Infusion device project
Infusion device solutions toolkit
Infusion device project – products developed:

- Decision-making checklist
- Two baseline assessments
- Usability questionnaire
- Centralisation advice (business case scoping)
- E-learning (in development)
- Economic appraisal indicator (spreadsheet)
- Patient information leaflet
- PaSA-hosted website
- Six pilot sites willing to share their experiences with others.
Infusion device solutions toolkit

Below are some frequently asked questions (FAQs) relating to the purchasing, management and use of infusion devices and the solutions toolkit developed by the National Patient Safety Agency (NPSA) and their partners.

- **What is an infusion device?**
  This is a medical device used to control the delivery of fluids and/or medication to patients. These devices must comply with the European Medical Devices Directives. This is evidenced by the presence of a CE mark on each device.

- **Are there different types of infusion devices?**
  There are many different types of infusion devices including volumetric pumps (for the delivery of larger volumes of fluid/medication) and syringe pumps (for the delivery of smaller high-risk IV medications where a smooth and accurate delivery is essential, eg infusing inotropes or anaesthetic drugs).

  There are also devices that are designed to be carried around by the patient (ambulatory) – these can be mechanical, electronic or disposable. Some other devices allow the patient to press a button and self-administer to control pain or other specific symptoms (eg nausea).

- **How do I know which infusion device to choose?**
  The important point here is that it is safer to use an infusion device that is an agreed “Trust standard” than to use a wide range of stock. The infusion device project promotes standardisation and outlines the processes your organisation should follow to achieve this. Purchasing the right infusion device should be the final step following the evaluation of a shortlisted few. This will be a part of the tendering process which should include contributions from interested parties, including the end user.

- **What is the aim of the infusion device project sponsored by the NPSA?**
  The NPSA has established that many of the incidents reported to the Medicines and Healthcare products Regulatory Agency (MHRA) can cause patient harm and, in a small number of cases, cause death. The root causes of these incidents have been difficult to identify, although there is a high probability that they are related to user error. The aim of the project is, therefore, to establish the root causes of infusion device incidents and identify solutions to prevent their recurrence.
Following extensive review, the root causes of infusion device incidents have become evident in the following areas: uncontrolled purchasing; uncontrolled device management; and little or no competency-based (assessed) training. If your Trust does not have a standardised stock of infusion devices; or the stock is not managed centrally; and staff are not trained and assessed competently, the likelihood is that your system needs to be reviewed.

The purpose of the solutions toolkit is to assist Trusts to carry out this review and improve their systems.

- **What solutions have been developed?**
  Four solutions have been developed to assist Trusts to Buy Right, Manage Right and Use Right. (A fifth solution is being reviewed – commercially-available ‘surveillance’ software which prevents the incorrect programming of the infusion device.)

  The focus of these solutions is to assist Trusts to identify weaknesses in their purchasing systems, identify the scope to develop and improve these systems and assist Trusts to deliver competently trained staff. The solutions toolkit can be accessed through: www.pasa.nhs.uk/infusiondevices

- **Why must infusion devices be standardised?**
  The NPSA pilot study in six Acute Trusts established that there were up to 45 different makes and models of infusion devices available for use. Common sense dictates that this situation could lead to confusion over use, contribute to programming errors, and cause patient harm.

  Training in the use of all of these devices would be costly, inefficient and impractical. Moving towards standardisation will contribute to the delivery of an efficient training programme and minimise the confusion of use – as well as making patient care safer.

- **Why do you need to centralise – eg set up an equipment library?**
  Within the pilot site testing of solutions a number of common themes emerged. One striking statistic was that on average 65% of infusion device stock was not used for most of the time.

  When you consider that infusion devices cost in the range of £1,000 to £3,000+, and many Trusts can hold a stock of around 1,000, it is clear that the financial burden to a Trust can be great. If we assume (for argument’s sake) that an infusion device costs £1,000 and a Trust has 1,000 such devices, this equates to £650k of stock not being used for most of the time. This is likely to be a national issue.

  Not every organisation will need an equipment library. However, most Trusts in the UK are of significant enough size to warrant the
development of one. The purpose of the centralisation solution is to assist each Trust to determine whether it has the scope to develop such a facility.

- **Is this going to cost much?**
  It is predicted that in the presence of an inefficient system (see question above) funding for centralisation could be found through significant efficiency savings. Centralisation will improve the quality of infusion device management and reduce costs to your organisation.

- **Will I be able to purchase infusion devices for my own area?**
  The main problem in the past was the uncontrolled and indiscriminate purchasing from within a number of organisational areas. This must be prevented from continuing and better control mechanisms must be developed – to ensure that the infusion device stock remains standardised.

  What should be encouraged is that stakeholders should be consulted during the purchasing and tender process. Staff should be involved in the selection process. This also means that there will be a need for compromise when selecting a specific device.

- **Is training for infusion device use mandatory?**
  There are national guidelines and standards stating clearly that staff who use medical devices must be trained and assessed as competent to do so. The Medical Devices Controls Assurance Standard (CAS), Welsh Risk Pooling Scheme and Clinical Negligence Scheme for Trusts (CNST) have standards within them that make this point clear. The Nursing and Midwifery Council (NMC) also provides guidance to nursing staff through their Code of Conduct.

  Trusts have an obligation to provide appropriate training on infusion device use as well as many other areas. This is covered by the Consumer Protection Act and Health and Safety at Work Act.

- **Do I need to be trained before I use an infusion device?**
  Yes – you must be trained and assessed as competent. This usually requires you to follow a structured training process that includes knowledge and skills training, both of which will require a form of recorded assessment.

- **Who is responsible in my Trust for ensuring that infusion devices are managed correctly?**
  Ultimate responsibility rests with the Trust’s Chief Executive. In practice, it is delegated to a board member who has specific responsibility for this process. The board member will link into a medical devices purchasing committee (with key stakeholder representation) who in turn should oversee the purchasing and
management of medical devices. Device users should also be involved by contributing to the decision as to which infusion device to buy.

• **What do I do if something goes wrong during the delivery of an infusion?**
  Incidents involving infusion devices should always be reported to your Trust using your local incident reporting system. You should also report medical device incidents to the MHRA, who will share this information with the NPSA.

• **How do I find out more about the infusion device project?**
  You can find out more by using the infusion device website at: [www.pasa.nhs.uk/infusiondevices](http://www.pasa.nhs.uk/infusiondevices)

• **What are the principles that underpin the infusion device project solutions?**
  The key principles of the infusion device project solutions are to get Trusts to:

  - **Buy Right** – promote standardisation.
  - **Manage Right** – promote centralisation.
  - **Use Right** – promote competency through web-based e-learning.

• **How do I go about implementing these solutions in my organisation?**
  Experience from pilot sites has indicated that the infusion device project solutions require the support of senior officers such as the Chief Executive Officer and/or Finance Director, if they are to be implemented successfully.

  Senior officers need to be aware of the issues and be persuaded to support the development of solutions in their organisation. If you have concerns about the system in which infusion devices are managed you should contact your head of risk management in writing. You might want to point out the solutions toolkit on the PaSA website, which should provide your organisation with all the help and guidance it needs.

• **How can I obtain manufacturers’ instructions for infusion devices?**
  Every infusion device purchased should come with a set of the manufacturer’s instructions. These should be available for reference wherever the device is used. If you cannot find these instructions you can contact your infusion device supplier via the manufacturers section on the infusion device website: [www.pasa.nhs.uk/infusiondevices](http://www.pasa.nhs.uk/infusiondevices)

• **How can I obtain updates regarding specific infusion devices?**
  The best way to obtain information that is product-specific is:
1 Contact your Electro Bio Medical Engineering (EBME)/Clinical Engineering departments. The staff in these departments should have received up-to-date information from the manufacturer and will be able to advise accordingly; or

2 You can ask the manufacturer. If you require evaluation information on a specific device you can contact the Bath Institute of Medical Engineering (BIME) who carry out evaluations on behalf of the MHRA. Contact details are available from the website. www.pasa.nhs.uk/infusiondevices

• **Who should I go to for advice on how to use infusion devices?**
  The following should be able to advise you on device use and training issues:

1 your ward/line manager;
2 Trust training department;
3 Clinical Engineering/EBME departments;
4 Trust governance leads;
5 Trust risk manager/medical devices liaison officer.

• **When should staff be trained in how to use infusion devices?**
  It is better to say that staff should not use an infusion device until they are trained and assessed as competent. If your work requires you to use an infusion device you should let your line manager know that you need training.

• **Where can I get information regarding analysing infusion device incidents?**
  The Risk Management department in your Trust should be able to advise you on this issue. It is common for this department to produce periodical reports providing feedback down through the directorate system as part of good clinical governance practice. You could check this with your line manager.
We recognise that healthcare will always involve risks. But that these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.