Patient Safety Notice

PSN013/JULY 2015

GIG CYMRU NHS WALES

Llywodraeth Cymru
Welsh Government

Managing risks during the transition period to new ISO connectors for medical devices used for enteral feeding and neuraxial procedures

To: All NHS Chief Executives, Medical Directors, Directors of Nursing and Patient Safety Teams, Directors of Therapies and Health Sciences, Chief Pharmacists

Background

From September 2015, newly designed enteral administration sets (fitted with new, non-Luer connectors) will be introduced into the NHS. All healthcare providers in Wales need to be vigilant and address the risks during the transition period.

Numerous publications have reported severe harm and death when medical devices and their associated connecting tubing, were inadvertently connected to devices intended to deliver medication via a different route. The risk of a misconnection of this kind is increased when devices involved are fitted with the universal Luer connector. Examples include the mistaken administration of medicines intrathecally (into the spinal canal) which are intended to be administered intravenously, and the unintended intravenous delivery of enteral feed.

To reduce the risk of misconnections, the International Organization for Standardisation (ISO) has developed a series of new International Standards for small bore connectors in a range of medical devices (ISO 80369).

The series of standards includes connectors specifically for breathing systems and driving gases, enteral feeding, limb cuff inflation devices, neuraxial devices (for spinal and epidural injections), and intravascular/ hypodermic applications (i.e. injections and infusions, for which Luer connectors will be retained). The standards define the design of the connectors for these applications so that the risk of misconnections with other connectors in the series is reduced.

Enteral Feeding Devices – ISO 80369-3

The first devices to be introduced with the new ISO connectors – also known as ENFit (ISO 80369-3) will be enteral feeding devices, with a phased implementation that will begin in September 2015 in the UK. Initially, only giving sets/extension sets with the new connector will be available, (these sets will include adapters), which will allow continued use with current designs of enteral feeding tubes and syringes. Together, the sets and adaptors will be known as 'transition sets'. In March 2016, enteral syringes and feeding tubes using the new connectors will be introduced into the UK. Some long term feeding tubes have replaceable connectors, and it is anticipated that ENFit compatible connectors will be available as replacements. This will allow reverse luer tubes to be converted to ENFit tubes without replacing the whole device.

Actions

Who: All healthcare providers in Wales

When: To commence immediately and be completed by no later than 13 August 2015

1. Identify if enteral feeding medical devices are being used in your organisation.
2. Large organisations such as Health Boards and Trusts should set up a multi-professional local group with appropriate expertise to help manage and communicate the enteral feeding device changeover.

   This group may include – Dietetics, Nutritional Support teams, Procurement, Practice Development Teams, Risk Managers, Infection Control, Pharmacy, Endoscopy/Gastroenterology departments and Radiology. The Chair of the local Medical Devices Group may be an appropriate Chair for the enteral group.
3. Health Boards should ensure they liaise with smaller organisations such as private nursing homes on this matter.

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Possible risks during this transition period may include the inability to deliver therapy due to device incompatibility, device shortages, logistical issues and awareness problems.

There will be no change to syringes designed for oral use only.

Devices affected by this change will include, but not be limited to:

- Nasogastric & nasojejunal feeding tubes (NG)
- Percutaneous endoscopic gastrostomy tubes (PEG)
- Cage retained gastrostomy tubes
- Balloon and pig-tail retained gastrostomy tubes NB only the extension sets associated with low profile devices will be affected, the low profile device itself will incur no change to the current system of connection
- Enteral feeding extension sets and administration sets
- Jejunostomy, naso-jejunal, transgastric jejunostomy feeding tubes.
- Enteral syringes.

Neuraxial & Epidural Devices – ISO 80369-6

This standard is due for publication during 2015, but a complete range of devices fitted with the ISO 'neuraxial' connectors are unlikely to be available in the UK before 2017.

Coordination in the Welsh NHS

The Welsh Non-Luer Connectors Reference Group (WNCRG) has been meeting since 2009 to advise and coordinate on the introduction of these new devices into the Welsh NHS. The group is linking with similar groups in England, Scotland and Northern Ireland to co-ordinate the introduction across the UK.

The Enteral Sub Group of the WNCRG are dealing specifically with the deployment of the enteral giving sets, feeding tubes and syringes. Welsh Procurement (NWSSP, Procurement Services), as members of these groups, are coordinating with industry and Health Boards to ensure a smooth transition.

Local groups for the neuraxial devices are already in place.

Local groups for the enteral devices should now be set up to communicate and coordinate these changes – see ACTIONS.

Further information will be added to the NHS Wales website as it becomes available www.smtl.co.uk/nhs-services/79-small-bore-connectors-in-the-welsh-nhs.html

Other resources to support organisations to prepare for the change can be found on the industry web site, www.stayconnected.org/

4. If devices affected by the change are being used, ensure that an action plan is in place to minimise the risks during the transition period.
5. Distribute this Alert to all staff involved in purchasing, training and distribution of affected medical devices.
6. Share any learning from local investigations or locally developed good practice resources by emailing: ImprovingPatientSafety@Wales.GSI.GOV.UK