Small Bore Connector Clinical Advisory Group

Wednesday 16th July 2014
Skills for Care, Lynton House, Tavistock Square

Draft minutes

1. Welcome and Chairman's Introduction

Dr Paul Sharpe, welcomed all members to the new group.
For a list of members attending and apologies see Table 1

2. Review of terms of reference for the group

Dr Cousins reviewed the terms of reference of the group. The main objectives for the group are to:

I. 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.

II. 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.

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

IV. 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.

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

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

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

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

IX. Advise on stakeholder engagement concerning draft implementation plans.

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

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

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

3. Review of recent wrong route/small bore errors in the NRLS

Dr Cousins reported that the incident reports to the National Reporting and Learning service indicate that violations of the safe systems for intrathecal chemotherapy have been reported since January 2014 e.g. both intravenous and intrathecal chemotherapy for the same patient were found in clinical areas at the same time. For epidural therapy , incidents where epidural infusions had been attached to intravenous lines , and intravenous bolus injections had been administered by the epidural line in error had been reported.

It was agreed that example incident reports were to be circulated to the group to further clarify the need for the small bore connection introduction (Appendix 1).

4. Update on implementation of the Patient Safety Alert on use of devices with non-Luer connectors for Spinal (intrathecal) chemotherapy

NHS England published a stage 3 Patient Safety Alert:on Non-Luer spinal (intrathecal) devices for chemotherapy in February 2014. NHS Trusts undertaking intrathecal chemotherapy were recommended to ensure that systems should be in place to ensure all spinal (intrathecal) chemotherapy bolus doses are performed using syringes and needles and other devices with non-Luer connectors that cannot connect with intravenous devices.

The target date for implementation of this guidance was 20th August 2014. NHS England had received information to indicate that 114 NHS organisations had declared that the Alert was relevant to them and over 78 organisations had already implemented the non-Luer devices for chemotherapy.

NHS England will post the details of compliance with the Patient Safety Alert on their web site in September 2014.

5. ISO Standards Update

The Group reviewed two reports prepared by Terry Longman and supplementary materials presented by group members. The various small bore standards in the ISO 80369 series were discussed.

80369-1 General requirements for small bore connectors

This revision is progressing slowly. At the ISO meeting in Berlin meeting the following major issues were discussed:

a) Alternative/proprietary connectors

Despite strong objections by the UK and several other countries to alternative/proprietary connectors being allowed in the standard the majority vote was to keep them in. However the requirements were strengthened and now state that manufacturers of alternative/proprietary connectors can no longer claim compliance to this 80369 series of standards.

b) Are these connector's devices?

Despite unanimous agreement that these connectors are not devices there was still opposition to actually stating this in the introduction.

c) Should part 4 Urinary be included?

Despite no work item proposal to write a part 4 the majority of those at the meeting to leave it in with a qualifier that this is yet to be developed.

d) Should this revision be postponed until all the other parts have been published.

The revision will be not be delayed.

e) Should there be only one connector per application unless there are technical or clinical reasons for more.

Agreed in principle but contradicts the alternative/proprietary connector requirement.

80369-2 respiratory

The task group is forging ahead with this project. The timescale has been set:

- Samples will be ready by 15th October 2104
- Performance Tests completed by December 2014
- A draft international standard to be circulated in January 2015
- Publication of the Final International Standard in November 2015

Action

Contact ABHI – to establish communications with respiratory manufacturers and suppliers.

Apply the criteria for the safe introduction of devices with new small bore connectors when available (see section 3 below).

Agree a target date for implementation in 2016.

Develop a communication strategy

80369-3 enteral

The had been a negative vote concerning the first draft international standard part 3 – enteral early in 2014. A second draft International Standard for Part 3- enteral is expected over the next few months.

Marcus Ineson from GBUK was concerned that the absolute earliest 80369-3 can become an ISO Standard is June/July 2015 and then only if the entire process from this point runs exactly as planned.

A provisional date of September 2015 has been identified as possible target date for the introduction of the enteral devices with 80369-3 connector design into practice in the NHS in England.

There is a risk that if the ISO process for 80369-3 is further delayed and the target date for the introduction of the devices with the new connector remains unchanged, that that the NHS in England will be changing before a Final Internal Standard has been formally agreed and published.

UK enteral product manufacturers present at the meeting were concerned that US companies were focused on meeting the Californian state legislation for the use of Non-Luer connectors and then the US market and commercial decisions concerning when supplies of enteral devices with connectors were introduced into Europe and the UK might be made on this basis, without fully considering all the issues..

Action

The Group agreed that a set of criteria should be developed that clearly sets out the safeguards that are required for the safe introduction into the NHS in England of devices with any of the new ISO small bore standards in the future. These criteria should be subject to stakeholder consultation before it is finally agreed.

As well as developing the criteria for the safe introduction of devices with new small bore connectors, a communication strategy needs to be developed that ensures that patients, carers, suppliers, healthcare professionals, students and organisations are made aware of the plans

for the introduction of devices with new connector from 12 months before the planned target implementation date.

Seek additional committee membership from BAPEN

80369-6 Neuraxial applications

A misconnection between two of the new design ISO small bore connectors had been identified in early 2014.

The misconnection identified was between the Part 3 (Enteral) female and the Part6 (Neuraxial) female. This misconnection could not be solved by changing the materials or dimensions and clinicians were asked if these were clinical hazards

The original CAD parameters to prevent interference were 0,2 mm but softer materials meant that this was not sufficient.

Unfortunately the CAD protocol for this 0,2 mm was never validated

Tests had been carried out on the sort of forces that users would exert before giving up. The mean value was around 24 N. However there was a paper in Anaesthesia by Tim Cook (Bath), which did not indicate that users would make misconnections at 70N and that this force would not be used during spinal and is unlikely to be used in epidural procedures. This is judged to be at the upper limits or beyond of forces expected to be used.

Tests were also carried out on leakage and it was shown that the misconnected -3 and -6 connectors leaked like a sieve (98%).

The results of a survey of Clinicians found that, with the above combination of force and leakage, 28 out of 28 considered that this did not represent a clinical hazard.

The task group had also looked at severity and probability of such a misconnection and calculated that the likelihood of such incidents would be in the region of 14 incidents per billion procedures.

The -6 task group proposals include:

- Increasing the thickness of the threads on both male and female connectors. Threads will not go right to the end to prevent 1½ turns of syringe

- Increasing the material stiffness from 700 to 950 MPa. Later discovered that the materials used were in fact 1200 MPa hardness.

- Introducing a leak test as a secondary test if the misconnecting parts stayed attached after being forced together.

A draft International standard and new timetable for 80369 – 6 neuraxial application has just been published June 2014.

Ballot on Draft International standard – November 2014
Publication of International standard June 2015
First shipment of neuraxial devices with new ISO connector Quarter 1 2016.

Action

Apply the criteria for the safe introduction of devices with new small bore connectors when available.

Agree a target date for implementation in 2016.

Develop a communication strategy

80369-5 Limb Cuff applications

The draft international standard was approved with two negative votes from the UK and Australia. The 50 odd pages of comments were discussed at the Philadelphia meeting.

Technical comments had been presented, the most significant of which were those from the UK and Australia regarding misconnection with Luer and the doubtful need for two connectors in this application. There was no clinical reason to have two connectors. It was proposed deleting the S2 connector as this connected with the Luer slip female. The ISO committee agreed to this proposal.

Deleting the S2 connector answered the fundamental reasons for the Australian and UK negative votes. It was agreed that -5 could be forwarded to ISO CS for circulation as an final draft international standard. Remembering that everything is on hold until the CAD tool is validated.

Action

Contact ABHI – to establish communications with limb cuff manufacturers and suppliers.

Apply the criteria for the safe introduction of devices with new small bore connectors when available.

Agree a target date for implementation in 2016.

Develop a communication strategy

80369-7 Vascular applications (Luer)

Awaiting circulation of final draft international standard.
Glass syringes and needle free devices had been excluded from the new international standard.

The new standard provided a more complete set of dimensions for the Luer connector to minimise the risk of mis-connection with order non-Luer connectors in the 80369 standards range.

Action

Contact ABHI – establish links to vascular applications.

80369-20 Performance test methods

Awaiting circulation of Final Draft International standard

The misconnections that have been highlighted by the -6 task group have called into question the CAD protocol. The fact that this protocol has never been validated is a cause for concern.

It has therefore been agreed that all parts of 80369 will be held pending validation of the CAD protocol using the new interference value of 0.4 mm instead of the 0.2 mm used previously.

6.Update on introduction of epidural reservoir connector

Dr Cousins reported that supplies of the proprietary Nonivlok epidural connector had been manufactured and included in epidural administration sets and epidural infusions. The obstetric department of Guy's and St Thomas's NHS Foundation Trust were evaluating these new devices. The company planned to introduce these products into other NHS hospital Trusts in coming months. The introduction of safer epidural reservoir connectors was seen as essential to minimise high risk wrong route errors with epidural products.

There was some discussion of a new work item for enteral device standard EN1615. However, it is still not clear whether a design has been formally submitted and it will be a minimum of three years before a international standard is formally agreed.

Small Bore Connector Clinical Advisory Group Meeting 16th July 2014

Attendance

Paul Sharpe	Chairman Leicester Teaching Hospitals
David Cousins	Secretary, Patient Safety Domain, NHS England Safe Medication and Devices
Philip Bickford Smith	Consultant anaesthetist, Topic Expert
Marcus Ineson	Enteral Products Suppliers Group / GBUK Ltd
Jemima Keyes	NHS Northern Ireland Observer
David Lovett	NHS Pharmacy Aseptic services and Cancer Network Representative
Dagmar Luettel	Patient Safety Domain, NHS England Safer Devices
Graham Millward	Enteral Products Suppliers Group / Vygon UK
Pete Phillips	Welsh Assembly Government Observer
Tom Woodcock	Safer Anaesthesia Liaison Group

By teleconference

Iain Robertson	Chair Scottish technologies group and interventional radiologist. Scottish Observer.
Innes Connor	Incident reporting and investigation centre in Scotland. Scottish Observer.
Stephen Kinsella	Obstetric Anaesthetist's Association

Apologies

Mathew Alderman	Category Manager, NHS Wales, Shared Services Partnership
Barbara Doveston	National Nutrition Nurses Group
Terry Longman	BSI/ISO small bore connector group chair
Caroline Lecko	Patient Safety Domain, NHS England Nutrition and hydration
Tony Moriarty	Consultant Anaesthetist, Topic Expert
Patrick Macaul	Technical adviser. Scottish Observer.
Joan Russell	Patient Safety Domain, NHS England Anaesthesia and surgical services
Alex Little	NHS Scotland Observer
Barry Walker	NHS Supply Chain