Safer insulin prescribing

Key therapeutic topic
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nice.org.uk/guidance/ktt20

Options for local implementation

- Clinicians should ensure that people with diabetes who are receiving insulin therapy are given information about awareness and management of hypoglycaemia.

- People with diabetes who use insulin and who drive should be aware of the need to notify the Driver and Vehicle Licensing Agency (DVLA). Clinicians should refer to chapter 3 of the DVLA’s Assessing fitness to drive – a guide for healthcare professionals for more information.

- Clinicians should be aware of ‘sick-day’ rules and should ensure that people with diabetes who are receiving insulin therapy are given appropriate information about these.

- Several new insulin products have been launched recently, including high-strength, fixed combination and biosimilar insulins. Clinicians should be aware of the differences between these products and ensure that people receive appropriate training on their correct use. People should be advised 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.

- Adults who are using insulin therapy should receive 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:
Recommendations on continuous subcutaneous insulin infusion (CSII or 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 mild which includes symptoms such as hunger, anxiety or irritability, palpitations, sweating, or tingling lips, to severe which can result in 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 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 for the management of hypoglycaemia. In cases of severe hypoglycaemia where a person has a reduced level of consciousness, intramuscular glucagon 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 and renal complications may mean that a person needs to stop driving and notify the DVLA depending on the circumstances. People with impaired awareness of hypoglycaemia 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 regarding safety issues with the use of insulin pumps have been issued. See the 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 recently 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 the difference in appearance between different insulin preparations to people, 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 clinicians 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 (IV) syringes, which are marked in 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) was developed which documents the patient’s current insulin products and enables 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 where 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; and 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, November 2016).

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.

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 which 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.

Prescribing data

There are currently no medicines optimisation key therapeutic topic (MO KTT) prescribing comparators for this topic. The development of a suitable comparator will be explored by the NHS England Medicines Optimisation Intelligence Group[1]. An MO KTT prescribing comparator on long-
acting insulin analogues is available to support the key therapeutic topic on **type 2 diabetes mellitus: medicines optimisation priorities**.

1. For details of any update to the comparators refer to the NHS Digital website and the Information Services Portal, Business Services Authority

**About this key therapeutic topic**

**January 2017**: This is a new topic for the 2017 update of medicines optimisation: key therapeutic topics. This document summarises the evidence base on this key therapeutic topic which has been identified to support medicines optimisation. **It is not formal NICE guidance.**

For information about the process used to develop the key therapeutic topics, see the integrated process statement.