

**Regional Medicines Optimisation Committee (RMOC)**

**Insulin preparations**

**Safety factors for local formulary decision-making.**

**Position Statement**

**June 2018**

At its meeting on 18th April 2018 the Regional Medicines Optimisation Committee (RMOC) (Midlands and East) reviewed issues pertaining to safety considerations when considering adding any insulin preparation to a local formulary. This topic had come to the RMOC from the Medicines Optimisation Priorities Panel, who were in turn responding to a request from a NHS Drug and Therapeutics committee for advice in this area.

Over the last few years, a variety of insulin preparations have become available—including high-strength U200, U300, U500 (i.e. more concentrated than 100 units per ml) insulins, biosimilar formulations, products with modified onset of action or combination products with non-insulin drugs. There is therefore a potential patient safety risk from either the wrong product being prescribed or dispensed or an incorrect dose being administered due to lack of information or familiarity.

Whilst guidance has been issued to health-care professionals to ensure safe and appropriate prescribing or administration of such products [1-3], there is limited advice around formulary choice for safety. The RMOC programme was requested to issue guidance to formulary committees/ Area Prescribing Committees around safe choice of agent when considering adding a new insulin preparation to a local formulary.

Formulary choices of agents should be made on the basis of clinical efficacy, cost effectiveness and safety data. NICE guidance recommends that formulary decisions should be based on the following criteria [4]:

• patient safety

• clinical effectiveness

• cost effectiveness or resource impact

• strength of evidence

• place in therapy relative to available treatments

• national guidance and priorities

• local health priorities

• equity of access

• stakeholder views.

In order to ensure that all of the above criteria are considered, the RMOC recommends that the following principles are taken into consideration when formulary committees/ Area Prescribing Committees are determining whether to add a new insulin formulation to the local formulary or reviewing existing formulary options. These principles should be given equal significance as clinical and cost-effective data in the decision-making process. In addition, committees should ensure that adequate representation is available to consider these specific issues, for example diabetologists and community nurses.

1. **Presentation**

Is it clear which presentations are been considered for addition to the formulary? Insulins are sometimes marketed in a variety of presentations— including pre-filled pens, cartridges for pens or pumps and/or vials. It may not be necessary or desirable to endorse all presentations of a new product. Are there clear criteria for different presentations? If vials are requested, they should be restricted to special circumstances in appropriate care settings.

1. **Risk Assessment**

Has a risk assessment of the product been conducted? The [UKMi In-use product risk assessment tool](https://www.sps.nhs.uk/articles/ukmi-product-assessment-tool/) is available for such an assessment. This may identify if there are risks to introducing this product locally—for example similar names/packaging to other products increasing the risk of the wrong product being prescribed/dispensed/administered. If a UKMi risk assessment has already been undertaken for the specific product, this should be used. These are published on the SPS website ([www.sps.nhs.uk](http://www.sps.nhs.uk)).

1. **Device**

Is the device already available on the formulary with other insulin products? Adding unfamiliar devices into the health community introduces additional safety risks and training requirements for staff who administer using multiple devices to patients in their care. It may be preferable to rationalise the number of different devices and limit the range of devices available locally.

1. **Product Usability**

Is the product easy to use on a day-to-day basis in practice? Can the packaging/ device/ dial be read easily, in particular by patients with poor vision? Is the dial easy to manipulate? Can the activation button be depressed easily, in particular by patients with poor dexterity?

1. **Training**

If the device is new to the formulary, is training available locally for patients? This should be given before the product is dispensed. Is training available for healthcare professionals AND carers in the device? This should include secondary care staff such as nurses, doctors and pharmacists, as well as primary care staff such as GPs, practice nurses, community nurses, community pharmacists, family carers and care home staff. Will training be available for new staff on an on-going basis? Are there any additional considerations if adding the new device to the formulary (e.g. impact on other local or neighbouring Trusts)?

1. **Supply**

Are arrangements in place for timely supply of refillable pen device, needles, etc? Is it clear which needles should be used? Is there a reliable on-going supply available through NHS supply chains in primary and secondary care? Safer sharps must be made available for healthcare workers who administer insulin to patients especially outside the clinical setting with no direct access to sharps bins. Primary care costs of needles etc need to be taken into account.

1. **Implementation**

Have practical implementation issues been considered? For example when discussing high-strength insulin, have appropriate safety steps been considered to isolate/identify them as high strength? These might include separate storage arrangements to standard strength insulins? Can warnings be put onto electronic or paper prescribing systems and pharmacy systems? Have all local community pharmacies been made aware?

1. **Support**

It is preferable for patients to self-administer their insulin where possible. If this is not practicable, is immediate support available to any healthcare professional on an unfamiliar device when treating/advising a patient? This could include access to specialist staff or online resources. Such support should be available in both primary and secondary care.

1. **Errors due to insulin withdrawal**

Errors have been reported with high-strength insulin if health-care professionals have withdrawn insulin from an unfamiliar device into a standard insulin syringe. **This practice should not happen** as the strength of insulin in pen devices varies, creating a risk of overdose if the strength is not taken into consideration when determining the volume required. Reports suggest this practice has occurred where staff have not had access to equipment for safely disposing of needles attached to pen devices, and/or lack training in the use of insulin pens [3]. Are systems in place to avoid this happening with the device under consideration? Do patients have all the relevant needles/ pen devices if they are transferred between wards and on discharge? Are ambulance staff made aware to bring in needles with pen devices when admitting patients on insulin from home/ care homes? Are appropriate safer sharps available to avoid resheathing insulin needles?

1. **Prescribing**

Insulin must be prescribed by brand name. Prescriptions should include the brand name, the strength of insulin and the device. Is there a system in place to ensure all prescribers follow this practice? Is there on-going education on this? Ensure clinical pharmacists and pharmacy technicians clarify the preparation during the medicines reconciliation process. Can an additional check be mandated on any medicines reconciliation process?

1. **Rationalisation**

Will any currently available products be removed from the formulary? If so, how will patients currently receiving these products be switched to alternative presentations? Will stocks of current products be used up to reduce wastage? Will community pharmacies be informed?

A check-list version of these principles is available at <https://www.sps.nhs.uk/articles/insulin-preparations-rmoc-recommendations-of-safety-considerations-for-formulary-decision-making/>.

**Actions**

* Provider Trusts and commissioners should ensure that the above principles are reviewed and a check-list be completed for each insulin product to accompany any clinical evaluation and supporting documentation as part of the decision-making process.
* A plan of action should be developed if completion of the checklist identifies areas where more work is needed before introducing the new product into the formulary.
* Commissioners should ensure that community services are fully engaged and consulted when a new insulin product is introduced to a local formulary.
* Provider Trusts and commissioners should ensure that training is made available to all relevant staff when a new insulin device is introduced to a local formulary.

*References*

1. Medicines and Healthcare products Regulatory Agency High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error 29 April 2015 (<https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error>)
2. NICE Safer insulin prescribing Key therapeutic topic [KTT20] January 2017 (updated February 2018) (<https://www.nice.org.uk/advice/ktt20>)
3. NHS Improvement Patient Safety Alert. Risk of severe harm and death due to withdrawing insulin from pen devices. Alert reference number: NHS/PSA/W/2016/011. November 2016 (<https://improvement.nhs.uk/news-alerts/risk-severe-harm-and-death-withdrawing-insulin-pen-devices/> )
4. NICE Developing and updating local formularies Medicines practice guideline [MPG1] March 2014( updated: October 2015) <https://www.nice.org.uk/guidance/mpg1/chapter/Recommendations#setting-decision-criteria>