Safety Issues with Improper use of Insulin Pen Devices

SITUATION

Concerns have been raised that a number of in-patient areas have been storing and using insulin pen devices improperly.

BACKGROUND

"Pen-shaped devices are commonly used by patients for subcutaneously injecting insulin. Compared to insulin syringes, the use of these devices has increased as they make it easier for patients to self-inject" (NHS Improvement, November 2016).

Issues identified with the use of insulin pen devices within NHS Grampian are:

- Using a needle and syringe to extract insulin from the insulin pen device or refill cartridge
- Storing opened unlabeled insulin pen devices in the fridge
- Potential for using the same insulin pen devices on multiple patients due to storage practice above.

ASSESSMENT

Extracting Insulin from Insulin Pen Devices

In 2016 NHS Improvement issued a Patient Safety Alert advising of the risk of severe harm and death due to withdrawing insulin from pen devices. The alert warns that "although the strength of insulin was previously standardised at 100 units/mL, this can vary in pen devices, currently by multiples of 100 units/mL. Pen devices can be adjusted to take account of this variation and ensure the correct dosage is delivered. The dose is set on the pen's dial and the device automatically determines the volume it delivers.

Insulin syringes have graduations only suitable for calculating doses of standard 100 units/mL. 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."

The alert also states that "extracting insulin from pen devices risks damaging the device's mechanism and will not be covered by the manufacturer's warranty."

This 2 minute video from NHS Improvement explains the risks associated with using insulin syringes and needles to extract insulin from pen devices and refill cartridges.

Nursing staff who are administering insulin to patients using a syringe and safety needle should withdraw the dose from insulin vials.

Storage of Insulin Pen Devices

Insulin pen devices that have not been opened (often referred to as 'not in use' insulin) should be stored in the refrigerator between 2-8ºC.

Once an insulin pen device has been opened it is 'in use' and should remain out of the refrigerator and stored at room temperature for up to 30 days (Tend Diabetes Injection Technique Matters: Best Practice in Diabetes Care). Individual brands Summary of Product Characteristics (SPC – or the insulin insert) should be referred to for specific storage advice.

Opened or 'in use' insulin pen devices should be labelled and stored in the patient's own drug (POD) locker. For patients in hospital who are self managing their own insulin the insulin pen device should be labelled and given to them to keep safely on their person in order to facilitate self administration.

This means that there should never be an open / in use insulin pen device in a medicines fridge.

Insulin Pen Devices are for Single Patient Use Only

This means that the same patient can use the same insulin pen device for multiple injections with a new needle for each injection. The outer packaging and/or guidance relating to individual pen devices usually

state that pen devices "must not be shared". This statement may be in small writing at the page footer as in this example. Even in the absence of statements to this effect from either the packaging or the guidance insulin pen devices should not be shared between patients.

Trend Diabetes Best Practice Guideline for Healthcare Professionals: Correct Injection Technique in Diabetes Care state on page 15 that "Health care settings where insulin pens are used must follow a strict one-patient/one-pen policy".

When opening a new insulin pen device in hospital it should be given to the patient for their use only. For patients not self managing their diabetes while in hospital nursing staff trained to use insulin pen devices may use the patient's own insulin pen device to administer the insulin otherwise they should use insulin syringes with safety needles and insulin vials.

Training on insulin administration can be found at the following locations within Turas:

- Diabetes MCN: has a number of resources and online training including Understanding Insulin – Online which covers types of insulins available, insulin injection technique and how to minimise the risk of insulin errors in insulin administration. Details on how to book sessions are on the Diabetes MCN Turas page.
- Diabetes Hub: has a variety of eLearning modules from NHS Education for Scotland (NES).

One of the NES eLearning modules "Insulin Administration" has a section on disposable pens in which the wording on reusing the disposable pen is ambiguous and feedback has already been given to NES asking for it to be made clear that insulin pen devices are for single patient use.

Labelling Insulin Pen Devices

Insulin pen devices should be labelled with the patient's name and the date it was opened. This ensures that the device is only used on the person it is intended for "one patient – one pen" and is not used beyond its expiry date.

This means that there should never be an open / in use insulin pen without a patient specific label.

RECOMMENDATIONS/ACTIONS

- The practice of extracting insulin from insulin pen devices and cartridges must stop immediately to reduce the risk of inadvertent overdose and patient harm.
- Ward areas must ensure they have the appropriate stock of insulin vials to enable nursing staff to draw up insulin safely where using insulin syringes with safety needles.
- Staff administering subcutaneous insulin have been appropriately trained to do so – details in Turas Diabetes MCN.
- Insulin pen devices must be labelled with the patient's name, CHI number and date opened. The label should be attached to the body of the insulin pen device (not the device cap) and must not obscure the name and strength of insulin printed on the insulin pen device.
- Insulin pen devices must be given to the patient or stored in the POD locker after opening and must not be returned to the fridge.
- Opened / in use insulin pen devices without an individual patient label should be disposed of in medicines waste.
- Any open / in use labelled pen devices found in a fridge should be removed and stored with the patient's other patient specific medicines.
- An information sheet is being developed which will include advice on various aspects of the safe use of insulin including labelling, storage and administration.

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