Terms of Reference

Small Bore Connector Clinical Advisory Group

1. Introduction

Wrong route errors have occurred in the UK and worldwide arising from the universal use of the Luer and IV spike connectors for all routes of administration. These incidents have included fatal incidents arising from intravenous administration of oral medicines, enteral feeds and flushes, intrathecal administration of intravenous chemotherapy, and intravenous administration of epidural infusions.

The National Patient Safety Agency Issued two Patient Safety Alerts that recommended the use of safer connector designs for oral/enteral use and spinal/intrathecal/epidural and regional anaesthesia use.[1 - 2]

New devices with 'non-standardised' non-Luer connectors for these routes of administration are now used in the NHS.

The International Standards Organisation (ISO) and healthcare industry have been working on a series of new International Standards for small bore (non-Luer) connectors in a range of medical devices.

The working group, ISO/TC 210 & IEC/SC 62D JWG4 is working on what's called the 80369 International Standard series[3].

- Part 2: Connectors for breathing systems and driving gases
- Part 3: Connectors for enteral applications
- Part 5: Connectors for limb cuff inflation applications
- Part 6: Connectors for neuraxial applications
- Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications

There are plans for the medical devices industry to introduce devices incorporating new ISO design small bore connectors into the UK over the next few years.

New risks to patient safety may be introduced by the introduction of devices with the new ISO connector designs and there is a requirement to identify and co-ordinate action across the NHS to minimise these risks

Risks may arise from the NHS, patients and carers not being fully aware of the connector design change, the implication on clinical use, the supply and use of current 'non-Luer' and Luer designs, incompatible equipment, device shortages, education and training issues etc.

2. Clinical governance arrangements

The Small Bore Connector Advisory Group will report to the Patient Safety Steering Group and work with other Patient Safety Expert Groups as appropriate for new small bore connector designs being introduced into practice. The Clinical Advisory Group will ensure a consistent safe approach to the introduction of these new connector designs in the NHS. Sub-groups of clinical users, supply chain, manufacturers and other stakeholders will be established to work with the clinical Advisory Group on developing and monitoring implementation plans.

The Small Bore Connector Advisory Group replaces NHS England External Reference Group on Neuraxial Devices.

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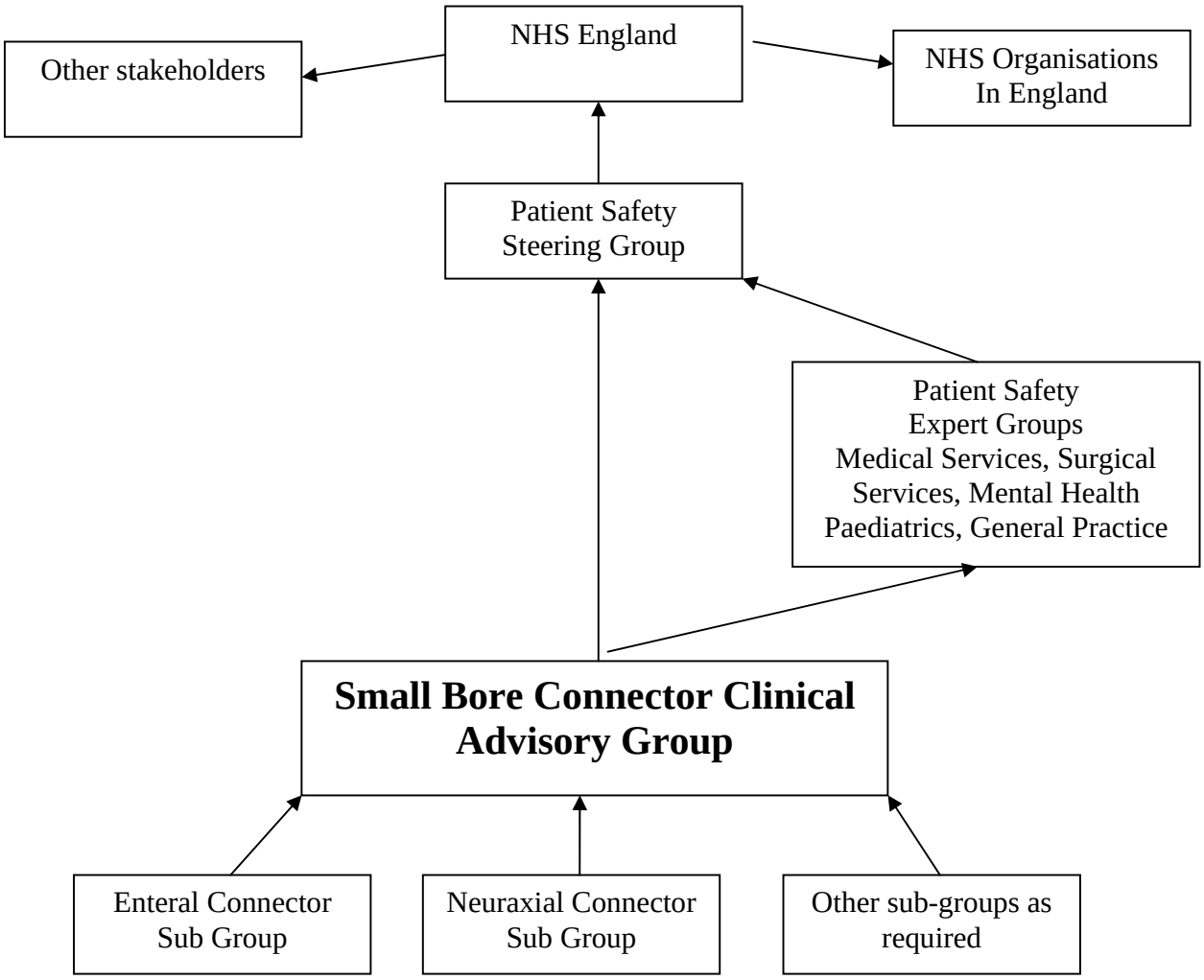

3. Objectives for The Small Bore Connector Clinical Advisory Group

1. Provide guidance on the introduction of medical devices with new small bore connectors to the NHS England Patient Safety Steering Group and other expert groups on patient safety.

2. Ensure that the NHS, patient groups and other major stakeholders are aware of the proposed introduction of new devices with new small bore connectors and have been given an opportunity to comment.

3. Provide similar guidance and advice on devices with connectors to replace the use of the Intravenous spike connection for non-intravenous applications.

4. Review the technical and usability information for the devices with the new connectors to ensure that the devices meet the needs of patients and healthcare staff.

5. Review the range of products available and supply chain issues to ensure that clinical and logistics issues are considered.

6. Help identify new risks arising from new devices and mitigating actions that can help to minimise these risks.

7. Advise on issues from the continued use of medical devices with Luer or non-standardised connectors or the introduction of new non-standardised devices.

8. Working with the NHS, industry and NHS supply chain to develop draft implementation plans for the introduction of devices with new connectors.

9. Advise on stakeholder engagement concerning draft implementation plans.

10. Review the comments arising from the stakeholder engagement and provide NHS guidance and advice to prepare final implementation plans.

11. Provide further advice and respond to questions and issues that arise following the publication of implementation plans.

12. Advise on what further initiatives are required to minimise risks with devices with small bore connectors.

4. Clinical Advisory Group Membership

Clinical Chair,
Deputy Chair,
Secretariat supplied by the Patient Safety Team, NHS England
Representatives from relevant Royal Colleges, Clinical Associations, NHS Organisations, NHS Supply Chain, MHRA, Medical Devices Industry
Observers from:
NHS Wales, Scotland and Northern Ireland

5. Meeting frequency

Meetings three times a year.
Some meetings will be held by webex.

6. Sub-groups

Clinical Chair
Secretariat supplied by the Patient Safety Team, NHS England
Clinical users, patients, supply chain, MHRA, medical devices manufacturers and suppliers

7. Meeting frequency

As required may be combined with full Clinical Advisory Group Meetings.
Some meetings will be held by webex.

6. Recording and circulation of minutes

- All meetings will be minuted
- Minutes will be circulated within two weeks of the meeting
- Any forthcoming agenda items must be submitted to the chair within 7 days of the forthcoming meeting to enable distribution prior to the meeting
- Agenda and relevant papers will be circulated one week prior to the meeting.

References

1. National Patient Safety Agency. Patient Safety Alert 19. Promoting safer measurement and administration of liquid medicines via oral and other enteral routes. 2007. Available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=59808
2. National Patient Safety Agency. Patient Safety Alert. Safer spinal, intrathecal, epidural and regional devices. 2009/2011. Available at: http://www.nrls.npsa.nhs.uk/alerts/?entryid45=94529
3. Association for the Advancement of Medical Instrumentation. Ambitious Standards Initiative on Small-bore Connectors Moves Forward. April 2013. Available at: http://www.aami.org/news/2013/042513_SmallBore_Connectors_Standard_Moves_Forward.html

14/2/2014