

Department of  
**Health, Social Services  
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

**HSS(MD)25/2004**

Chief Executives of HSS Boards and Trusts  
Medical Directors of HSS Trusts  
Directors of Nursing of HSS Trusts and Boards  
Directors of Pharmacy of HSS Trusts and Boards  
Directors of Public Health HSS Boards  
Regional Governance Manager (*for cascade to  
governance leads in Trusts and Boards*)  
Ms Anne O' Brien, Director, CSCG Support Team  
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Your Ref:  
Our Ref: **HSS(MD)25/2004**

Date: 05 August 2004

Dear Colleague

### **Improving Infusion Device Safety**

The purpose of this letter is to alert you to the results of a pilot study, led by the National Patient Safety Agency (NPSA), on improving infusion device safety. This study has helped to confirm the root causes of those incidents where no fault with the equipment has been identified.

The NPSA has issued a Safer Practice Notice (attached) to the NHS, which makes recommendations to reduce the risk of patient safety incidents involving infusion devices. In addition, this safety notice identifies a website where a toolkit of solutions may be accessed [www.pasa.nhs.uk/infusiondevices](http://www.pasa.nhs.uk/infusiondevices). This toolkit contains advice to promote best practice in relation the purchasing, usage, storage and maintenance of infusion devices.

The NPSA Safer Practice Notice makes reference to over 700 unsafe incidents reported each year, of which 19 per cent are attributed to user error. In Northern Ireland, approximately 15% of adverse incidents reported to the Northern Ireland Adverse Incident Centre (NIAIC) are associated with infusion devices and their accessories with user error being a factor in many of these incidents.

Whilst the Safer Practice Notice has been written to account of policy and procedures within the National Health Service in England and Wales, HPSS organisations here will wish to consider how these recommendations might be applicable to local organisations.

The Notice lists existing guidance concerning Infusion Devices. HPSS organisations should note that the equivalent HPSS Controls Assurance Standard for Medical Device and Equipment Management is available at: [www.dhsspsni.gov.uk/hss/governance/assurance\\_standards.asp](http://www.dhsspsni.gov.uk/hss/governance/assurance_standards.asp)

**HSS(MD)25/2004**

A Northern Ireland version of the MHRA Device Bulletin 2003(02) "*Infusion Systems*" has not been published as yet but the MHRA version is available at the web site address contained in the Safer Practice Notice. Further advice concerning this Device Bulletin and how to report adverse incidents can be obtained by contacting NIAIC at:

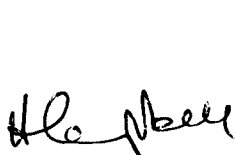
E-mail: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

Website: [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

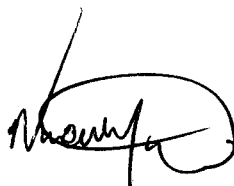
or by contacting:

Mr Brian Godfrey  
NIAIC Manager  
Health Estates  
Estate Policy Division  
Stoney Road  
Dundonald  
BT16 1US  
Tel. 028 9052 3714

Yours sincerely



**Dr Henrietta Campbell**  
Chief Medical Officer



**Dr Norman Morrow**  
Chief Pharmaceutical Officer

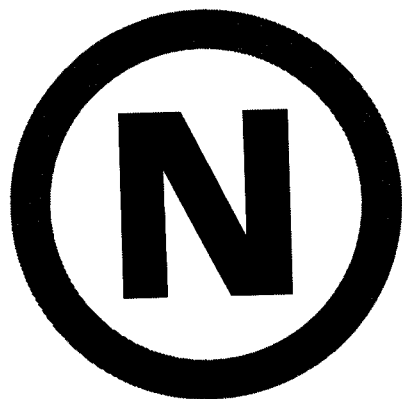


*pp.* **Miss Judith Hill**  
Chief Nursing Officer

This letter is available at [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk) and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.

# Safer practice notice

01



## Notice

20 May 2004

Issue 1

### Improving infusion device safety

Fifteen million infusions are performed in the NHS every year. The vast majority are delivered safely. However, at least 700 unsafe incidents are reported each year, of which 19 per cent are attributed to user error.

A National Patient Safety Agency (NPSA) pilot study has helped to confirm the root causes of those incidents where no fault with the equipment has been identified. These are:

- 1 trusts have a wider range of infusion device types than they need and too many with a higher specification than is necessary;
- 2 staff training is not a priority or competency-based;
- 3 devices of the same type have multiple configurations and react differently under the same circumstances.

#### Action for the NHS

To reduce the risk of patient safety incidents involving infusion devices, NHS acute trusts in England and Wales are advised to take the following steps within the NHS financial year 2004/5:

- 1 review how purchasing decisions are made;
- 2 evaluate the necessity for an infusion device before it is purchased;
- 3 reduce the range of infusion device types in use and, within each type, have agreed default configurations;
- 4 investigate the benefits of a centralised equipment library.

The NPSA has developed a toolkit to help trusts review their existing device management systems, as well as assess the potential for significant cost benefits and improved patient safety.

#### For response by:

- NHS acute trusts in England and Wales

#### For action by:

- Safety Alert Broadcast System liaison officers (England) and clinical governance leads (Wales) - to distribute to:
- Heads of clinical/medical engineering departments

#### We recommend you also inform:

- Finance directors
- Board member with responsibility for device management

- Nursing directors
- Medical directors
- Medical device liaison officers
- Risk managers
- Procurement managers
- Communications leads
- PALS officers (England)

#### The NPSA has also sent to:

- Chief executives of NHS acute trusts in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic

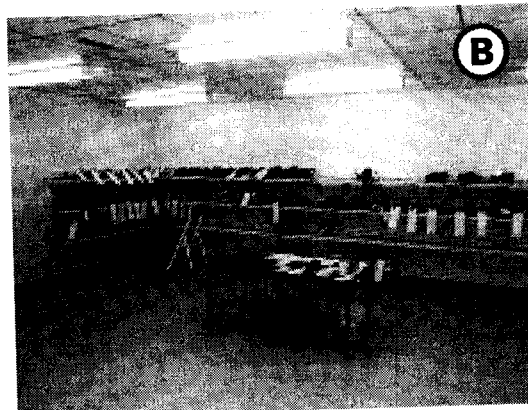
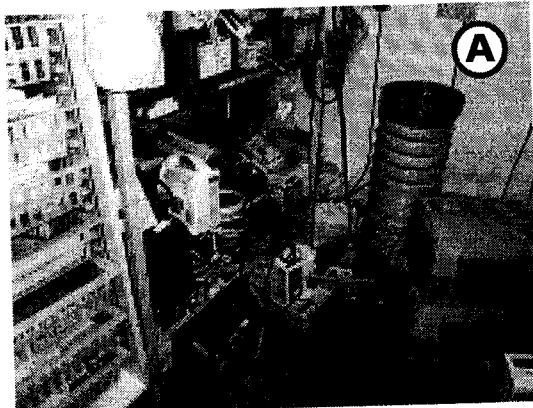
health authorities (England) and regional offices (Wales)

- Medicines and Healthcare products Regulatory Agency (MHRA)
- The Independent Healthcare Forum (IHF)
- The Healthcare Commission (CHA)
- Royal College of Nursing/Midwives/Physicians/Anaesthetists
- Community Health Councils (Wales)
- Healthcare Inspectorate Wales (HIW)
- Welsh Health Supplies
- Infusion device manufacturers

A summary of this safer practice notice is on the NPSA website and can be used for briefing NHS staff and patients.

**Are there areas in your hospital that look like this?**

Picture (A) was taken by one of the pilot sites as part of its review. The trust found that many devices were not being used, and is now setting up an equipment library (as depicted in picture (B))



### **The NPSA toolkit**

The NPSA recommends that clinical governance leads identify a senior member of staff, such as the head of clinical/medical engineering, to coordinate the review.

The toolkit and further information are on a website hosted by the NHS Purchasing and Supply Agency (NHS PASA) at [www.pasa.nhs.uk/infusiondevices](http://www.pasa.nhs.uk/infusiondevices)

On the website are:

- the NPSA toolkit:
  - baseline assessment and decision-making guidance;
  - questionnaire which helps evaluate the usability of a particular type of infusion device prior to purchase;
  - advice on developing a centralised equipment library;
  - spreadsheet for carrying out an economic appraisal to establish potential cost benefits;
- links to manufacturers' websites;
- evaluation of the NPSA pilot study;
- NHS PASA guidance on tendering and purchasing infusion devices;
- patient information tested in the pilot sites, for including in patient publications.

### **Benefits**

Implementing the actions recommended above has the potential to:

- 1 reduce the risk of patient harm or death through better management of infusion devices;
- 2 save money through better purchasing decisions and more efficient use of stock. Based on the information provided by the NPSA pilot study, the Department of Health estimates that trusts could save £120,000 a year;
- 3 reduce the number of patient safety incidents that lead to litigation;
- 4 improve Controls Assurance, Clinical Negligence Scheme for Trusts (CNST) and Welsh Risk Pool scores.



### **Next steps**

The NPSA will review the toolkit's success in a year's time.

More work still needs to be done by the NPSA to address other risks highlighted during the project. The NPSA and the NHSU are developing an accredited e-learning programme for NHS clinical staff using infusion devices. The aim is that this will be available in the autumn.

### **Background**

The Medicines and Healthcare products Regulatory Agency (MHRA) receives over 700 reports of unsafe incidents with infusion devices (including ten deaths) every year. 19 per cent of problems are attributed to user error.

### **The NPSA pilot study**

The NPSA pilot study in six acute trusts found an average of:

- 321 reported incidents linked to infusion devices annually in those six trusts;
- 31 different types of infusion device available for use;
- 65 per cent of infusion devices idle for most of the time.

In response to these findings, five of the acute trusts participating in the pilot study are implementing a central system for purchasing, managing and maintaining infusion devices. The sixth trust was an exemplar site that already had most of the systems in place. The trusts have also put in place measures for:

- involving stakeholders in the purchasing process;
- purchasing based on appropriate information;
- sharing data on how infusion devices are being used with purchasers and manufacturers.

An evaluation of the pilot study can be found on the NPSA website at [www.npsa.nhs.uk](http://www.npsa.nhs.uk)



## **Existing guidance and standards on infusion device management**

Controls Assurance: Standard 15 (Medical Device Management) National Health Service Litigation Authority (NHSLA) – National guidance on purchasing, management and user practice. Trusts are assessed annually to ensure progress is being maintained against standards. [www.hcsu.org.uk](http://www.hcsu.org.uk)

Clinical Negligence Scheme for Trusts (CNST) NHSLA. [www.nhsla.co.uk](http://www.nhsla.co.uk)

There is a separate risk standard for Wales under the Welsh Risk Pool Scheme (Welsh Risk Management Standard 30). [howis.wales.nhs.uk](http://howis.wales.nhs.uk)

Medicines and Healthcare products Regulatory Agency (MHRA): Device Bulletin 2003 (02) '*Infusion Systems*' – This document has practical, evidenced-based guidance on infusion device management and use. The advice is underpinned by the European Medical Devices Directive and follows recognised standards of practice. [www.medical-devices.gov.uk](http://www.medical-devices.gov.uk)

## **Further details**

For further details about this safer practice notice please contact the NPSA patient safety manager in your area. You can find their contact details on the NPSA website at [www.npsa.nhs.uk/static/contacts](http://www.npsa.nhs.uk/static/contacts)

Representatives from pilot study trusts can advise on using the NPSA toolkit. Your patient safety manager can give you their contact details.

### **Ms Julie Storr**

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020 7927 9500

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ID-SPS/2004/01

This safer practice notice is written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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HCC

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