Small Bore Connector Clinical Advisory Group

Wednesday 16 March 2015, 10:30am to 2:30pm

Skipton House, London

		ACTIONS
1	**Welcome and Chairman's Introduction** The Chairman, Dr Paul Sharpe, welcomed group members to the meeting. For a list of members attending and apologies see Appendix 1.	
2	**Review of minutes from last meeting – November 2014** A correction to the update on introduction of epidural reservoir connectors (discussed under AOB) is required: Dr Paul Sharpe reported the issue he had been made aware of was purely a stiffness issue (not cross connection as previously recorded). Paul Sharpe is going to meet with a company at the end of March to discuss further spike connectors. Updates on previous actions: Paul Sharpe raised a question at the last meeting relating to connecting different devices together and if this would constitute a new medical device. MHRA have confirmed that the practice of 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, would be considered off-label use. David Bogod was asked for a legal opinion and advised that a clinician/trust, who is adopting this practice, is responsible for using the devices in this way. Paul Sharpe reported that clinical evaluations of hybrid connections (Surety epidural connectors with Smiths Portex epidural catheters) have been undertaken in Leicester. An unexpected frequency of occlusions was seen. As a result, the evaluation has been suspended and alternative connectors are being assessed. PS agreed to summarise findings so they can be shared more widely and ongoing discussions on finding solutions can take place. It was suggested to publish the information on the RCOA/ SALG and NHS England/ Patient Safety First website. NHS Scotland requested information for distribution through their website also.	Amend minutes from the last meeting and publish final version on NHS England website (DL) Send information to Dagmar Luettel/ Tom Woodcock (PS)
3	**Review of recent wrong route/ small bore errors in the NRLS** A review of NRLS incident data has been undertaken by Dagmar Luettel to identify any recent wrong route errors of	Share NRLS review with Pete Phillips - for sharing with Welsh

	intrathecal/ spinal/ epidural administrations. Several incidents were found, which occurred in the time between July and December 2014, in which medication was given via the wrong route (i.e. epidural instead of intravenous and vice versa). None of these incident was reported as resulting in serious harm, however, there is potential for all these incidents to have long term effects on the patient. There were also some near misses involving chemotherapy and describing that recommended practice was not always followed.	Non-Luer Connectors Reference Group for information (DL)
4	**Update from the GEDSA meeting on 9th March 2015** Paul Sharpe presented the UK experience of the roll out of the non-luer connectors for neuraxial procedures at the recent GEDSA meeting. This included the various initiatives over the last years but also the difficulty of not having all equipment available. It was noted by various members of the group that it is vital to have a complete product range for neuraxial procedures available before implementation (and the necessary volumes). However, there is a risk that companies may introduce their new equipment at different stages and that the roll-out of the ISO compliant devices happens in an un-coordinated way. David Cousins suggested developing a clear position statement from the UK NHS for device manufacturers outlining that it is expected to have the equipment available in the UK – no later than six months after US implantation. The group agreed and suggested that this could be a joint statement from various organisations and support should be sought from e.g. Royal Colleges, NHS Supply Chain, devolved governments, BAREMA, ABHI, EPSG and SALG. It was also suggested to arrange a meeting at the end of June with all industry key players to explain the statement and to ensure devices manufacturers understand what the NHS needs to be able to safely implement the new devices without increasing any risks to patient safety.	Develop Position Statement (All) Plan meeting with industry for the end of June (PS/DL)
5	**Draft Patient Safety Alert** A Patient safety Alert has been drafted to raise awareness of the new devices and to inform healthcare organisations that enteral devices with new connectors will be introduced from September 2015. This will be a phased implementation; initially only giving sets will be available, together with an adapter to allow continued use; newly designed enteral syringes and feeding tubes will be introduced in March 2016. The decision of a phased implementation had been made by device manufacturers, although clinical experts have strongly raised their concerns about this approach. Whilst it was reported that some clinicians could see some benefits to a phased implementation, other expressed their concerns. AK states that local planning is difficult and that it is currently unclear what role feed companies will play in the clinical implementation. Prototypes for training purposes are	

	needed but it is still unclear what the design/format of feed sets will be. There will be adapters but it is not known yet for how long they will be available and how many adapters will be needed. BD states that feed companies cannot clearly state a change over time for hospitals (more easily managed in community) and that the transition time will now be extended as transition sets will be needed for a further six months. The internal workload will be significantly increased for trusts and this needs to be made clear to commissioners.	
	The group felt that it is important to ensure that the implementation plans are well communicated (in all care settings) and that risks associated with the new devises are managed. It was suggested to draft a Patient Safety Risk Assessment, which organisations can use as a template for local risk assessments during the transition period. This could include a list of potential risks, such as unavailability of equipment, adapter choking hazards, etc. The draft risk assessment could be made available as supporting information on the NHS England/ Patient Safety First website.	Draft risk assessment for introduction of newly designed enteral devices (All)
	As the two-phase approach was a decision taken by the feed companies, they should provide a copy of their risk assessment that has led them to this view. GM to request from feed companies/GEDSA.	Request risk assessment from feed companies/ GEDSA (GM)
	It was also suggested to publish a list of all devices affected as support material.	NHS Supply Chain to consider if list can be produced (BW)
	The draft Patient Safety Alert was reviewed and some minor amendments have been suggested to further improve clarity of the Alert.	Develop final version and issue Patient Safety Alert via central Alerting System (CAS) (DL)
6/7	**Update from the BSI Committee and ISO standards** Terry Longman gave a update on recent developments and reported that Parts 3, 5, 6 & 7 are expected to go to FDIS for publication of final standard this year. Part 2 (breathing systems/ driving gases) is currently being discussed, in particular the issue of misconnections between air & oxygen. It was identified that a fir tree connection change	NRLS

	would continue to allow mix-ups to occur. There is a proposal to replace the fir-tree connector (which makes the final outlets identical) with different connectors for air and oxygen. This would mean that a third connector is added to ISO 80369-3 (gas-specific connector R2 for Oxygen and the new R3 for Air). Another suggestion is to use the screw threads on the flow meters that are already different. The tubing standard is currently under review and may end up dictating format of connections. ISO 80369-2 (gas connectors) – CAD identified a number of possible misconnections. These have been reduced by tweaks to dimensions, but not entirely eliminated. Functional and usability testing needed before DIS vote closes (ISO time restrictions). PP not sure that the testing can be completed in time and may need to be deferred by group and would then need to have new NWIP issued. PP to keep advised. Enteral reservoir connectors (ISO 18250) standardisation process is nearly complete.	review on wrong gas to inform discussions (DL)
8	**NHS England website** General information on ISO 80369 and the Clinical Advisory Group has been published on the NHS England website. The members of the group agreed on the draft safety criteria and suggested that these should be made available on the NHS England website as recommendations. NHS Wales, Scotland and Northern Ireland are invited to adopt and support the final safety criteria to enable a UK wide approach to implementation of new small bore connector devices.	Publish safety criteria on NHS England web site (DL)
9	**OTHER issues** **Dose accuracy in enteral syringes** A paper from Pete Phillips was discussed outlining the risks of overdosing when using reverse Luer systems to deliver small doses of medicines and a 'cup fill' method. Most systems generally deliver between 30%-75% more medicine than the user intended to give. This could be a particular risk when opiates are being administered to neonates. The accuracy of all the systems becomes better if either a syringe cap is inserted into the syringe after filling, and removed before delivery or if an adaptor/drawing up straw is used to fill the syringe. Other solutions, such as diluting the medication, were discussed. The possibility of a Patient Safety Alert to raise awareness if this new risk was considered and it was agreed to take the issue to the paediatric Patient Safety Expert Group (PSEG) for further discussion.	Issue to be discussed at the next paediatric PSEG meeting (DL)

10	**AOB** – none.	
	Date and time of next meeting 3 June 2015 11:30 – 2:30	

Table 1: Small Bore Connector Clinical Advisory Group Meeting 16 March 2014

Attendance

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

By teleconference

Iain Robertson	Chair Scottish technologies group and interventional radiologist Scottish Observer
Paul Hornby	Strategic Sourcing Manager for Scottish National procurement Division

Apologies and not attended

Joan Russell	Patient Safety Domain, NHS England
Tony Moriarty	Consultant Anaesthetist, Topic Expert
Alex Little	NHS Scotland Observer
Marcus Ineson	Enteral Products Suppliers Group/ GBUK Ltd
Innes Connor	Incident reporting and investigation centre in Scotland Observer
Patrick Macaulay	Technical advisor, Scottish Observer
Jemima Keyes	NHS Northern Ireland Observer
Mike Kinsella	Obstetric Anaesthetist's Association
Caroline Lecko	Patient Safety Domain, NHS England