ISO 80369-6 Implementation of neuraxial / neural devices in the UK.

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This paper is a case study of local practice and was reviewed by the NHS Small Bore Connector Clinical Advisory Group, who agreed that the information would be useful for other Trust when implementing new neuraxial connectors.

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Headline messages

1) The change to an Internationally agreed (ISO) connector for neuraxial / neural devices is soon to be deployed.

2) The change is currently anticipated to commence at the end of the first quarter of 2017.

3) Most Luer and proprietary non-Luer connectors currently in use will cease to be produced.

4) The change affects a wide distribution of users within your organisations, many more than you may be aware of.

5) It is anticipated that the preparation to change in your organisation may take over 6 months to co-ordinate.

Guide to transition process:

Introduction

This document distils the experiences of two English teaching hospitals in converting from Luer neuraxial devices to non-Luer (Surety), with the aim of producing a HOWTO guide for others to access when ISO 80369-6 (a new standard for non-Luer neuraxial connectors) is deployed in Spring 2017.

Those of you who have already made the change to proprietary non-Luer (pn-L) devices may still find additional tips within this document to facilitate smooth transition to the new ISO system.

The switch from Luer to non-Luer connectors on neuraxial medical devices was initiated by the NPSA/2009/PSA004, a response of the National Health Service in the United Kingdom to a number of Serious Untoward Incidents, in particular the incorrect administration of Vincristine into the CSF which resulted in a number of fatalities.

ISO 80369-6 (also known as 'NRFit') details a neuraxial specific connector intended for use in spinal needles, epidural needles and catheter connectors and a range of other neuraxial devices, and has been ratified by ISO. Eventually neuraxial devices currently on the market using the Luer and pn-L connectors will cease to be manufactured.

April 2017 is the target date to start the introduction of ISO 80369-6 devices into the UK, but it is not a deadline. It is anticipated that this will take a number of months to complete.

The ISO 80369-6 standard will make the conversion much simpler than previously. It should be possible to simply replace your current product (Luer or pn-L) with the same device containing the new 80369-6 connector, as the connector is common across all manufacturers.

Alternatives to the IV bag-spike for local anaesthetic, epidural and regional infusions are presently being developed by ISO, but this is probably at least 2-3 years away.

Step 1: Identify the disciplines affected by the conversion.

Planning the conversion process requires a multidisciplinary team from the beginning. We found that a minimum of six months is required to fully prepare for the conversion. You should be aware that a number of specialties may be using current Luer and pn-L equipment "off-label", you will also need to engage with these users as described below. Experience has shown the following groups will be affected and should be involved:

- Safety & Risk Management
- Supplies Management/Procurement
- Pharmacy
- Anaesthesia
- Oncology/Haematology services
- Neurology services (who may also represent General Medicine).
- Radiology services
- Paediatrics
- Pain Specialists
- Pain nurses
- Medical Director or a representative of their team

Step 2: Recruit staff to be involved in the changeover.

A local implementation group should be set up of users actually using the devices.

Ensure that this group includes a procurement representative. Procurement nurse specialists will be particularly useful for this exercise.

Identify a single point of contact (a 'Champion') who is responsible for coordinating the exercise for each site. This person needs to be identifiable within your organisation and be willing to devote sufficient time to the process.

Step 3: Identify what kit you currently use.

Construct a list of items ordered by each clinical area when planning the conversion. From this list, construct a master list (such as a spreadsheet) of each Luer or pn-L device which needs replacing by an ISO 80369-6 alternative.

We recommend asking your local procurement team to help with this, and then using clinicians to review the list. Clinical review is vital, as it is not always evident exactly what equipment is required. For example, 3 way taps and extension lines may be vital for procedures, but may not be immediately obvious as required devices just looking at a list of “neuraxial” products.

A report which helps identify the final delivery location for the affected products should be run, as this may highlight additional users of the items. This will be especially useful for off-label usage.

Step 4: Check with your supplier that they will provide ISO 80369-6 versions of these devices.

Contact manufacturers individually, or discuss with NHS Supply Chain, to discover if and when they are going to adopt the ISO 80369-6 connector, and whether all of the portfolio your hospital relies on will be covered.

There has been significant work to identify what are the "essential items" for successful adoption. The NHS England small bore connectors clinical advisory group has a spreadsheet of essential equipment that manufacturers are committed to producing, this will be a useful reference resource and is available from – https://goo.gl/KEkCxn .

Note that as we approach the introduction date, it is expected that some devices previously thought of as non-essential may be identified as essential, and individual hospitals may also have different requirements. This list is therefore fluid and should be adapted to local circumstances.

Step 5: Ensure that your expert advisors have early sight of the new devices.

The ISO process has involved a complex set of laboratory tests (to show the connectors do not leak for example), usability tests (to show that they are clinically acceptable) and CAD tests (to ensure that they do not easily connect to Luer devices, pn-L products or other connectors in the ISO 80369-6 series).

However, it is possible that manufacturers may take the opportunity of introducing the new connector to make changes to the current device design, so it is important to give key opinion leaders the opportunity to see samples of the new equipment, to ensure they are fit for purpose. Manufacturers will have had to satisfy their regulatory bodies regarding product usage when gaining CE marking for their product, this includes clinical testing if that regulator requests it, although this is not anticipated to be the case.

Step 6: Understand your off-label usage and ensure continued supply

Many clinicians use spinal needles for non-spinal/non-neuraxial procedures. For example, in orthopaedics it is common to use these needles to inject into joints. Obstetrics may use them for amniocentesis and ENT to inject drugs in to the ear.

List the areas where off-label usage is practiced and contact manufacturers to check whether a Luer version of the device will continue to be made available, as certain lengths and gauges may not be available after the introduction of the 80369-6 portfolios.

It is anticipated that some manufacturers will continue to make 'long Luer needles' for these procedures, which will no longer be labeled or sold as "spinal" needles, and a list of possible suppliers for these off-label uses should be developed.

If devices presently used 'off-label' are no longer available with a Luer connector, and the only alternative is to use neuraxial-specific devices, a risk assessment should be undertaken and if necessary an entry made in the organisation's risk register. Support from the organisation's Medical Director may be necessary in some circumstances.

Step 7: Ensure that the pharmacy aseptic service has appropriate device options;

Many pharmacy aseptic units prepare pre-filled syringes with medicines for the spinal route (such as spinal chemotherapy).

They should ensure that any of the bespoke equipment they require will be available with ISO 80369-6 connectors (e.g. syringes, drawing-up needles, filters, syringe caps (some units may require these to be tamper evident)), or undertake a risk analyses to assess whether they can continue compounding with their currently used devices. It is thought that because pharmacy compounding is well-controlled, the risks of continuing to use Luer filling devices **only** within the pharmacy department may be acceptable until a full range of devices becomes available. This may be the case with devices such as elastomeric and cassette pumps until full 80369-6 versions become available.

The NHS England Small Bore Connector Clinical Advisory Group, in conjunction with NHS pharmacy aseptic and quality assurance groups has produced advice for manufacturers on the evidence they will be required to provide to NHS customers for devices used for aseptically produced pre-filled syringes, most commonly associated with chemotherapy. This includes microbiological integrity testing. It is anticipated that this evidence will be made available to hospitals through an easily accessible website (for example, via the BAREMA or PASG websites).

Step 8: Obtain senior management approval

Once you have made decisions on the devices to be replaced and ensured that all *essential items* will be available, ask the Senior Management Team, or the Medical Director for approval to initiate the change. Do this early, as it is likely to need discussion at Board level quality and safety meetings.

Step 9: Plan the timetable

The time from approval to deployment is likely to be at least 12 weeks.

Decide how and when each hospital will change (all together, one per week etc). This will depend on the size of the institution and the geographical distribution of clinical areas involved.

Ensure that coordination with specialist departments (such as Pain clinics/ Acute pain teams) is undertaken to minimise disruption. For example, Monday can be a good day to convert as there will have been no elective patients over the weekend who need to be attended to on the Monday, ensuring availability of staff.

Create a checklist of all devices which need to be changed and in which wards or departments they will be found.

Step 10: Educate your staff

Awareness of the change is vital. Low level information can start early in the process. However, if undertaken too soon, staff will forget about the changeover. We recommend messaging starts in earnest about 6 weeks before the changeover date.

The cascade process may include the following:

- Presentation at Nurse Directors meeting.
    - Dissemination through ward managers.
    - Use of posters on wards and in theatre common rooms.
- Presentation at Clinical Directors meeting.
- Presentation at Directorate meetings by appointment.
    - In particular, Anaesthesia/ Oncology & Haematology, Neurology & Radiology.
- E-mail to all consultants, pharmacists & ward managers.
- Web-based learning packages can be created and reach large numbers of staff. This will need to be created in-house to meet your local needs.

Messages should include:

- date of the changeover;
- a FAQ on the changeover – for example, GEDSA have an FAQ[1] which could be adapted for local use;
- contact names and numbers for advice before, during and after the changeover;

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- lists of all devices and area affected by the changeover
- strategies for patients with a working epidural. For example, will they require continued access to Luer or pn-L devices for a short period? If so, ensure that sufficient Luer or pn-L devices are still available in an appropriate and convenient safe location. This is a potential risk and needs careful management and controlled access.

Step 11: Provide demonstration sets

Provide sets containing the full range of needles and syringes that will be supplied with the new connectors, and make available at meetings (such as audit meetings or training days) to allow staff to pick up and play with the needles.

Step 12: Coordinate with your suppliers

Once the fixed date for each site has been agreed, coordinate with your suppliers so that you can:

- quarantine or remove all the old Luer or pn-L equipment;
- introduce the new ISO equipment;

If your establishment consists of multiple hospital sites you could consider reducing waste. If you change one site at a time you can move Luer or pn-L stock to the other site/s until you change there too.

Ask suppliers to have staff available on the day of conversion, as there is likely to be a lot of equipment to be moved around, and this will require additional help.

Step 13: Produce an exchange box for each clinical area;

Using the original spreadsheet of affected devices, produce an 'Exchange Box' for each clinical area (ward by ward, theatre by theatre). This should contain every item used by that clinical area, at a level of stock that they normally carry, and should include information for a point of contact for clinical staff to go to if they encounter problems on changeover day. These boxes should be labeled for the target clinical area and sealed.

Around 1 week before changeover, deliver the exchange boxes to each area. They should be quarantined in that location to ensure the new devices are not introduced in to clinical practice too early, as combinations of Luer, pn-L and new ISO non-Luer devices on the same shelves will undoubtedly lead to misconnection errors.

A central storage area should be identified which can hold extra supplies of the entire range of ISO equipment that the hospital uses should any of the exchange boxes be found to have items missing.

Contingency stock of Luer or pn-L devices should be kept available in a centralised safe area for 1 month after the changeover in case problems are experienced with the new ISO non-Luer devices.

Step 14: Conversion Day.

Ensure sufficient numbers of procurement, supplier and clinical staff are available on the day.

Identify staff (such as ward managers/ ward stock controllers) who will be on wards to facilitate exchange. At the designated time it is their responsibility to ensure that unused Luer or pn-L supplies are removed from stock shelves, exchange boxes are unsealed and new ISO compliant equipment is put into place.

All Luer or pn-L equipment should then be placed into the exchange box which should be resealed and returned to the procurement team or quarantined until it can be collected.

Ensure that staff have an emergency contact telephone number, which is manned by procurement staff, to deliver extra kit to clinical areas if unexpected deficiencies are noted.

Note that at this point any ordering catalogues used by staff should be altered to have the new ISO order codes rather than the Luer or pn-L codes.

Step 15: Continue to provide support

Keep a team available as long as necessary (we suggest at least a week) to provide advice and extra supplies. We anticipate that after 3-4 days problems will be intermittent. Some patients with epidurals may straddle the changeover period, and it may be useful to continue to treat them with Luer or pn-L compliant devices as long as is necessary. Changing over on a Monday may minimise the number of epidurals affected.

The time taken to achieve conversion will depend on the size of the institution and the number of personnel you have available. It is likely to take up to a week to convert a single hospital to all non-Luer equipment. Remember that you will need to change all of the elements of each clinical procedure in one clinical area at the same time, to ensure you can proceed with the clinical service safely. If you have multiple hospital sites the conversion to non-Luer across all sites may be best managed in a staggered fashion, rather than all sites at once. It must be remembered though, that staff and indeed patients, may move across these clinical sites during the transition period. It is vital therefore, that staff are aware of this and plans are in place to minimize the risk of confusion and errors in clinical practice.

Useful Documents and Web Sites (accessed 1/6/2016)

- http://stayconnected.org/wp-content/uploads/2015/10/GEDSA-Neuraxial-FAQv1.4.pdf
- http://www.nrls.npsa.nhs.uk/resources/?entryid45=94529
- https://www.england.nhs.uk/patientsafety/medical-device-incidents/small-bore-connectors/