Section 3

Appendices

Appendix 1: Wrong route administration

Comment from the National Patient Safety Agency

Developing and implementing devices with safe connectors

Dr David Cousins,
Head of Safe Medication Practice and Medical Specialties, NPSA

The National Patient Safety Agency (NPSA) published a risk assessment in 2004 that identified the need for research to develop and evaluate safe connector designs for neuraxial applications including the need for a new spike connector for neuraxial infusions.[1]

Safe connectors are small bore, non-luer connectors that are fitted to neuraxial devices to prevent misconnection with luer devices intended for intravenous and hypodermic use.

Department of Health funded research project

A Department of Health study to further reduce the risk of wrong route errors with spinal/epidural (neuraxial) devices was completed at the end of October 2008. Some parts of this research study have already be published and the final part will be published in the same location shortly.[2–4] The project required laboratory, simulation and clinical evaluation methods for safe connectors to be developed. The research provided proof of concept that new safe connector designs could be developed and one design completed all stages of evaluation. The successful connector is suitable for further development by the medical devices industry, alongside other safe connector design that may also be developed. This research will assist the commercial development of safe connectors into medical devices over the next few years.

Standards development

A new European standard EN 15546-1:2008; Small bore connectors for liquids and gases in healthcare applications. Part 1, *General Requirements*, has recently been published.[5] The standard is intended to be a reference document that can be used as a tool to minimise the risk of misconnections of small bore connectors between different medical applications. It provides a framework to assess non-interchangeability of small bore connectors based on their inherent design and dimensions.

Work is underway to develop detailed Part 2 standards for specific small bore connector applications via ISO Standards groups.[6] No specific dates or timescales have been set for the completion of this work and as with all standards – industry compliance with these standards will be voluntary.

Standards work can take a long time to complete. However, healthcare organisations do not have to wait for the standards work to be completed before requiring devices with safe connectors from their suppliers.

Purchasing for safety

The NPSA has been asked to oversee the introduction of neuraxial devices with safe connectors into the NHS as soon as possible. The Agency is holding meetings with industry and healthcare stakeholders between September 2008 – May 2009 before the publication of NPSA Purchasing For Safety Guidance for the NHS in England and Wales planned for June 2009.

The NPSA actions are similar to the recommendations issued by The Joint Commission in the USA in Sentinel Event Alert 36 (2006)[7] concerning tubing misconnections. In Alert 36 Healthcare Organisations in the USA were recommended not to purchase non-intravenous equipment that is equipped with connectors which can physically mate with a female luer intravenous line connectors. The Joint Commission urged manufacturers to implement 'design incompatibility' to prevent dangerous misconnections of tubes and catheters.

More information concerning the safe connect initiative is available on the NPSA website.[8]

References

1 Cousins D, Boult M. Risk assessment of spinal procedures with current safeguards and with proposed new connector design options for the Department of Health. *NPSA* February 2004. Available at: www.npsa.nhs/nrl/medication-zone.

2 Davies C. Pre-marketing assessment of non-luer connectors for use in the administration of spinal injections. *NHS Purchasing and Supplies Agency (PASA)* 2007. Available at: www.pasa.nhs.uk/pasa/Doc.aspx?Path=%5BMN%5D%5BSP%5D/NHSprocurement/CEP/Anaesthetic/CEP07013.pdf.

3 NHS Patient Safety Research Portfolio. Call For Proposals PS / 038: A prospective hazard analysis and pre-implementation evaluation of non-luer spinal connectors 2005 (available at: www.pcpoh.bham.ac.uk/publichealth/psrp/documents/PS038_Call_for_proposals_Spinal_connectors.pdf).

4 Lawton R, Green B. Phase 1 – The Potential Hazards Associated With The Implementation of the Prototype Non-Luer Spinal Connectors (June 2006 – March 2007). Research Report Summary for the NHS Patient Safety Research Portfolio, 2008. Available at: www.pcpoh.bham.ac.uk/publichealth/psrp/documents/PS038_Presentation_Lawton_July07.ppt.

5 BSI British Standards BS EN 15546-1 Small bore connectors for liquids and gases in healthcare applications July 2008. Available at: www.bsigroup.com/en/Shop/Publication-Detail/?pid=000000000030153338.

6 The Association For The Advancement of Medical Instrumentation (AAMI). Forthcoming Standards To Focus On Tubing Misconnections. *AAMI News* 2008;**43**:8. Available at http://www.aami.org/publications/AAMINews/sep2008/tubing.html.

7 Joint Commission. A persistent and potentially deadly occurrence. *Sentinel Event Alert* 36 2006. Available at: http://www.jointcommission.org/SentinelEventAlert/sea_36.htm.

8 National Patient Safety Agency. Safe Connector initiative. Available at: www.npsa.nhs/nrl/medication-zone/safe-connectors.

Appendix 2:

Example discharge advice for patients who have received CNB (Wrexham Maelor Hospital)

Trust ADDRESS

Post Epidural Infusion / Injection Patient Instruction Leaflet/ Discharge Instructions

Introduction

Serious complications from epidural analgesia are **rare (1 in 10,000)**. Because the epidural space is close to the spinal cord a collection of pus, or a blood clot can cause pressure on the spinal cord. In the **unlikely event** that there is pressure on the spinal cord it is crucial to diagnose and treat it as quickly as possible; this must be done by expert hospital doctors to prevent delays in treatment and long lasting damage. This leaflet tells you what to look for and what action to take if you think that you have a problem.

Assessment before the removal of epidural catheter

At the end of treatment with your epidural infusion the team of doctors and nurses caring for you will examine you to ensure that you do not have any residual numbness or weakness of your legs from the action of the drugs in your epidural infusion. They will ask to you move your legs and examine you to make sure that the sensation in your legs is as it was before the operation. It is important to remember that some operations can cause altered sensation in the legs therefore any changes experienced may be as a result of the surgery and not the epidural. If you do have altered sensation when the epidural is removed the attending team can discuss this with you.

If you experience any of the listed **signs and symptoms** (see list below) as a new problem, after your epidural infusion has been stopped as an inpatient ask the nurse in charge of the ward to contact the Pain Team or on call anaesthetist immediately.

If you have been discharged it is important that you contact the on call anaesthetist at the hospital **immediately** (Telephone **XXXX XXXXXX** and ask the switchboard operator to **bleep XXXX**). After speaking to the on call Anaesthetist they will arrange to see you in the Accident and Emergency department in order to examine you.

Signs and symptoms

- Redness, pus, tenderness, or pain at the epidural wound site
- Feeling generally unwell despite the fact that all seems to be well with the surgical wound
- High temperature, neck stiffness
- Numbness and or weakness in your legs / inability to weight bear
- Difficulty passing water / incontinence of faeces

Further Information

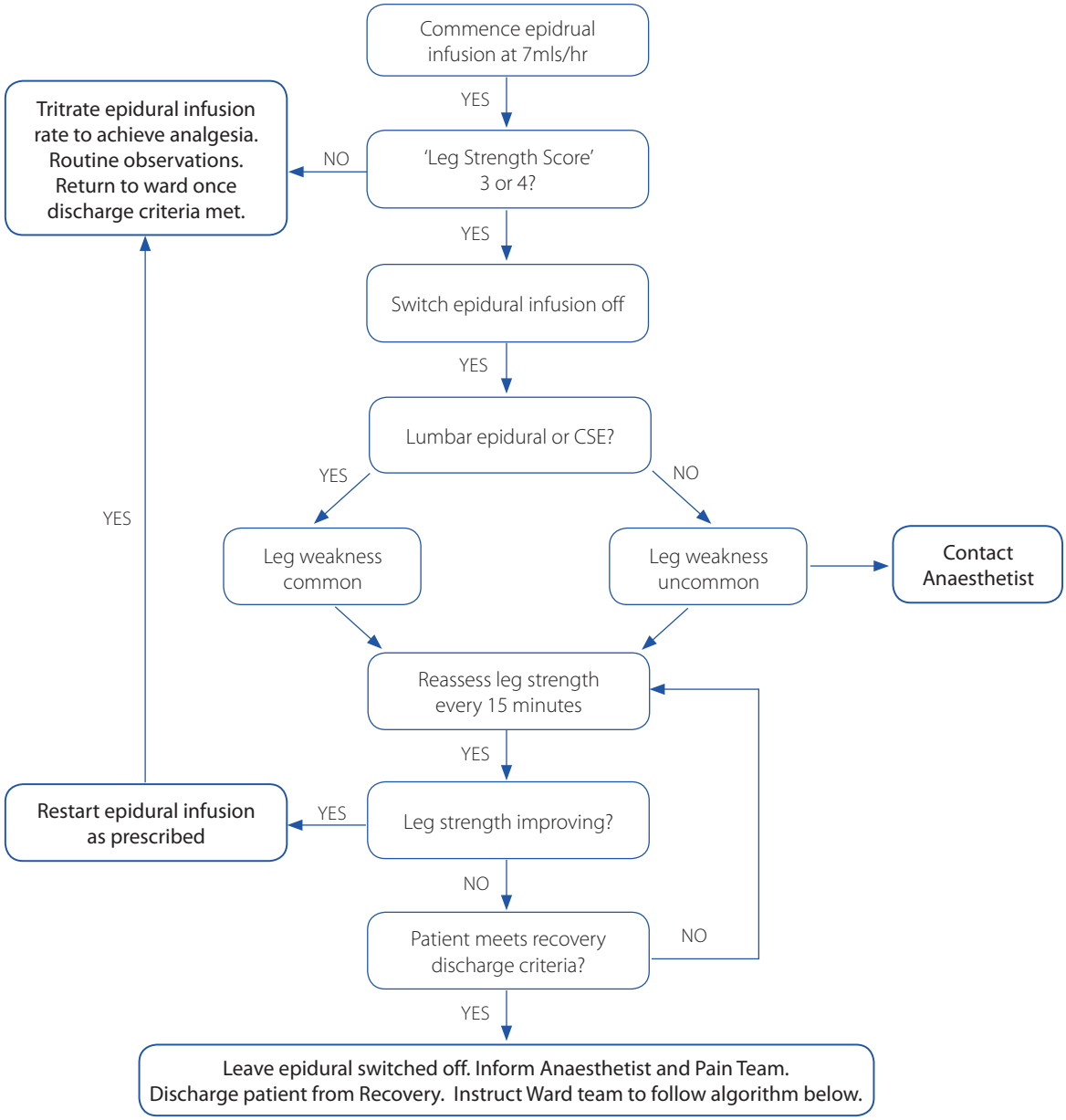
For further information on this subject, please contact: Pain Nurse Specialist on Ext XXXX or Bleep XXXX.

Appendix 3:

Management of weak legs during CNB: Example algorithms for recovery and on the wards (Derriford Hospital, Plymouth)

Management of leg weakness with Epidural Analgesia in Recovery Areas

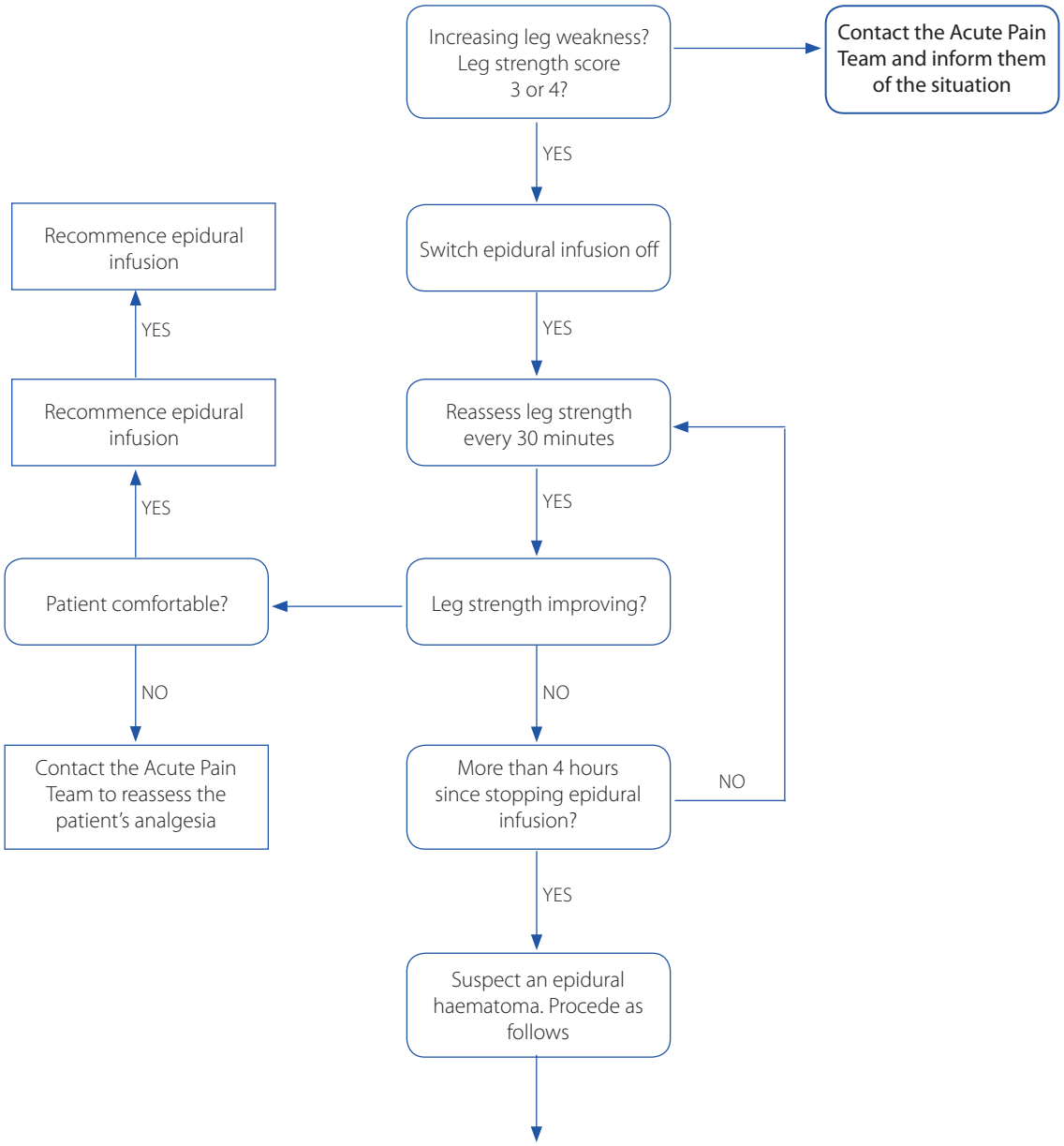
Leg strength is used as a critical monitor of spinal cord health. Leg weakness in patients receiving epidural analgesia is to due either the local anaesthetic infusion or a spinal cord injury (epidural haematoma). Differentiation is achieved by switching the epidural infusion off – failure to recover suggests spinal cord injury. Epidural haematomas usually develop soon after either insertion or removal of the epidural catheter. In a patient receiving a CSE, it is important to demonstrate that the leg weakness due to the spinal is wearing off before starting the epidural, otherwise an epidural haematoma might be missed. All patients receiving epidural analgesia must have their leg strength assessed regularly using the 'leg strength score' that appears on the epidural observation chart. Follow the algorithm below.



Inform the Pain Team (in hours) or the Anaesthetist on call (after hours) of all patients that are discharged from recovery with their epidural infusion turned off. Once on the ward the "Managment of Leg Weakness with Epidural Analgesia" algorithm must be followed. Ensure that the ward staff are aware of the implications. An epidural haematoma must be evacuated within 8 hours of the onset of symptoms for the patient to have the best chance of recovery.

Management of leg weakness with epidural analgesia

All patients receiving epidural analgesia must have leg strength assessed regularly using the 'leg strength score' that appear on the epidural observation form. Thoracic epidural analgesia should not cause profound leg weakness. Increasing leg weakness usually means the infusion rate is too high. However it may mean that the patient is developing an epidural haematoma. If not diagnosed and treated promptly, this will lead to paraplegia. Use this algorithm to help differentiate.



During weekday office hours contact a member of the Acute Pain Team (XXXX or bleep YYYY) who will arrange an urgent spinal MRI scan through the neuroradiology department and contact the neurosurgical team on take. After hours and weekends contact the Anaesthetist on call (bleep ZZZ) who will arrange an urgent spinal MRI scan through the on call radiologist and neurosurgical teams. An epidural haematoma has to be evacuated within 8 hours of the onset of symptoms for your patient to have the best chance of recovery of neurological function. Do not delay.

Description of the Bromage Scale

The Bromage scale was graded as set out in the table below.[1] A modification of the scale has also been described by Breen et al.[2]

Grade	Criteria	Degree of block
1	Free movement of legs and feet	Nil (0%)
2	Just able to flex knees with free movement of feet	Partial (33%)
3	Unable to flex knees, but with free movement	Almost complete (66%)
4	Unable to move legs or feet	Complete (100%)

References

1 Bromage PR (Ed). Epidural Analgesia. *WB Saunders*, Philadelphia 1978: pp 144.

2 Breen TW et al. Epidural anesthesia for labor in ambulatory patient. *Anesth Analg* 1993;**77**:919–924.

Appendix 4: Full Results

Table 1: Cases by complication

	Spinal cord Ischaemia		Vertebral canal Haematoma		Vertebral canal abscess		Infective meningitis		Other Nerve and spinal cord injury	
	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic
Cases	6	6	8	8	20	20	6	6	18	18
Correct diagnosis	6	5	8	8	17*	15	3	3	14	11
Correct diagnosis, in dates and NHS	5	4	6	6	15*	13	3	3	14	11
Included pessimistic	4		5		8		0		7	
Included optimistic		0		4		3		0		3
Final outcome	n=4	n=0	n=5	n=4	n=8	n=3	n=0	n=0	n=7	n=3
Sensory	0	0	0	0	1	0	0	0	2	2
Motor	0	0	4	3	4	3	0	0	4	0
Paraplegia	4	0	1	1	1	0	0	0	1	1
Death	0	0	0	0	2	0	0	0	0	0

*includes 1 case case of discitis wihtout abscess

Table 1 continued

	Wrong route		CVS collapse		Miscellany		ALL cases	
	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic
Cases	11	11	6	6	9	9	84	84
Correct diagnosis	9	9	6	4	3	3	66	58
Correct diagnosis, in dates and NHS	8	8	6	4	3	3	60	52
Included pessimistic	1		3		2		30	
Included optimistic		1		2		1		14
Final outcome	n=1	n=1	n=3	n=2	n=2	n=1	n=30	n=14
Sensory	0	0	0	0	1	0	4	2
Motor	0	0	0	0	1	1	13	7
Paraplegia	0	0	0	0	0	0	7	2
Death	1	1	3	2	0	0	6	3

Table 2: Cases by clinical indication

	Peri-operative		Obstetric		Chronic pain		Paediatric		ALL cases	
	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic
Cases	64	64	16	16	3	3	1	1	84	84
Correct diagnosis	50	42	13	13	3	3	0	0	66	58
Correct diagnosis, in dates and NHS	45	37	12	12	3	3	0	0	60	52
Included pessimistic	25		4		1		0		30	
Included optimistic		13		1		0		0		14
Final outcome	n=25	n=13	n=4	n=1	n=1	n=0	n=0	n=0	n=30	n=14
Sensory	3	2	1	0	0	0	0	0	4	2
Motor	10	6	3	1	0	0	0	0	13	7
Paraplegia	7	2	0	0	0	0	0	0	7	2
Death	5	3	0	0	1	0	0	0	6	3

Table 3: Cases by type of Central Neuraxial block

	Epidural		Spinal		Caudal		CSE		ALL cases	
	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic	pessimistic	optimistic
Cases	51	51	22	22	2	2	9	9	84	84
Correct diagnosis	42	39	16	12	2	2	6	5	66	58
Correct diagnosis, in dates and NHS	38	35	16	12	1	1	5	4	60	52
Included pessimistic	18		7		1		4		30	
Included optimistic		10		3		0		1		14
Final outcome	n=18	n=10	n=7	n=3	n=1	n=0	n=4	n=1	n=30	n=14
Sensory	3	2	0	0	0	0	1	0	4	2
Motor	9	6	3	1	0	0	1	0	13	7
Paraplegia	5	1	2	1	0	0	0	0	7	2
Death	1	1	2	1	1	0	2	1	6	3