Neuraxial and regional anaesthesia devices with non-Luer connectors

An updated statement from:

The Association of Anaesthetists of Great Britain and Ireland

The Royal College of Anaesthetists

The Obstetric Anaesthetists' Association

Regional Anaesthesia UK

The Association of Paediatric Anaesthetists of Great Britain and Ireland

The Faculty of Pain Medicine of the Royal College of Anaesthetists

Royal College of Anaesthetists Patient Liaison Group

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The Association of Anaesthetists of Great Britain & Ireland

The Royal College of Anaesthetists

RA-UK Regional Anaesthesia United Kingdom

APA

Faculty of Pain Medicine of the Royal College of Anaesthetists

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An updated statement from the Association of Anaesthetists of Great Britain & Ireland (AAGBI), the Royal College of Anaesthetists (RCoA), the Obstetric Anaesthetists Association (OAA), Regional Anaesthesia UK (RA-UK), the Association of Paediatric Anaesthetists of Great Britain & Ireland (APAGBI), the Faculty of Pain Medicine of the RCoA (FPMRCA) and the Patient Liaison Group of the RCoA

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INTRODUCTION

- The failure to implement a single design of non-Luer connector for neuraxial and regional anaesthesia that has undergone full and coordinated bench and human testing before its introduction has led to differences in the implementation of the NPSA's 2009 Safety Alert Part A between different devolved UK countries, and between different regions within England [1,2].
- We advise hospitals to make their own decisions about the introduction of new connectors, with the goal of maximising patient safety, on the basis of the information available, and involving all relevant speciality groups in this process.
- This update presents new or relevant information that may inform these decisions.

STERILITY CONCERNS ABOUT SYRINGES WITH NON-LUER CONNECTORS

- The NHS Pharmaceutical Aseptic Services Group (PASG) issued a position statement in November 2012 that raised concerns about the microbiological safety of syringes with some designs of new, non-Luer connectors when sealed with purpose-made caps and used for the preparation of aseptic solutions in pharmacies [3]. This statement was based in part on the results of tests commissioned by the Welsh Government [4,5].
- Further tests demonstrate the integrity of sealed syringes in "dye intrusion" tests [6,7], but there remain concerns about microbiological safety.
- Whether to prepare prefilled syringes with new connectors for spinal or epidural injection or infusion is a decision that should be taken locally by clinicians and aseptic pharmacists after consideration of the available evidence and the conduct of routine, local Quality Assurance procedures.
- There is no evidence that the sterility of syringes and needles provided in sterile packages for use immediately after opening, e.g. for spinal anaesthesia, is compromised.

NEW CONNECTORS UNLIKELY TO BE COMPLIANT WITH FUTURE INTERNATIONAL STANDARDS

- The International Standards Organisation (ISO) committee (ISO TC210 JWG4) charged with developing standards for non-interchangeable connectors for use in neuraxial and regional anaesthesia, and other medical applications, has indicated that these standards may be finalised as soon as 2015 [8].
- It is likely that none of the currently available non-Luer connectors that are compliant with the NPSA's 2009 Safety Alerts [2,9] will meet the requirements of the ISO standards [8].

CONTINUED USE OF THE RISK REGISTER MAY BE ADOPTED BY SOME TRUSTS

- Hospitals' use of their local Risk Register to explain non-compliance with the NPSA directives may be seen as the best option if clinicians are concerned about potential adverse patient safety issues relating to the introduction of non-Luer neuraxial and regional anaesthesia connectors.
- We believe that the introduction of a non-Luer connector for neuraxial and regional anaesthesia will ultimately prove to be in the interests of patient safety.
- Permanent use of the Risk Register is not likely to be a feasible option, but hospitals that decide to use it may wish to continue its use until they are satisfied that the available non-Luer connectors are effective and safe for their patients, and available for all neuraxial and regional applications.

IMPLEMENTATION OF PART B ONLY WEEKS AWAY

- With a target implementation date of 1st April 2013 for Part B of the NPSA directive [9], and thereby the extension of the use of non-Luer connectors from spinal to epidural and regional anaesthesia devices, hospitals that have not already introduced non-Luer connectors may wish to delay decisions about their introduction until a full range of equipment is available for all neuraxial and regional anaesthetic applications, and any other concerns about the use of this equipment have been resolved.
- The NHS Commissioning Board has issued a Neuraxial Update [10] that advises that peripheral nerve blocks are not covered by Part B of the NPSA directive, whereas suprascapular nerve blocks are covered. This suggests that there remains a degree of confusion about some of the areas of anaesthetic practice covered by Part B.
- Work is progressing on the development of an infusion bag/giving set spike system that will not cross-connect with bags of fluid or giving sets intended for intravenous administration.

FURTHER DEVELOPMENTS

- News of further developments in the introduction of non-Luer neuraxial connectors will be made available here: http://www.aagbi.org/safety/safer-spinal-epidural-and-regional-devices

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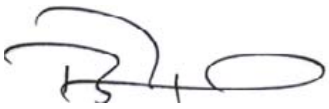

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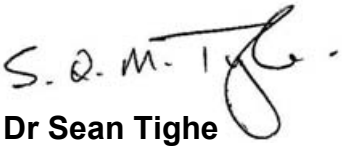

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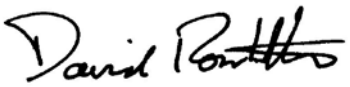

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