

Safer insulin prescribing

Key therapeutic topic

Published: 16 January 2017

www.nice.org.uk/guidance/ktt20

Key points

- Several new insulin products have been launched in recent years, including high-strength, fixed-combination and biosimilar insulins.
- The Medicines and Healthcare products Regulatory Agency (MHRA) has issued [advice for healthcare professionals](#) to minimise the risk of medication error with these products.
- Hypoglycaemia is an inevitable adverse effect of insulin therapy. All the NICE guidelines on diabetes recommend that people receiving insulin therapy are provided with education and information about awareness and management of hypoglycaemia.
- Diabetes features in the [NHS Long Term Plan](#) published in January 2019.
- **Options for local implementation:**
 - Be aware of the differences between insulin products and ensure that people receive appropriate training on their correct use. Advise people to only use insulin in the way they have been trained because using it any other way may result in a dangerous overdose or underdose.
 - Ensure that people with diabetes who are receiving insulin therapy are given information about awareness and management of hypoglycaemia.
 - Ensure that people with diabetes who use insulin and who drive are aware of the need to notify the Driver and Vehicle Licensing Agency (DVLA). Healthcare professionals should refer to chapter 3 of the DVLA's [Assessing fitness to drive: a guide for healthcare](#)

- – [professionals](#) for more information.
- Be aware of 'sick-day' rules and ensure that people with diabetes who are receiving insulin therapy are given appropriate information about these.
- Give adults who are using insulin therapy a patient information booklet and an Insulin Passport.

Evidence context

This key therapeutic topic focuses on safety issues with insulin, rather than treatment recommendations. Recommendations on the choice of insulin are provided in the NICE guidelines on:

- [type 1 diabetes in adults: diagnosis and management](#)
- [type 2 diabetes in adults: management](#)
- [diabetes \(type 1 and type 2\) in children and young people: diagnosis and management](#)
- [diabetes in pregnancy: management from preconception to the postnatal period.](#)

Recommendations on continuous subcutaneous insulin infusion (CSII; insulin pump) therapy are provided in the NICE technology appraisal guidance on [continuous subcutaneous insulin infusion for the treatment of diabetes mellitus](#).

Hypoglycaemia

Hypoglycaemia is an inevitable adverse effect of insulin therapy. It can range from hunger, anxiety, irritability, palpitations, sweating or tingling lips, to convulsions, loss of consciousness, and coma.

All the NICE guidelines on diabetes recommend that people receiving insulin therapy are provided with education and information about awareness and management of hypoglycaemia. NICE's guidelines on type 1 diabetes in adults, type 1 and 2 diabetes in children and young people, and diabetes in pregnancy, recommend that people receiving insulin therapy should always have available a fast-acting source of glucose to manage hypoglycaemia. In cases of severe hypoglycaemia where a person has a reduced level of consciousness, intramuscular glucagon that is given by another person is recommended.

Driving

People with diabetes who are using insulin therapy must notify the Driver and Vehicle Licensing Agency (DVLA). In order for the DVLA to license a person with insulin-treated diabetes, certain criteria must be met depending on whether they are seeking a group 1 (car and motorcycle) or group 2 (bus and lorry) licence. The presence of certain diabetes complications such as visual, renal and limb complications may mean that a person needs to stop driving and notify the DVLA depending on the circumstances.

People who have impaired awareness of hypoglycaemia, or people who have had more than 1 episode of severe hypoglycaemia while awake in the last 12 months, must not drive and must notify the DVLA. Monitoring of blood glucose is mandatory for drivers with insulin-treated diabetes in line with recommendations in chapter 3 of the DVLA's [Assessing fitness to drive: a guide for healthcare professionals](#).

'Sick-day' rules

The NICE guidelines on type 1 and 2 diabetes in children and young people, and type 1 diabetes in adults recommend that clear guidance ('sick-day' rules) should be given to all people with type 1 diabetes (and their family or carers where appropriate) to help them to manage their condition appropriately during periods of illness. In children and young people, this individualised guidance should include information on monitoring blood glucose, monitoring and interpreting blood ketones, adjusting insulin regimens, food and fluid intake, and when and where to seek further advice and help. The NICE guideline on type 1 diabetes in adults recommends that 'sick-day' information should help adults with type 1 diabetes to adjust their insulin dose during periods of illness, and that ketone monitoring (blood or urine) to facilitate self-management of an episode of hyperglycaemia should be considered. [Diabetes UK](#) provides information for people with diabetes on [dealing with illness](#).

Continuous subcutaneous insulin infusion (insulin pump) therapy

Continuous subcutaneous insulin infusion therapy makes use of an external pump that delivers insulin continuously from a refillable storage reservoir by means of a subcutaneously placed cannula. The pump can be programmed to deliver a basal rate of insulin throughout the day, with higher infusion rates triggered by the push of a button at meal times. This may be a bolus, or over a period of time. The pump can also deliver different basal rates of insulin at different times of the day and night. Several medical device alerts about safety issues with the use of insulin pumps have been issued. See the Medicines and Healthcare products Regulatory Agency (MHRA) [alerts and](#)

[recalls for drugs and medical devices](#) page for more information.

Insulin prescribing and administration: reducing errors

Several new insulin products have been launched in recent years and the European Medicines Agency has issued guidance on [preventing medication errors with high-strength insulins](#). This includes advice for healthcare professionals such as ensuring people are provided with adequate information about their insulin, prescribing insulin doses in units ensuring that the word 'units' is spelled out in lower case, only using high-strength insulin with the pre-filled pen it is supplied in, explaining to people the difference in appearance between different insulin preparations, and telling people to closely monitor their blood glucose levels when starting high-strength insulin and in the weeks afterwards.

In the [April 2015 edition of Drug Safety Update](#), the MHRA issued advice to health professionals to minimise the risk of medication errors with recently launched high-strength, fixed-combination and biosimilar insulin products. Recommendations included that healthcare professionals should consult the summary of product characteristics and any educational material relevant to the insulin product, ensure that people read and understand the patient leaflet and any patient education material, and ensure that people receive appropriate training on the correct use of the product. People should also be advised to only use insulin in the way they have been trained because using it in any other way may result in a dangerous overdose or underdose.

In 2010, the National Patient Safety Agency (NPSA), which is now part of [NHS Improvement](#), issued a [rapid response report](#) about the safer administration of insulin. The report highlighted that errors in the administration of insulin by clinical staff are common. In certain cases, they may be severe and can cause death. Two common errors were identified: the inappropriate use of non-insulin (intravenous; IV) syringes, which are marked in millilitres (ml) and not in insulin units, and the use of abbreviations such as 'U' or 'IU' for units (when abbreviations were added to the intended dose, the dose was misread). The report made several recommendations including suggesting that a training programme should be put in place for all healthcare staff (including medical staff) expected to prescribe, prepare and administer insulin.

In 2011, the NPSA issued a [patient safety alert](#) on the adult patient's passport to safer use of insulin. The alert discussed that errors involving using the wrong insulin product, omitted or delayed insulin dose, and wrong insulin dose accounted for 60% of 16,600 insulin-related adverse drug events (including 6 deaths) reported in the UK between November 2003 and November 2009. The NPSA made recommendations to improve patient safety by empowering patients to take an active role in their treatment with insulin.

A patient information booklet and a patient-held record (the Insulin Passport) were developed, which document the patient's current insulin products and enable a safety check for prescribing, dispensing and administration. It was recommended that all adults who are using insulin therapy should receive a copy of these. The [April 2015 edition of Drug Safety Update](#) reinforced this message, reminding healthcare professionals that all people starting treatment with a high-strength, fixed-combination or biosimilar insulin product should be provided with a patient booklet and Insulin Passport (or safety card).

The NPSA patient safety alert also recommended that when prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals cross-reference available information to confirm the correct identity of insulin products, and that systems should be put in place enabling hospital inpatients to self-administer insulin (where feasible and safe), to reduce the harm associated with incorrectly timing insulin administration with food, and deaths and severe harm caused by errors.

In November 2016, NHS Improvement issued a [patient safety alert](#) about the risks associated with using an insulin needle and syringe to administer insulin withdrawn directly from a pen device or replacement cartridge. Insulin syringes have graduations only suitable for calculating doses of 100 units/ml strength insulin. If insulin extracted from a pen or cartridge is of a higher strength, and that is not considered in determining the volume required, it can lead to a significant and potentially fatal overdose. A total of 56 incidents associated with withdrawing insulin from insulin pens or refill cartridges were reported to the [National Reporting and Learning System \(NRLS\)](#) between 1 January 2013 and 30 June 2016.

The alert recommends that organisations should warn staff that extracting insulin from pen devices or cartridges is dangerous and should not happen. Organisations should ensure staff are trained and competent in using insulin pens and that training is available. Staff, and where appropriate, patients who use pen devices, should be routinely provided with safety needles and access to equipment capable of safely removing and disposing of used insulin pen needles. This will ensure insulin can be given safely if a patient is not able to self-administer. It is essential that staff are also trained in correctly using safety needles.

Examples of other patient safety incidents received by NHS Improvement to the NRLS involving insulin include:

- failure to manage insulin, resulting in death
- dosing error, wrong frequency of insulin, omitted or delayed insulin, and administration of the wrong insulin, all of which resulted in severe harm. (Personal communication: NHS)

- Improvement 2016).

In October 2016, the MHRA issued a [press release](#) highlighting that it had become aware that some people with diabetes treated with insulin had been directly contacted by a manufacturer or other organisation inviting them to trial a new insulin delivery system. Suddenly stopping or changing insulin delivery devices can put people at risk of hypoglycaemia, hyperglycaemia or diabetic ketoacidosis. The MHRA advised that people only use insulin delivery devices that are recommended by their diabetes specialist and urged people not to make changes to their device or delivery system without first seeking guidance from their specialist.

A free e-learning module, [the six steps to insulin safety](#), which was developed by the Primary Care Diabetes Society in association with Training, Research and Education for Nurses in Diabetes (TREND-UK) is available for all those prescribing, managing or administering insulin, with the overall aim of reducing errors in clinical practice.

The Regional Medicines Optimisation Committee (RMOC) programme has issued guidance on safety considerations when adopting insulin preparations onto a local formulary (see [insulin preparations: safety considerations for local formulary decision making](#)).

Safety alerts

In the [June 2019](#) edition of [Drug Safety Update](#), the MHRA warned about reports of diabetic ketoacidosis in people with type 2 diabetes on a combination of a glucagon-like peptide-1 (GLP-1) agonist and insulin who had doses of concomitant insulin rapidly reduced or discontinued.

Prescribing data, metrics or supporting resources

At this point, the following metrics have been identified to support this topic.

- A medicines optimisation key therapeutic topic [prescribing comparator](#) on long-acting insulin analogues is available (see the key therapeutic topic on [type 2 diabetes mellitus: medicines optimisation priorities](#)).

Update information

September 2019: This topic was retained for the 2019 rapid update of medicines optimisation: key therapeutic topics. Minor editorial changes have been completed and an MHRA safety alert has been added.

About this key therapeutic topic

This document summarises the evidence base on this key therapeutic topic that has been identified to support medicines optimisation. **It is not formal NICE guidance.**

ISBN: 978-1-4731-2292-5