Small Bore Connector Clinical Advisory Group

Wednesday 5th November 2014

Skipton House, London

1) Welcome and Chairman's Introduction

The Chairman, Dr Paul Sharpe, welcomed group members to the meeting. Dr David Cousins has retired from his post as Senior Head of Medication and Medical Devices Safety in the Patient Safety Domain in NHS England. Ms Dagmar Luettel, Lead for Medical Device Safety, NHS England will take over as secretary of the clinical advisory group. Dr Cousins will be working part-time as a medication/medical device safety officer in a medical homecare company and hopes to continue as a member of the group. For a list of members attending and apologies see Appendix 1.

2) Review of minutes from last meeting – July 2014

Correction to the ISO Update meeting report presented by Terry Longman: Neuraxial applications; 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 (~~Bristol,~~ 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.
Action: the minutes for the last meeting were amended.

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

This information was not available and will be circulated to the group members for information before the next meeting
Action: Dagmar Luettel

4) Draft safety criteria for the introduction of new design small bore connectors into the NHS

Dr Cousins presented six draft safety criteria. The group agreed with these criteria and made suggestions to further clarify these criteria (see Appendix 2). NHS Wales have also arranged for additional surveillance for incidents arising from the introduction of new devices. The surveillance service is funded by the Welsh Assembly. The Department of Health in England has indicated in the past that central funding for additional surveillance in England is not available and existing device vigilance

reporting methods via the National Reporting and Learning System and the MHRA will be used to monitor incidents.
Action: All members - Review and amend draft safety criteria

NHS Wales, Scotland and Northern Ireland to be invited to adopt and support the final safety criteria to enable a UK wide approach to implementation of new small bore connector devices

Action: Dagmar Luettel – Collate final safety criteria and publish on NHS England web site

5) Draft communication strategy

A Sentinal Event Alert: Managing the risk during transition to the new ISO tubing connector standards published by The Joint Commission, in the USA was reviewed by the group. The Alert recommends the following actions:

- In preparation for the new ISO connector standards
- Effective clinical processes and procedures for using these devices
- Appropriate education and training
- Effective communication
- Leadership
- Safety culture
- Related Joint Commission requirements
- Resources/references

A communication strategy from NHS England can include: Small Bore Connector information hosted as part of the medical devices web pages, in the Patient Safety Domain on the NHS England web site. Possible content for these web pages – see Appendix 3. Consideration could also be given to the use of Patient Safety Alerts to formally communicate 1) the anticipated changes arising from the range of new ISO connector standards 2) plans for the introduction of devices with specific small bore connectors. Support for PSA's will be required from NHS England Patient Safety Expert Groups.
Action Dagmar Luettel and David Cousins: Develop and publish small bore connector web pages on NHS England web site. Develop draft content for a possible Patient Safety Alert on the introduction of devices with new ISO standard small bore connectors.

6) BSI Committee

Terry Longman is the chairman of BSI CH/210/ 5 small bore connectors for medical devices group. Liz Osborne (liz.osborne@bsigroup.com) is the lead programme manager. Clarification was provided on the respective roles of the two groups. The BSI group is intended to provide the technical input into the ISO standard development process and will vote on draft International Standards. Implementation of devices with new small bore connectors is not in scope for this group. The main role of the NHS England Clinical Advisory Group is to provide advice on the safe

implementation of devices with new small bore connectors. The respective roles of the two groups are complementary.

7) ISO standards update

a. 80369-1.2 Small bore connectors for liquids and gases in healthcare applications – Part 1. **General Requirements**. Being developed for publication and voting. Issues for further clarification:
    - testing for misconnection involving other no ISO connectors not included in CADD analysis such as conical connectors, fir tree connectors and temperature ports;
    - Use of proprietary connectors – that will meet Part1 – but will not meet secondary standards parts 2 – 6 etc.

b. Part 3 **enteral connector and reservoir connector**
Draft International Standard for connectors for enteral applications issued and closing date for comments and votes 25th November 2014
- UK voting against for the following reasons
    - Misconnection between ISO female connector and Luer slip female connector. Possible action to withdraw standard /use of Luer slip connectors.
    - Misconnection between ISO male connector and tracheal tube end. Back collar/finger grip dimensions not included in connector standard –expected to be included in device standard
- Further clarification required on connector gender orientation
- Revised ISO timeline for the publication of the Final International Standard is August 2015
- Industry proposing a staggered introduction of enteral products with new ISO connector from September 2015 with enteral administration sets being introduced first and all other products by March 2016
- The UK clinicians and BAPEN representatives tell us they want all equipment available before any role out in UK, not a staggered role out.
- Previous decision on target date for introduction of a complete range of enteral products of September 2015 is no longer possible. Recommend a revised target date of March 2016, to be updated as more information becomes available.
- Draft International Standard for enteral reservoir connectors issued – based on current deigns already in use.

c. Part 6 neuraxial connector
Draft International Standard for connectors for neuraxial applications issued and closing date for comments and votes 4th February 2015.
Issues for further clarification:
- Misconnection male ISO connector to female luer slip. Possible solution to thicken ISO connector collar to prevent

misconnection. Possible action to withdraw standard /use of Luer slip connectors.

- Revised ISO timeline for the publication of the Final International Standard is September 2015. Availability of a full range of products 3 or 4th quarter 2016

d. Part 2 respiratory connectors

Process delayed – awaiting production of prototypes for testing – expected January 2015. Then testing required.
Draft International Standard expected 2nd Quarter 2015.

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

Dr David Cousins reported that we have 100% compliance with the interim arrangements. All 143 trusts, which provide an intrathecal chemotherapy service, have reported that they have completed the actions as outlined in the alert.

9) AOB

Update on introduction of epidural reservoir connector

Dr Paul Sharpe reported some issues with these connectors (i.e. stiffness). Currently only one company is supplying the bags and this might become a supply issue.
Action: Dr Paul Sharpe to discuss with company

Dr Paul Sharpe also raised the question what actions need to be taken by a Trust if they adopt the following practice: taking a Portex epidural catheter and replacing the proprietary epidural connector and filter with a non-Luer connector and filter from a third party, all CE marked for the purpose of use in epidural practice.

Action Dagmar Luettel to ask MHRA if this would constitute a new medical device
Action Paul Sharpe: asking David Bogod for legal opinion

NHS England to nominate Dr Paul Sharpe as a new member of the BSI Committee
Action: Dagmar Luettel

Date and time of next meeting

16th March 2015 10:30 – 2:30

Table 1: Small Bore Connector Clinical Advisory Group
Meeting 5th November 2014

Attendance

Paul Sharpe	Chairman, Leicester Teaching Hospitals
David Cousins	Patient Safety Domain, NHS England
Dagmar Luettel	Secretary, Patient Safety Domain, NHS England
Alisa Kennedy	BAPEN, PEN Group BDA
Andrew Vaughan	ABHI
Barbara Doveston	National Nutrition Nurses Group
Barry Walker	NHS Supply Chain
David Lovett	NHS Pharmacy Aseptic services
Graham Millward	BAREMA/ Enteral Products Suppliers Group - Vygon UK
Richard Benhem	Enteral Products Suppliers Group - GBUK Ltd
Matthew Alderman	Category Manager, NHS Wales, Shared Services Partnership
Pete Phillips	Welsh Assembly Government Observer
Philip Bickford Smith	Consultant anaesthetist, Topic Expert
Terry Longman	BSI/ISO small bore connector group chair
Tom Woodcock	Safer Anaesthesia Liaison Group

By teleconference

Innes Connor	Incident reporting and investigation centre in Scotland Observer
Iain Robertson	Chair Scottish technologies group and interventional radiologist Scottish Observer
Patrick Macaulay	Technical advisor, Scottish Observer
Jemima Keyes	NHS Northern Ireland Observer
Caroline Lecko	Patient Safety Domain, NHS England, Nutrition and hydration
Mike Kinsella	Obstetric Anaesthetist's Association

Apologies and not attended

Joan Russell	Patient Safety Domain, NHS England, Anaesthesia and surgical services
Tony Moriarty	Consultant Anaesthetist, Topic Expert
Alex Little	NHS Scotland Observer
Marcus Ineson	Enteral Products Suppliers Group/ GBUK Ltd

Appendix 2: Draft safety criteria for the introduction of new design small bore connectors into the NHS Version 2

No	Safety criteria	Further information
1	A final International Standard has been published	This will include a ISO connector standard and where available and appropriate a ISO device standard
2	Technical evidence for the safe use of new devices and ancillary products	Compliance with functional and clinical application tests required by the specific 80369 standard The ISO connector standard process may not have undertaken all the technical testing required to support safe clinical use e.g. microbiological and physical integrity testing for syringes and syringe caps used to prepare, store, transport and administer intrathecal chemotherapy. Other tests include drug and device stability tests
3	User evaluation evidence for the safe use of new devices and ancillary products, including labelling and packaging.	Clinical acceptance testing including cross connection and review of labelling and packaging
4	Evidence that a complete range devices and ancillary products with the new small bore connector for specified clinical application are available	Evidence that all devices and ancillary products necessary for a specified clinical application e.g. enteral/oral, neuraxial are available prior to implementation.
5	Evidence that there is sufficient stocks of new devices and ancillary products in the UK to meet expected demand	Between 3 – 6 months stock
6	Evidence of industry support to aid the NHS introduce the new devices and ancillary products safely	Required support includes awareness raising, education and training for procurement, distribution, and clinical staff

Appendix 3: **Draft content on small bore connectors for small bore connector strategy**

The Safe Introduction of Medical Devices With New Small Bore Connectors Into Use in The NHS

Introduction

Wrong route errors have occurred in the UK and worldwide arising from the use of the Luer connectors in medical devices for all routes of administration.

Following initiatives from the former National Patient Safety Agency and NHS England new devices with 'non-standardised' small bore (non-Luer) connectors for oral/enteral and neuraxial routes of administration have already been introduced into use, to minimise risks of wrong route errors in practice.

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

The working group, ISO/TC 210 & IEC/SC 62D JWG4 are responsible for the 80369 International Standard series to introduce new designs for small bore connectors:

- 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

Some ISO standards are nearing completion and industry are planning to manufacture devices incorporating new ISO design small bore connectors and place these on the market in the UK, with the intention of these products replacing similar devices with Luer and 'non-standardised' connectors.

NHS England supports the planned introduction of devices with ISO design connectors, so that medical devices used in the UK are harmonised with those used in other countries, and there is a controlled connector design standard process to minimise the risk of cross connections of devices intended for different clinical applications.

New risks to patient safety could arise from the un-coordinated introduction of devices with new ISO connector designs into the NHS.

Risks may arise from healthcare organisations, professionals, patients and carers not being fully aware of the connector design change, and implication on clinical use. New risks include the supply and attempted use of incompatible devices and ancillary products, incorrect use of the new connectors and device shortages.

NHS England has set up a Small Bore Connector Clinical Advisory Group Under the Chairmanship of Dr Paul Sharpe a Consultant Anaesthetist from Leicester Teaching Hospitals. The aim of the group is to advise NHS England on the safe introduction of medical devices with these new connector designs into the NHS. The group is working with health professionals, supply chain, manufacturers and other stakeholders. The Small Bore Connector Advisory Group replaces NHS England External Reference Group on Neuraxial Devices.

Useful information on medical devices with small bore connectors will be posted on this webpage.

Safety Criteria

In order to minimise the risk of unattended harm, a draft set of safety criteria have been developed to assist NHS England to determine if key safeguard are in place before a timetable for the introduction of devices with new small bore connectors for a specified clinical application should be procured and introduced into practice..

Link to draft safety criteria for the introduction of medical devices with small bore connectors

NHS England Small Bore Connector Clinical Advisory Group

Link to minute from the July 2014 meeting

Link to terms of reference

ISO/TC 210 & IEC/SC 62D JWG4

ISO 80369-1:2010

Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements. http://www.iso.org/iso/catalogue_detail.htm?csnumber=45976

British Standards Institute

Committee: CH/210/5 Small Bore Connectors for Medical Devices
Under the direction of CH/210, is responsible for the UK input to ISO/TC 210/JWG 04 and to CEN/CLC TC3 WG2 and the preparation, revision and amendment of British Standards for small bore connectors

https://standardsdevelopment.bsigroup.com/Home/Committee/50077991

Association for the Advancement of Medical Instrumentation

This organisation provides the secretariat for ISO/TC210

http://www.aami.org/hottopics/connectors

GEDSA

The Global Enteral Device Supplier Association (GEDSA) was formed to help introduce international standards in medical device tubing connectors, which will enhance patient safety. GEDSA will facilitate a stronger flow of communication to raise awareness and encourage adoption

http://www.gedsa.org/