Pharmaceutical Aseptic Services Group

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Briefing: deployment of ISO 80369-6 devices in the NHS during 2017

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Introduction

The standard small-bore connector in the medical device field for many years has been the Luer connector, used in many different types of device applications, such as vascular, enteral, respiratory, epidural, and intrathecal. The consequence of this has been that devices that were never intended to be connected together can, in some circumstances allow the fatal wrong route administration of fluids and gases, such as the delivery of toxic chemotherapy drugs into the spinal canal.

The NPSA published a series of alerts in 2009 and 2011 requiring the UK NHS to use non-Luer devices for neuraxial bolus doses and infusions. This was partly successful with many English Trusts adopting proprietary systems for chemotherapy use in particular. Other Trusts and the Devolved Administrations such as Wales decided to wait for the ISO standard to be published.

The ISO standard and compliant devices

ISO 80369-6, the international standard for neuraxial connectors, intended to replace Luer connectors on spinal needles, epidural catheters and other regional anaesthetic and intrathecal devices, was published in 2016. **Industry are now confident that they will start supplying a core set of medical devices using these new NRFit connectors available from approximately April 2017**.

As well as reducing the risk of the delivery of IV drugs into the neuraxial space, use of the ISO 80369-6 connectors will also mitigate against wrong-route delivery of neuraxial medicines (such as bupivacaine) intravenously.

Which devices?

Many of the core devices will be available from April 2017 with ISO 80369-6 compliant connectors includes **spinal needles, neuraxial syringes (a new device), epidural catheters/filters, epidural infusion sets, manometers, three way taps, and drawing up needles**. However, some key suppliers will not have their devices available until either Summer 2017 or, in some cases, Autumn 2017. A full list of the core devices (drawn up between NHS England and NHS Wales non-Luer groups) is available at:- https://goo.gl/KEkCxn

We are aware that there are some niche areas of clinical practice where neuraxial devices such as spinal needles are used for non-neuraxial procedures (such as injecting into joints during orthopaedic procedures) or IV devices are used for neuraxial procedures (such as the use of burette sets to aid neonatal epidural placement). If you are aware of any of these rare procedures please contact us so we can discuss alternatives.

Planned Rollout

Rollout in England will be by individual Trusts from April 2017 onwards. NHS Wales is planning a co-ordinated rollout starting in Autumn 2017 and with an anticipated completion by Spring 2018.

For information relating to Scotland & Northern Ireland see the contact details for each devolved administration included within the FAQ link under Further Resources below.

Pharmacy and Aseptic filling of syringes

Some pharmacy departments aseptically fill syringes in their Aseptic Suites to reduce the risk of syringe contamination and, in the case of chemotherapy agents in particular, to reduce the risk of staff exposure to hazardous chemicals on the wards and in clinics.

We are waiting for the NRFit device manufacturers to validate the new syringes for medicines storage (standard syringes are intended only for immediate use) and hope that this will be complete by the time of deployment. Until this validation data is available it will delay the deployment of the new ISO compatible syringes in those NHS hospitals compounding intrathecal chemotherapy and those using pre-filled epidural syringes.

Intelligent scheduling of the deployment will help reduce this impact.

Elastomeric Devices/Cassettes

Elastomeric devices and cassettes for epidural/regional use will need to have an ISO 80369-6 (NRFit) connector on the line that connects to the patient. We believe that some suppliers will be ready in Q2 2017, although timescales for all suppliers are not yet understood.

Eventually the filling port on elastomeric devices for epidural/regional use should also be ISO-compliant but timescales from industry are not yet available.

Because cassettes are filled through the administration line there is no separate requirement for a filling port on these devices. Small scale filling of these cassettes for epidural/regional use could be carried out using NRFit syringes. However, for larger scale batch production this may present an issue for aseptic units (NHS or commercial) using automated filling pumps until the filling lines used in these pumps become available with an ISO compatible connector for connection to the cassettes.

We advise NHS and commercial aseptic compounding units using automated filling pumps to fill cassettes for epidural/regional use raise this with their pump manufacturer and advise them to contact Smiths Medical (the manufacturer of CADD cassettes) for a solution to this issue. Whilst initially this will only be a problem for cassette filling, in the longer term it will

also apply to elastomeric devices for epidural/regional use when the manufacturers of these devices change the filling ports from luer to NRFit connectors.

Epidural Infusion Bags/Reservoirs

It is acknowledged that epidural infusions would be safer if the reservoirs (bags) could not be attached to an IV giving set, reducing the risk of the IV infusion of bupivacaine for example. Whilst an ISO standard is in development (ISO/CD 18250-6, "*Connectors for reservoir delivery systems for healthcare applications -- Part 6: Neural applications*"), we do not anticipate the replacement of IV ports or additive ports with neuraxial port connectors on epidural infusion bags in the near future.

For the time being, NRFit giving sets will have the usual spike at the reservoir end, and an NRFit connector at the patient end.

Conclusion

Industry are confident that most of the devices we require will be available from April 2017, although the availability of validated storage data may affect the start of deployment in some hospitals. At present we are aware that some key equipment will not be available until July or August 2017.

The NHS in the home nations are continuing to liaise with industry and check progress with their stability testing schedules. As we approach April 2017, we will need to check whether the planned deployments are still possible or whether further delays are necessary. Surveillance is expected to continue for 6 months post-deployment.

Further Resources

The following resources are available:

1. A HOWTO guide which outlines a method previously used successfully in some NHS England Trusts to change from Luer to non-Luer devices;
2. A draft FAQ about the new devices is almost complete;
3. NHS England portal on small bore connectors;
4. AAGBI web page on small bore connectors;
5. Test Requirements For Neuraxial Syringes For Drug Storage

Contact

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