National Patient Safety Alert

Transition to NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks

Date of issue:	31 January 2024	Reference no:	NatPSA/2024/002/NHSPS

This alert is for action by: All organisations where intrathecal, epidural or regional block procedures are undertaken.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in anaesthesia, those involved with intrathecal and epidural procedures and delivery of regional blocks, procurement leads, medical device safety officers and chief pharmacists.

Explanation of identified safety issue:

The NHS has long used a range of medical devices with the universal Luer connector to administer medicines via different routes of administration, including the intravenous, intrathecal and epidural routes.

This commonality of connector carries significant risk of accidental wrong route administration of medication. The potential for a fatal outcome from this, especially if medication for intravenous administration is given via the intrathecal or epidural route, is well known[1] and previous patient safety alerts have been issued.[2]

In 2010, a new international standard for small bore connectors (ISO 80369) was developed.[3] This included a dedicated connector for neuraxial applications (NRFit™ ISO 80369-6) defined as "those for administering medications to neuraxial sites, wound infiltration anaesthesia delivery and other regional anaesthesia procedures, or to monitor or remove cerebrospinal fluid for therapeutic or diagnostic purposes".[3, NOTE A]

While access to a full portfolio of NRFit™ devices and supply chain fragility has delayed its full implementation in the NHS, industry throughout the UK has now adopted NRFit™.[NOTE B]

Some organisations have already transitioned to these devices, supported by a joint statement from the Association of Anaesthetists, Royal College of Anaesthetists and the Safe Anaesthesia Liaison Group,[4] but many have yet to do so completely.

Actions required

Actions to be completed by 31 January 2025

1. Prioritise the establishment of a short-life working group (SLWG) to scope out and co-ordinate the transition to NRFit™ across all relevant clinical specialties:
   a. Identify a clinical lead to chair the group.
   b. Ensure local procurement leads are included to identify all devices that need to transition to NRFit™.
   c. Plan and risk assess the most appropriate and safe process for transition and to monitor implementation.[NOTE C]
2. To ensure comprehensive transition from Luer to NRFit™ devices is managed and supply chain continuity maintained, local procurement leads must:
   a. Engage with NHS Supply Chain to agree a timeline for transition to NRFit™.
   b. Identity all device locations and order codes and revise stock management systems.
3. After completion of Action 2, the SLWG will:
   a. Clearly communicate the agreed timeline and implementation plan to all relevant clinical staff.
   b. Ensure all relevant policies, procedures and educational and training resources for intrathecal, epidural and regional block procedures are updated with reference to use of NRFit™ devices and are fully accessible.

For further detail, resources and supporting materials see: https://www.england.nhs.uk/2024/01/transition-to-nrfit-connectors-for-intrathecal-and-epidural-procedures-and-delivery-of-regional-blocks

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

NOTES:

A: The abstract on the landing page of the referenced ISO standard (Part 6) provides additional information organisations may find helpful to support the implementation of this alert.

B: Although some NRFit™ products have been available since 2017, access to the full portfolio of relevant devices and fragility in the supply chain has delayed full transition to the NRFit™ connector. NHS Supply Chain, working alongside manufacturers of NRFit™ devices, has provided assurance that a complete portfolio of NRFit™ products is now available.

C: Organisations manufacturing or purchasing ready to administer injectable medicines need to engage with their suppliers early in the transition process to ensure ongoing supply of products with NRFit™ devices.

Patient safety incident insight (PSI171.2023): Although rare, the potentially fatal consequences of the inadvertent intrathecal administration of a medication intended to be given by the intravenous route has been known since the 1980s and such an incident in 2001 led to a major investigation.[5] As this is a well-known patient safety issue, we did not undertake a full NRLS/LFPSE search for incidents, but are aware that these types of incidents still occur; for example, abridged text from incident reports:

- "Patient received muscle relaxant via epidural instead of the intended IV route."
- "... two patients were given inadvertent injection of the wrong medications via epidural catheter one oxytocin and the other phenylephrine."

References:

1. Viscusi ER et al. Neuraxial and peripheral misconnection events leading to wrong-route medication errors: a comprehensive literature review. Regional Anesthesia & Pain Medicine 2021;46:176-181
2. Previous patient safety alerts:
   2007 NPSA Patient Safety Alert: Epidural injections and infusions
   2009 NPSA Patient Safety Alert Part A & Part B: Safer spinal (intrathecal), epidural and regional devices
   2011 NPSA Patient Safety Alert Update: Safer spinal (intrathecal), epidural and regional devices
   2014 NHSE Patient Safety Alert: Non-Luer spinal (intrathecal) devices for chemotherapy
   2015 NHSE Patient Safety Alert: Managing risks during the transition period to new ISO connectors
   2017 NHSE Patient Safety Alert: Resources to support safe transition from the Luer connector to NRFit for intrathecal and epidural procedures, and delivery of regional blocks
3. ISO International Standards: Small-bore connectors for liquids and gases in healthcare applications:
   Part 1: General requirements (ISO 80369-1:2018)
   Part 6: Connectors for neuraxial applications (ISO 80369-6:2016)
4. Royal College of Anaesthetists: Transition to non-Luer (NRFit™) devices August 2022
5. Noble DJ, Donaldson LJ. The quest to eliminate intrathecal vincristine errors: a 40-year journey. BMJ Quality & Safety 2010;19:323-326.

Resources to support transition:

A. NHS Wales video resources for general specialties and for anaesthetics
(with thanks to NHS Wales for access to these resources)
B. NHS Supply Chain have supporting resources on their website including ICN 890.

Stakeholder engagement:

- Royal College of Anaesthetists / Association of Anaesthetists
- NHS Supply Chain
- NHS and commercial suppliers of relevant products
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel see 'Our National Patient Safety Alerts' webpage)
- Focus groups across all devolved nations to support transition to NRFit™ across the UK.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2023/0032 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the nominated executive lead in their new process to co-ordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.