk priority for investigation.

3.2 Decision to investigate

3.2.1 HSIB's Chief Investigator authorised a full national investigation based on HSIB's patient safety risk criteria (see below).

Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?

National patient safety alerts have highlighted that errors in insulin administration can cause severe harm and death (National Patient Safety Agency, 2010; NHS Improvement, 2016).

Administering high-strength insulin using equipment and techniques other than those recommended by the manufacturer can lead to the patient receiving the incorrect amount of insulin. This can result in erratic blood glucose control and avoidable harm, including severe physical and/or emotional harm, a longer stay in hospital and even death. It can also contribute to a loss of trust and confidence between patients and their families and staff. National patient safety alerts have highlighted that errors in insulin administration can cause severe harm and death (National Patient Safety Agency, 2010; NHS Improvement, 2016).

Systemic risk – how widespread and how common a safety issue is this across the healthcare system?

Complications with administering high-strength insulin cross organisational and departmental boundaries and involve multiple healthcare professionals and services. The complexity of insulin prescribing and administration is likely to increase as more insulins enter the market and growing numbers of patients require high-strength versions. This increasing complexity and variation will challenge the safety of healthcare systems.

Eleven insulin overdoses resulting from use of the incorrect administration device, classed as Never Events, were reported on the NHS National Reporting and Learning System between 1 April 2017 and 31 March 2022 (NHS England and NHS Improvement, 2019a, 2019b, 2020, 2021, 2022a). A review published in 2022 confirmed this safety alert as an enduring standard that remains valid and is unlikely to change in the immediate future, with actions 'that should be embedded systematically across NHS provider organisations' (NHS England and NHS Improvement, 2022b).

Learning potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

Evidence from the referral suggested potential learning around:

- use of and staff knowledge of Humulin R U-500 insulin, which is unlicensed for use in England
- staff knowledge of high-strength insulin
- the role of the diabetes specialist nurse team
- procurement processes across the NHS for pen needles for insulin pen devices.

3.3 Evidence gathering and investigation

3.3.1 Evidence gathered during the investigation included:

- a review of Kathleen's clinical records, the Trust incident report and relevant Trust policies and procedures
- interviews with Kathleen, her Husband and her Daughter
- interviews with healthcare staff involved in Kathleen's care
- a review of the research literature, guidance and position papers associated with the use of high-strength insulin and administering insulin in hospital.

The start of the investigation was delayed by ongoing demands on NHS provider services and HSIB processes caused by the COVID-19 pandemic.

3.4 Investigation process and methodology

3.4.1 The investigation used the Systems Engineering Initiative for Patient Safety (SEIPS) (see figure 4) to explore issues relating to the reference event (Carayon et al, 2006; Holden et al, 2013).

Figure 4 A representation of the SEIPS framework

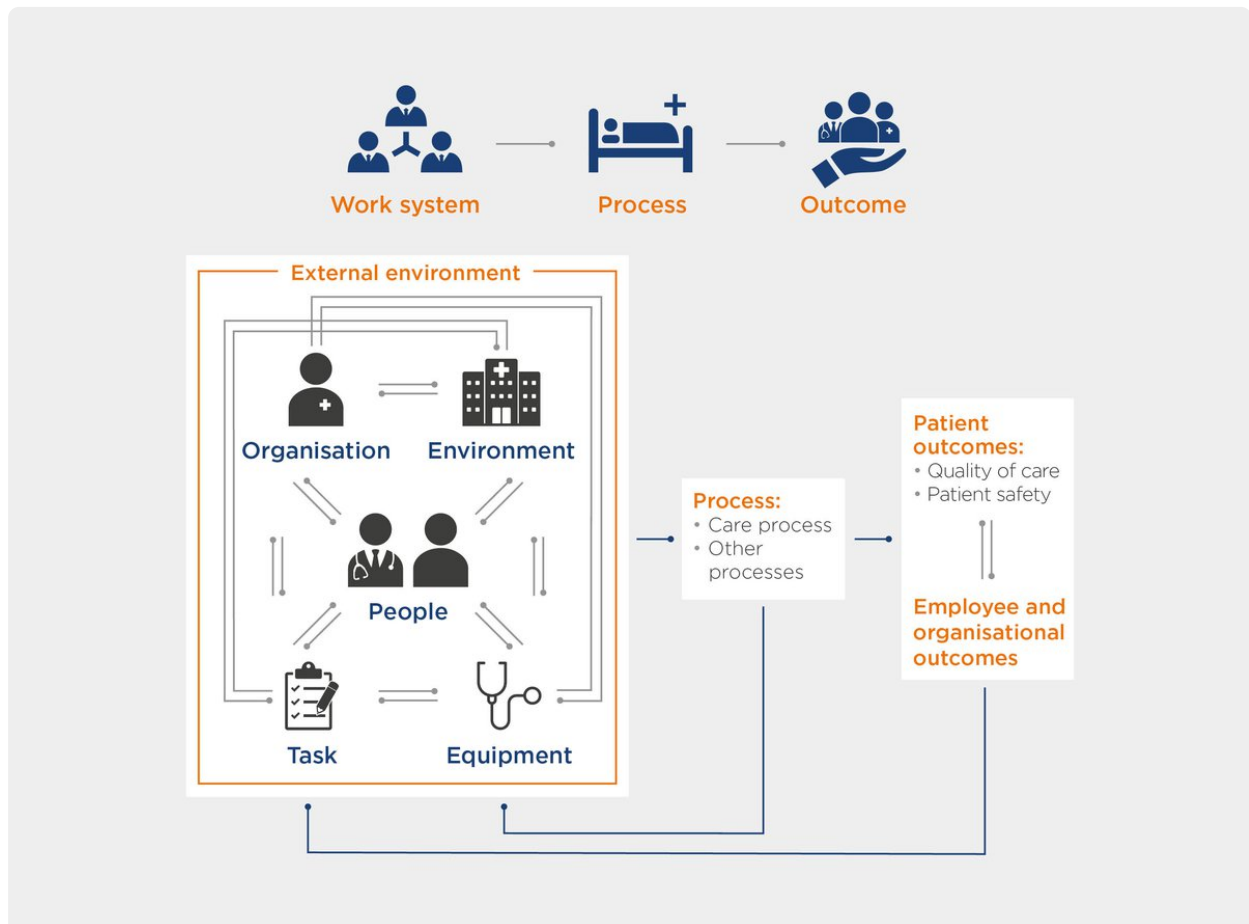


Figure 4 A representation of the SEIPS framework

4 Analysis and findings – the reference event

This section describes the investigation findings in relation to the reference event. The reference event highlights a range of systemic factors that contributed to Kathleen's insulin overdose, and which may impact on other potential cases of overdose of high-strength insulin. The investigation focussed solely on administering high-strength insulin. Other aspects, such as prescribing, were outside of the investigation's scope.

4.1 Unlicensed high-strength insulin in semi-routine use

4.1.1 The decision to prescribe high-strength insulin to Kathleen was made by the diabetes consultant responsible for Kathleen's diabetes care. The use of high-strength insulin enabled the same insulin dose to be given in a smaller volume of fluid (see figure 5). The investigation heard that the Trust had had a maximum of 14 patients on Humulin R U-500 insulin under their care. Those patients who had initially been prescribed the vial presentation were transferred over to the KwikPen when it became available.

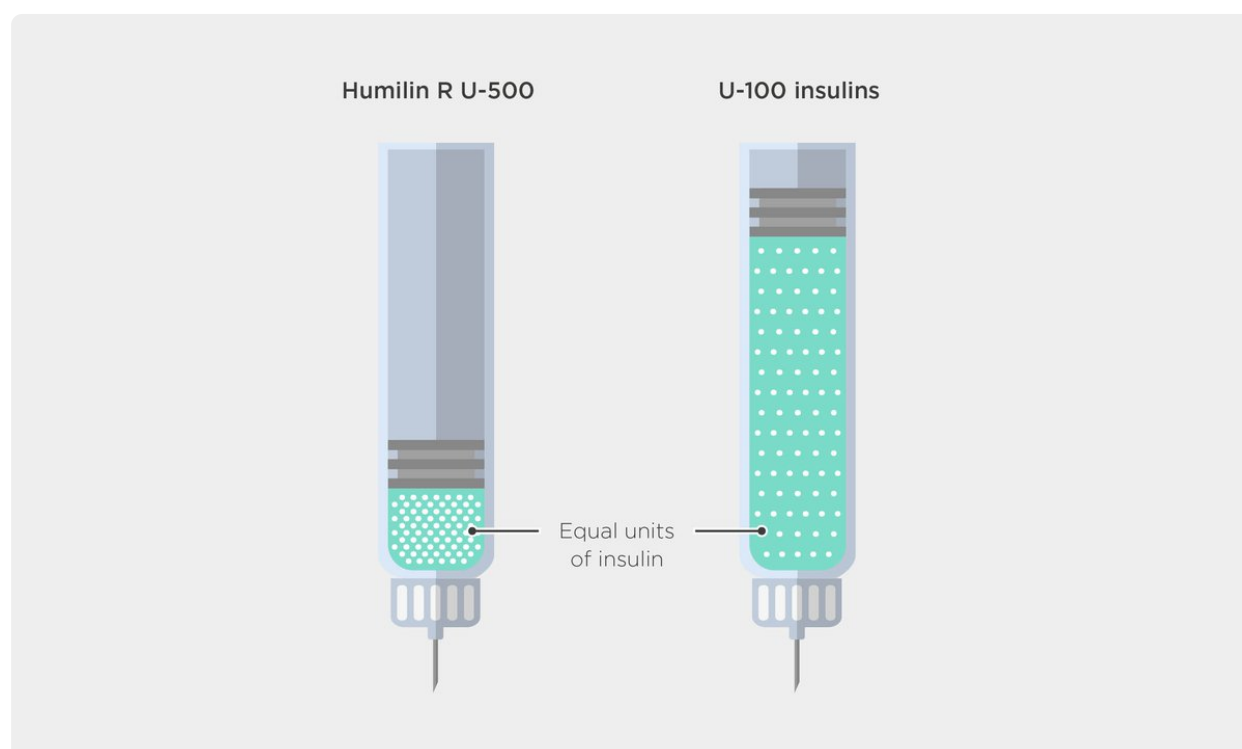


Figure 5 Illustration to show the effect of changing from a 500 unit/ml preparation

4.1.2 To prevent errors with administering this insulin, Kathleen and her Husband were given comprehensive training on its use. This safeguard was lost when Kathleen was admitted to hospital and staff took over the role of administering her insulin.

4.1.3 Nurses involved in Kathleen's care at the time of the incident told the investigation they were unfamiliar with this insulin. The investigation heard from the diabetes specialist nurses (DSNs) that there was only one other patient under the Trust's care on Humulin R U-500 insulin that the team was aware of at the time of the interview. Previously there had been a "handful" of patients that the Trust managed on this insulin.

4.1.4 The Lead Diabetes Consultant told the investigation that Humulin R U-500 insulin was only prescribed by a consultant diabetologist and was considered it to be a 'non-formulary' medication within their Trust. A formulary is a list of medications that have been approved as

safe, effective and cost-effective to use within a defined geographical area. Where a medication is not on the formulary list, the prescriber needs to gain approval for its use, from the Trust or Area Prescribing committee according to local policy. Different safety controls may exist for formulary and non-formulary medications.

4.1.5 The DSN who recommended reducing Kathleen's insulin dose by 20% to 38 units did not know that the pen device could only measure in 5 unit increments. The investigation heard that the Trust had a 'U-500' policy, but this was not readily accessible and did not include recommendation on device use. The investigation highlighted gaps in knowledge within the specialist team about the insulin pen device.

4.2 Staff knowledge of high-strength insulin

4.2.1 The investigation met with the Kathleen and her family, who described their concerns that professionals generally appeared to lack knowledge of high-strength insulin. Kathleen's Husband said that although he told the nurses about the high-strength insulin when Kathleen was admitted to hospital, he worried this would not be understood.

4.2.2 Kathleen's family had concerns that the nurse administering Kathleen's insulin in hospital might not be the staff member they had spoken with. Because of this, her Husband felt that "...it puts the responsibility on me" to ensure that Kathleen was given the correct dose.

4.2.3 During interviews and observations, the nurses who had been involved in Kathleen's care talked about how their experience had changed their working practices.

4.2.4 One of the nurses told the investigation:

"Insulin is complicated. Once upon a time it was really straightforward, and I know it's better for the patients that there's more of a selection, but it means everyone needs to be an expert in diabetes – as well as everything else. I haven't even come across a U-500 [insulin]. It's not that common to get the 200 or 300 [units/ml insulin]. I'm not sure I would even notice unless it was pointed out."

4.2.5 Electronic prescribing and administration systems may be effective at reducing insulin errors (Rayman and Kar, 2020). The investigation heard that nursing staff were used to the electronic prescribing and administration system highlighting high doses and concentrations. They felt that there were opportunities to apply similar safeguards for Humulin R U-500 insulin, to draw the nurse's attention to the high-dose formulation during administration.

4.2.6 The investigation noted that Kathleen's prescription did not state that the insulin should be administered via the KwikPen device (see figure 6).

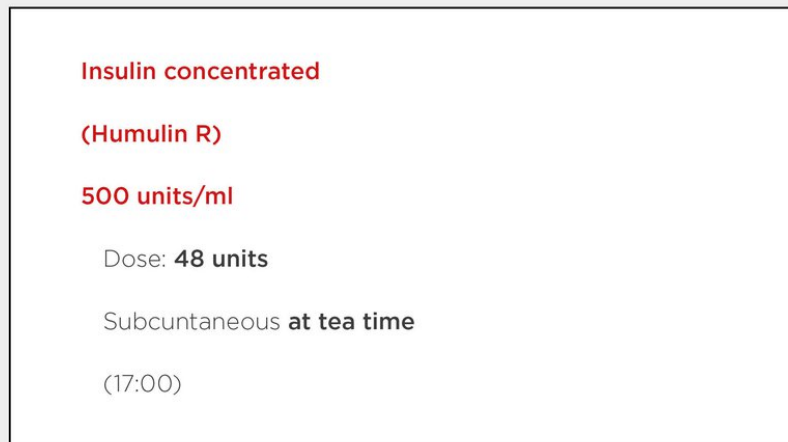


Figure 6 Kathleen's electronic prescription record

4.3 Insulin training

4.3.1 The DSNs told the investigation that many resources and education on insulin are offered, to staff including education on how to use insulin pen devices. They explained that their role is to try to “support and educate” Trust staff without issuing blame for mistakes.

4.3.2 A full day of interactive insulin safety training, which included training on the use of insulin pen devices, was offered twice yearly to staff who wished to access it. The investigation was told that barriers to receiving this training included a high rate of staff turnover and a high staff workload, which prevented staff from being released for training. The DSNs interviewed reported that they had “worked tirelessly” to prevent staff withdrawing insulin from insulin pen devices.

4.3.3 The diabetes team said that they had been campaigning to mandate the national ‘Safe Use of Insulin’ e-learning programme (e-learning for healthcare, 2021) for Trust staff involved with insulin use for several years. However, at the time of the incident, this request had been rejected due to the volume of other mandated training. Insulin safety is now included in the Trust's mandatory training.

4.3.4 One ward nurse told the investigation that they had had it “drilled in [to] never, never omit insulin”. When left with the dilemma that Kathleen was due a dose of insulin and there were no pen needles on the ward, the nurse felt that she had no other way to give the insulin than to withdraw it from the insulin pen device. She shared that she had done this before, and that it used to be common practice to withdraw insulin from insulin pen cartridges some time ago. The investigation was told that withdrawing insulin from a pen device with a needle was not unique to their Trust, but was a practice that did still occur nationally.

4.3.5 The DSNs interviewed were aware of previous occasions when insulin had been withdrawn from a pen device using an insulin syringe and needle. A matron at the reference Trust told the DSNs that staff were doing this “much more” than the DSNs were aware.

4.4 The role of diabetes specialist nurses

4.4.1 Nurses at the Trust at which the reference event occurred told the investigation that they value the expertise of the DSNs. The specialist diabetes team covers multiple base sites, including the one where the reference event occurred. They also cover community hospitals, community diabetes services and mental health inpatient services.

4.4.2 The DSNs provide a service for new emergency admissions 7 days a week and support to other inpatient services Monday to Friday. This may align with the national recommendation to use a robust system to identify people with diabetes admitted to hospital for triage and referral to the diabetes team (Rayman and Kar, 2020).

4.4.3 Ward nurses told the investigation that they appreciate the guidance and contributions from the DSN team and would like more. They commented that staff caring for people admitted as an emergency were more used to dealing with people with complex diabetes medication regimens than staff working in non-emergency areas. The nursing staff felt that this was because DSNs were more present and visible in these clinical areas. They commented that a lack of resources meant that patients who are transferred from the emergency admissions wards “do not always get followed up” by DSNs while on other wards.

4.4.4 The Trust model of diabetes care meant that, at times, additional training and in-person support from the diabetes team was not always available in non-emergency admission areas.

4.4.5 The investigation heard that not all members of the diabetes team were familiar with the Humulin R U-500 pre-filled pen device (see section 4.2.5). Where patients are treated with infrequently used insulins or insulin administration devices, it is important that the diabetes team are trained in their use. The investigation was told that another option would be to consider changing to a different insulin or device.

4.4.6 The DSNs who contributed to the investigation talked about wanting funding to undertake courses on prescribing, and greater resources to offer 24/7 services.

4.5 Supply of pen needles

4.5.1 The investigation explored the reasons for taking insulin from the insulin pen device. Pen devices require insulin pen needles. The investigation heard that the supply of insulin pen needles on the ward was erratic. Staff would often use the pen needles that patients brought into hospital with them. After the supply of needles that Kathleen had taken into hospital was used up, no pen needles (standard or safety) could be found on the ward.

4.5.2 Lack of availability can result from storage issues, but also from problems with procurement. In the reference event, lack of availability of pen needles led to insulin being removed from the pen device and a readily available insulin syringe being used to administer the dose. The investigation was told that there was a lack of robust ordering and supply mechanisms at the ward level to prevent pen needles from running out. This is at odds with the patient safety alert requirement that provider organisations should ensure staff are 'routinely provided with safety needles' (NHS Improvement, 2016).

4.5.3 Safety pen needles are supplied directly to healthcare organisations across the NHS through NHS Supply Chain. At the time of the reference event, the safety pen needle had been removed from the product catalogue because the pen needle supplier had not renewed its contract with NHS Supply Chain.

4.5.4 The Trust told the investigation that it was not offered an alternative equivalent safety pen needle by NHS Supply Chain. Instead, as the pen needles in use disappeared from the list of products that could be ordered, wards and departments became individually responsible for purchasing pen needles from an alternative supplier, leading to a lack of or variation in procurement. Changing to a different pen needle may also require training staff in its use if the technique was different from the pen needle that it replaced.

4.5.5 NHS Supply Chain told the investigation that it had robust systems and process in place to support Trusts with alternatives when one product is no longer listed in the catalogue (see section 5.3.5). The investigation was not able to resolve the discrepancy in what it was told by the Trust and NHS Supply Chain.

5 Analysis and findings – the wider investigation

The reference event occurred in 2019 and since then other initiatives and recommendations have been made to improve insulin safety within the NHS.

The national investigation was limited in its scope by the COVID-19 pandemic and its impact on the NHS. The investigation was unable to conduct additional observation visits at other hospitals to gather specific further evidence on clinical practice that may have supported the wider findings in relation to high-strength insulin administration.

However, the investigation was able to review the relevant research literature and engage with national leaders in this area. Through this, the investigation has been able to make evidence-based safety observations to improve patient care within the hospital setting.

5.1 Unlicensed high-strength insulin in semi-routine use

5.1.1 The results of a national audit by the Association of British Clinical Diabetologists to understand the use of Humulin R U-500 in the UK were reported in 2016 (Dashora et al, 2016). A total of 67 out of 119 clinicians who responded to the survey said they were using 500 units/ml insulin; the most common reason for its use was that the patient needed a high daily insulin dose. The audit showed that use of 500 units/ml insulin varied across clinicians (see table 2). Most were using it in just a few patients, but some clinicians had more than 10 patients on the medication.

Table 2 Use of 500 units/ml insulin (Dashora et al, 2016)

Number of patients on 500 units/ml insulin	Clinicians responding, n (%)
0	52 (43.7)
1–5	46 (38.7)
6–10	11 (9.2)
11–20	8 (6.7)
21–50	2 (1.7)

5.1.2 The National Severe Insulin Resistance Service is a specially commissioned service that manages those patients who are most likely to require high-strength insulin. Its guidance for jointly managing patients on Humulin R U-500 insulin with GPs explains that these patients may require up to 2,000 units of insulin per day (Cambridgeshire and Peterborough Clinical Commissioning Group and Cambridge University Hospitals NHS Foundation Trust, 2020).

5.1.3 At the start of June 2022, three high-strength insulin preparations were licensed for use in the UK (MIMS, 2021). None of these has the same onset and duration of action in a person's body as Humulin R U-500 insulin. However, they add weight to the clinical need for insulin preparations with a concentration above 100 units/ml.

5.1.4 Information on the use of high-strength insulins in secondary care from 1 November 2020 to 31 October 2021 inclusive was obtained from NHS England and NHS Improvement. This showed that most high-strength insulins were provided as pre-filled disposable pen devices containing Toujeo (300 units/ml insulin glargine) or Humulin R U-500 (500 units/ml insulin human). The volumes of 200, 300 and 500 units/ml insulin and frequent use of pre-filled disposable pen devices suggests that high-strength insulin is becoming an increasingly common medication that NHS staff may encounter when caring for patients with diabetes.

5.1.5 The information from NHS England and NHS Improvement indicated that 500 units/ml insulin is usually supplied in the pre-filled disposable KwikPen device. However, 56 vials of 500 units/ml insulin were also issued from November 2020 to October 2021.

5.1.6 Problems are uncommon when people use Humulin R U-500 insulin at home or in their usual care setting. However, when they are admitted to hospital, the lack of familiarity with 500 units/ml insulin can lead to medication errors; such errors were widely reported before the pre-filled pen device became available (Institute for Safe Medication Practices, n.d.).

5.1.7 The annual use of more than 13,000 of the 500 units/ml insulin pre-filled disposable KwikPen devices (see section 5.1.4) suggests that it has become 'semi-routine'. However, because of restrictions on marketing unlicensed medications, information on such preparations is rarely included in reference texts and training material. It maybe helpful if unlicensed medications that are in widespread use were tracked by the regulator to enable an exploration of whether it might be appropriate for the manufacturer to apply for a UK marketing authorisation (product licence).

5.1.8 The Medicines and Healthcare products Regulatory Agency (MHRA) told the investigation that it does not monitor unlicensed medication volumes. The MHRA suggested that it is the responsibility of a medication's manufacturer to apply for the appropriate licence based on its knowledge of the volumes used in any geographical location, as it is in the manufacturer's best interests to ensure appropriate licences are sought.

HSIB makes the following safety observation

The intention of this safety observation is to ensure that there is oversight of when an unlicensed medication is being widely used by the medication regulator, as the restriction on advertising an unlicensed medication prevented this from being included in routine training and texts.

Safety observation O/2022/177:

It may be beneficial for systems to support regulators in identifying when large volumes of unlicensed medication are regularly being prescribed to patients. Regulators can then engage in dialogue with the manufacturer about applying for a UK product licence.

5.1.9 Adverse events relating to the use of unlicensed medications should still be reported to the Yellow Card scheme to enable the MHRA to evaluate further. The Yellow Card scheme is a voluntary reporting scheme that can be used by healthcare professionals, patients, carers and members of the public (Medicines and Healthcare products Regulatory Agency, 2022). Through this scheme, anyone can report an adverse reaction to a medication, be it mild or severe. This includes suspected adverse drug reactions associated with a medication overdose.

5.1.10 The entry of new medications into the market in the UK is managed through recognised processes. These include steps to identify and manage the risks associated with new products via regulatory processes, and there is specific guidance to minimise errors with high-strength insulin (see section 1.6). In the case of high-strength insulin, the regulatory process would include reviewing the strength and effectiveness of the warnings on the insulin pen, which aim to alert the user to the presence of high-strength insulin and associated risks (see figure 3). In Kathleen's case, the warnings on the pen proved ineffective. It is possible that use of an unlicensed medication bypasses these established processes.

5.1.11 The investigation heard that another system safeguard was the use of a local formulary. A formulary is a list of medications that have been approved as safe, effective and cost-effective to use within a defined geographical area. National guidance is available for the safety factors to consider when adding a new insulin preparation to a local formulary (Specialist Pharmacy Service, 2018). Where a medication is not on a local formulary, this safety net may also be bypassed. The investigation noted that the guidance only refers to when a new preparation is being considered, and not to products already listed on the formulary. This means that these products may not have undergone the same safety review as newer insulins added to the formulary.

5.2 Staff knowledge of high-strength insulin and insulin training

5.2.1 High-strength insulin presents challenges for hospital nurses, who are likely to be caring for patients using a range of insulin pen devices and insulin preparations. These include unfamiliarity with specific insulin preparations and the devices used to administer them. Dealing with high-strength insulin may require additional support from diabetes specialist nurses. The challenge of ensuring the staff are aware of and understand high-strength insulin and its

associated administration devices may also apply to other non-specialist practitioners in primary and acute care. In some organisations, especially non-hospital and long-term care settings, medication may be administered by a variety of different healthcare practitioners.

5.2.2 Training courses on insulin are readily available and free to healthcare professionals in the NHS (Cambridge Diabetes Education Programme, 2022; e-learning for healthcare, 2021; Primary Care Diabetes Society, 2020; University of Southampton, n.d.; EDEN, n.d.). Some of these courses include training on 500 units/ml insulin.

5.2.3 The investigation engaged with the NHS England and NHS Improvement National Diabetes Programme to understand the training and support available to ensure healthcare professionals are knowledgeable about insulin use relative to their clinical role. The investigation was told that the programme supports the cascade of workforce training by well-established national and regional clinical networks.

5.2.4 The investigation was told that training, appropriate to the person's level of responsibility, should be provided to all healthcare staff involved with insulin. The 'Diabetes: getting it right first time' report recommended that this should include a competency assessment (Rayman and Kar, 2020), as different competencies are required for different healthcare professionals depending on their role in prescribing, dispensing or administering insulin to patients. The investigation engaged with national leaders to consider how training and support for healthcare professionals could be enhanced to increase the knowledge around insulin use relative to each clinical role. The investigation was told that this would require support from a range of national stakeholders, and would need to be co-ordinated by a central NHS body to ensure it was effective.

HSIB makes the following safety observation

The intention of this safety observation is to ensure that the workforce has the necessary knowledge and skills to care for patients on insulin.

Safety observation 2022/175:

It may be beneficial for insulin training to be competency based and specific to the healthcare practitioner's role, in line with the 'Diabetes: getting it right first time' national specialty report.

5.2.5 The investigation was told that there is a national movement to increase the number of DSNs. The role of DSNs is to support non-specialist nurses in managing patients with diabetes. DSNs with the appropriate competencies – in education and training, as well in the clinical

aspects of managing patients with diabetes – can support non-specialist nurses to build their confidence in managing the complex tasks associated with diabetes management, including insulin administration.

5.2.6 A position statement from Diabetes UK (2019b), 'Defining who is a diabetes specialist nurse', recognises a lack of clarity around the role of the DSN. The statement recommends that there should be one common pathway to becoming a DSN, with an agreed minimum level of qualification.

HSIB makes the following safety observation

The intention of this safety observation is to ensure that there is clarity and consistency in the role and competency of the diabetes nurse specialist.

Safety observation O/2022/178:

It may be beneficial to conduct work to standardise the role, qualifications, training and competency of diabetes nurse specialists, as recommended in the Diabetes UK Position Statement.

5.2.7 In 2016, NHS Improvement issued a safety alert warning against withdrawing insulin from an insulin pen (NHS Improvement, 2016). A video to support this alert highlights the commonly used 100 units/ml insulin and the less commonly used 200 and 300 units/ml insulin (NHS Improvement, 2017). The video does not mention the unlicensed 500 units/ml insulin.

5.2.8 Strategies have previously been suggested to ensure a clear understanding of high-strength insulin (Dashora et al, 2016) and of the more commonly encountered 200 and 300 units/ml insulins (Johnson et al, 2017) among both health professionals and patients. In addition, the European Medicines Agency (2015b) advises patients, carers and healthcare professionals to 'take extra care when using high-strength insulin medicines and to carefully follow the recommendations'. Such publications have not proven to be a robust barrier to prevent high-strength insulin administration errors.

5.2.9 Further national work to address these issues may help to improve patient safety in this area.

HSIB makes the following safety observation

The intention of this safety observation is to ensure that there is a nationally agreed approach to how high-strength insulins should be safely used.

Safety observation O/2022/176:

It may be beneficial if national work was undertaken to review the robustness of the strategies to prevent administration errors with high-strength insulin and update accordingly.

5.2.10 Since this investigation started, Humulin R U-500 has been included in the British National Formulary (the key reference text for best practice, legal and professional guidelines relating to medication in the UK) (Joint Formulary Committee, 2022).

HSIB notes the following safety action

Safety action A/2022/052:

The British National Formulary has been updated to provide information to healthcare practitioners on Humulin R U-500 insulin.

5.3 Supply of pen needles

5.3.1 Regardless of whether an insulin pen is disposable or reusable, a single-use needle is required to administer the insulin. If the device is not being used for patient self-administration then these should be safety needles, which are designed to prevent needlestick injuries and the subsequent risk of transmitting a blood-borne infection. Wards where insulin pens are being used therefore need a robust supply of needles.

5.3.2 The guidance is that when professionals administer insulin from a pen device they should use safety, not standard, pen needles (FIT UK & FIT Ireland Forum for Injection Technique, 2020).

5.3.3 Huang and Dutta, (2000) commented that in healthcare, re-sheathing needles was common 'despite universal condemnation' and that this should not happen 'under any circumstances'. The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, state that:

'Needles must not be recapped after use unless the employer's risk assessment has identified that recapping is itself required to prevent a risk.'

(Health and Safety Executive, 2013).

5.3.4 The Health and Safety Executive (2013) also highlights the situation where patients may provide needles, such as for insulin administration, and expect a healthcare professional to use them. Employers should conduct a risk assessment to determine whether this might occur and, if this is foreseeable, 'make arrangements to ensure to ensure that employees have safe systems of work and the appropriate information, training and equipment to deal with this situation'.

5.3.5 The investigation engaged with NHS Chain Supply to explore a possible recommendation to ensure that essential equipment remains available to staff to deliver care as intended. NHS Supply Chain explained that it has robust procedures and processes to support trusts in obtaining alternative products when a product is no longer listed in the catalogue. It said that a range of insulin safety pen needles has always been available to trusts, and that they are interchangeable between insulin pen devices. This meant that one pen needle being delisted would not prevent a trust from ordering another insulin safety pen needle.

5.3.6 NHS Supply Chain told the investigation a rigorous response process is activated when it becomes aware of supply disruption issues or when products in the catalogue and within the existing framework become unavailable. This is the 'SIREN' safety intervention, which involves understanding the extent of the supply problem and determining who relies on the affected product, how much is used and what alternatives can be offered. This information is shared with trust procurement leads via an 'Important Customer Notice', which informs local clinical choice to enable safe care to continue. NHS Supply Chain works in collaboration with the Department of Health and Social Care and NHS England and NHS Improvement.

5.4 Summary and conclusion

5.4.1 The investigation explored the systemic risks associated with administering high-strength insulin from a pen device to people in hospital, and the barriers in place to mitigate against these risks.

5.4.2 The investigation learnt that high-strength insulin preparations have been introduced to healthcare to cater for people with diabetes who require a high dose of insulin and are increasingly being prescribed within England.

5.4.3 It is widely recognised that high-strength insulins need careful management to minimise the risk of medication errors. Safety measures include ensuring that high-strength insulins are only supplied in a pre-filled pen device, and that insulin should only be administered using that device.

5.4.4 For these measures to be effective, however, staff caring for people on high-dose insulin must: (1) be aware of the risks; (2) have access to the required equipment for delivering high-dose insulin; and (3) have the relevant competencies. Where the system does not support staff to meet these requirements, staff may adapt care processes to ensure that patients continue to receive their insulin.

5.4.5 Insulin syringes are designed to measure the insulin dose of the standard 100 units/ml solution. It is important that high-strength insulin is not withdrawn from an insulin pen device with an insulin syringe and needle as this can lead to the patient receiving of insulin overdose, which may cause severe patient harm and even death.

6 Summary of findings, safety observations and safety action

Risks associated with the safe administration of high-strength insulin from a pen device to people in hospital have been identified across England. The investigation worked with healthcare staff, regulators, and professional and other national bodies to understand why these risks persist across the system.

6.1 Findings

The investigation's findings are summarised below.

Use of high-strength insulin

- Trusts vary in their use of high-strength insulin and the number of patients on these medications.
- Healthcare staff in any speciality may be required to care for hospital patients prescribed high-strength insulin.
- Restrictions on promoting the use of an unlicensed medication have made it difficult to communicate the risks associated with the 'semi-routine' use of Humulin R U-500 insulin.

Staff knowledge and skills

- Nursing staff were not always familiar with the range of different high-strength insulins and associated pen devices.
- Variation was seen in the training and competency assessment of healthcare professionals with respect to the administration of insulin.
- National safeguards are inadequate to support the safe use of high-strength insulin by healthcare professionals.

- There is a lack of standardisation in the role and training of diabetes specialist nurses.
- Inconsistent numbers of diabetes specialist nurses employed across trusts to support upskilling of ward staff in relation to diabetes management, including on the use of high-strength insulin.

Equipment

- Administering a high-strength insulin via a pen device is a complex task that requires co-ordination across and between different departments to ensure that the insulin and associated equipment required are readily available in the clinical area when they are needed. The consequences of not using the insulin pen administration device as intended can be significant, particularly with high-strength insulins.
- The equipment for administering insulin via a pen device would usually be obtained through NHS Supply Chain.
- Contract changes meant that a safety needle in widespread use across England disappeared from the catalogue.
- NHS Supply Chain has confirmed it has systems and processes in place to support trusts with an alternative where a previously available product is no longer listed.

6.2 Safety observations and safety action

HSIB makes the following safety observation

The intention of this safety observation is to ensure that the workforce has the necessary knowledge and skills to care for patients on insulin.

Safety observation O/2022/175:

It may be beneficial for insulin training to be competency based and specific to the healthcare practitioner's role, in line with the 'Diabetes: getting it right first time' national specialty report.

The intention of this safety observation is to ensure that there is a nationally agreed approach to how high-strength insulins should be used safely.

Safety observation O/2022/176:

It may be beneficial if national work was undertaken to review the robustness of the strategies to prevent administration errors with high-strength insulin and update accordingly.

The intention of this safety observation is to ensure that there is oversight of when an unlicensed medication is being widely used by the medication regulator, as the restriction on advertising an unlicensed medication prevented this from being included in routine training and texts.

Safety observation O/2022/177:

It may be beneficial for systems to support regulators in identifying when large volumes of unlicensed medication are regularly being prescribed to patients. Regulators can then engage in dialogue with the manufacturer about applying for a UK product licence.

The intention of this safety observation is to ensure that there is clarity and consistency in the role and competency of the diabetes nurse specialist.

Safety observation O/2022/178:

It may be beneficial to conduct work to standardise the role, qualifications, training and competency of diabetes nurse specialists, as recommended in the Diabetes UK Position Statement.

HSIB notes the following safety action

Safety action A/2022/052:

The British National Formulary has been updated to provide information to healthcare practitioners on Humulin R U-500 insulin.

7 References

Cambridge Diabetes Education Programme. (2022) Home / safe use of insulin in hospital [Online]. Available at <https://www.cdep.org.uk/safe-use-of-insulin-in-hospital.html> (Accessed 12 June 2022).

Cambridgeshire and Peterborough Clinical Commissioning Group and Cambridge University Hospitals NHS Foundation Trust. (2020) Shared care guideline Humulin R® U500 insulin for patients with severe insulin resistance. Version 4 [Online]. Available at <https://www.cambridgeshireandpeterboroughccg.nhs.uk/easysiteweb/getresource.axd?assetid=10913&type=0&servicetype=1> (Accessed 25 November 2021).

Carayon, P., Schoofs Hundt, A., Karsh, B. T., Gurses, A. P., Alvarado, C. J., Smith, M. and Flatley Brennan, P. (2006) Work system design for patient safety: the SEIPS model. Quality and Safety in Health Care, 15 (1), i50-i58 [Online]. DOI: 10.1136/qshc.2005.015842

Dashora, U., Macklin, A., Ryder, B., Castro, E. (2016) Clinical use of Humulin R U-500 insulin in the UK: results of the first Association of British Clinical Diabetologists' U-500 audit. British Journal of Diabetes, 16 (4), 185-187.

Diabetes UK. (2019a) New stats people living with diabetes: number of people with diabetes reaches 4.7 million [Online]. Available at https://www.diabetes.org.uk/about_us/news/new-stats-people-living-with-diabetes (Accessed 26 April 2022).

Diabetes UK. (2019b) Defining who is a diabetes specialist nurse (adult nursing). [Online]. Available at <https://www.diabetes.org.uk/resources-s3/2019-03/Position%20statement%20defining%20who%20is%20an%20Adult%20Diabetes%20Specialist%20Nurs> (Accessed 12 April 2022).

EDEN. (n.d.) Education [Online]. Available at <https://www.edendiabetes.com/education> (Accessed 12 June 2022).

e-learning for healthcare. (2021) Safe use of insulin [Online]. Available at <https://www.e-lfh.org.uk/programmes/safe-use-of-insulin/> (Accessed 16 March 2022).

European Medicines Agency. (2015a) Good practice guide on risk minimisation and the prevention of medication errors [Online]. Available at www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-risk-minimisation-prevention-medication-errors_en.pdf (Accessed 12 June 2022).

European Medicines Agency. (2015b) Guidance on prevention of medication errors with high strength insulins [Online]. Available at https://www.ema.europa.eu/en/documents/medication-error/insulins-high-strength-guidance-prevention-medication-errors_en.pdf#:~:text=EMA%2F134145%2F2015%20Guidance%20on%20prevention%20of%20medicati (Accessed 12 June 2022).

FIT UK & FIT Ireland Forum for Injection Technique. (2020) The UK & IRE injection and infusion technique recommendations, 5th edition II [Online]. Available at https://www.fit4diabetes.com/files/3816/2374/8804/BD5119_FIT_UK_Recommendations_2020_AW.pdf (Accessed 16 March 2022).

Health and Safety Executive. (2013) Health and safety (sharp instruments in healthcare) regulations 2013: guidance for employers and employees [Online]. Available at <https://www.hse.gov.uk/pubns/hsis7.pdf> (Accessed 25 April 2022).

Healthcare Safety Investigation Branch. (2021) National learning report never events: analysis of HSIB's national investigations [Online]. Available at https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Never_Events_-_analysis_of_HSIBs_national_investigations_Report_V09.pdf (Accessed 16 March 2022).

Holden, R. J., Carayon, P., Gurses, A. P., Hoonakker, P., Hundt, A. S., Ozok, A. A. and Rivera-Rodriguez, A. J. (2013) SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics*, 56 (11), 1669-1686.

Huang, A. and Dutta, D. (2000) Needles should not be re-sheathed. *Postgraduate Medical Journal*, 76 (891), 32.

Institute for Safe Medication Practices. (n.d.) U-500 insulin errors – consumer med safety [Online]. Available at <https://consumermedsafety.org/tools-and-resources/insulin-safety-center/u-500-insulin-errors> (Accessed 25 November 2021).

Johnson, J. L., Downes, J. M., Obi, C. K., Asante, N. B. (2017) Novel concentrated insulin delivery devices: developments for safe and simple dose conversions. *Journal of Diabetes Science and Technology*, 11 (3), 618-622.

Joint British Diabetes Societies for Inpatient Care. (2022) The hospital management of hypoglycaemia in adults with diabetes mellitus [Online]. Available at https://abcd.care/sites/abcd.care/files/site_uploads/JBDS_Guidelines_Current/JBDS_01_HypoGuideline%20_March_2022.pdf (Accessed 4 April 2022).

Joint Formulary Committee. (2022) Insulin: medicinal forms [Online]. Available at <https://bnf.nice.org.uk/medicinal-forms/insulin.html> (Accessed 25 April 2022).

Medicines and Healthcare products Regulatory Agency (2014) The supply of unlicensed medicinal products ("specials"). MHRA guidance note 14 [Online]. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf (Accessed 22 November 2021).

Medicines and Healthcare products Regulatory Agency. (2022) Yellow Card [Online]. Available at <https://yellowcard.mhra.gov.uk> (Accessed 20 January 2022).

MIMS. (2021) Insulin preparations [Online]. Available at <https://www.mims.co.uk/table-insulin-preparations/diabetes/article/1427971> (Accessed 5 June 2022).

MIMS. (2022) Insulin delivery devices [Online]. Available at <https://www.mims.co.uk/insulin-delivery-devices/diabetes/article/1579758> (Accessed 5 June 2022).

National Patient Safety Agency. (2010) Rapid response report 013. Safer administration of insulin [Online]. Available at <https://webarchive.nationalarchives.gov.uk/ukgwa/20171030124645/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=74287> (Accessed 10 June 2022).

NHS. (2019) Diabetes [Online]. Available at <https://www.nhs.uk/conditions/diabetes> (Accessed 22 November 2021).

NHS England and NHS Improvement (2019a) Never Events reported as occurring between 1 April 2017 and 31 March 2018 – final update [Online]. Available at https://www.england.nhs.uk/wp-content/uploads/2020/08/Annual_NE_report_1_April_2017_to_31_March_2018_FINAL_V5.pdf (Accessed 30 November 2021).

NHS England and NHS Improvement (2019b) Provisional publication of Never Events reported as occurring between 1 April 2018 and 31 March 2019 [Online]. Available at https://www.england.nhs.uk/wp-content/uploads/2020/08/Provisional_publication_-_NE_1_April_2018_to_31_March_2019.pdf (Accessed 30 November 2021).

NHS England and NHS Improvement. (2020) Never Events reported as occurring between 1 April 2019 and 31 March 2020 – final update [Online]. Available at <https://www.england.nhs.uk/wp-content/uploads/2021/01/Final-update-NE-1-April-2019-31-March-2020.pdf> (Accessed 30 November 2021).

NHS England and NHS Improvement. (2021) Provisional publication of Never Events reported as occurring between 01 April 2020 and 31 March 2021 [Online]. Available at <https://www.england.nhs.uk/wp-content/uploads/2021/05/Provisional-publication-NE-1-April-2020-31-March-2021.pdf> (Accessed 30 November 2021).

NHS England and NHS Improvement. (2022a) Provisional publication of Never Events reported as occurring between 01 April 2021 and 31 March 2022 [Online]. Available at <https://www.england.nhs.uk/wp-content/uploads/2022/05/Provisional-publication-NE-1-April-31-March-2022.pdf> (Accessed 18 June 2022).

NHS England and NHS Improvement. (2022b) Enduring standards that remain valid from previous patient safety alerts [Online]. Available at <https://www.england.nhs.uk/patient-safety/patient-safety-alerts/enduring-standards/standards-that-remain-valid/> (Accessed 11 April 2022).

NHS Improvement. (2016) Risk of severe harm and death due to withdrawing insulin from pen devices [Online]. Available at https://www.england.nhs.uk/wp-content/uploads/2019/12/Patient_Safety_Alert_-_Withdrawing_insulin_from_pen_devices.pdf (Accessed 22 September 2020).

NHS Improvement. (2017) Risk of severe harm and death due to withdrawing insulin from pen devices [Online]. Available at <https://www.bing.com/videos/search?q=NHSengland+allert+withdrawing+insulin+from+a+pen+&&view=detail&mid=749445CCC98F1D6CB7> (Accessed 16 May 2021).

NHS Improvement. (2018) Never Events policy and framework [Online]. Available at <https://www.england.nhs.uk/wp-content/uploads/2020/11/Revised-Never-Events-policy-and-framework-FINAL.pdf> (Accessed 22 December 2021).

NHS Improvement. (2021) Never Events list 2018 [Online]. Available at <https://www.england.nhs.uk/wp-content/uploads/2020/11/2018-Never-Events-List-updated-February-2021.pdf> (Accessed 10 May 2022).

Primary Care Diabetes Society. (2020) The six steps to insulin safety [Online]. Available at <https://diabetesonthenet.com/cpd-modules/the-six-steps-to-insulin-safety> (Accessed 12 June 2022).

Rayman, G. and Kar, P. (2020) Diabetes: GIRFT programme national specialty report [Online]. Available at <https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2020/11/GIRFT-diabetes-report.pdf> (Accessed 24 November 2021).

Specialist Pharmacy Service. (2018) Insulin preparations: RMOc recommendations of safety considerations for formulary decision making [Online]. Available at <https://www.sps.nhs.uk/articles/insulin-preparations-rmoc-recommendations-of-safety-considerations-for-formulary-decision-making> (Accessed 12 June 2022).

University Hospitals of Leicester. (2019) Inpatient diabetes training and support. Daily diabetes review and monitoring [Online]. Available at <https://www.inpatientdiabetes.org.uk/diabetes-review-and-monitoring> (Accessed 22 November 2021).

University of Southampton. (n.d.) Understanding insulin [Online]. Available at <https://www.futurelearn.com/courses/understanding-insulin> (Accessed 12 June 2022).