Infusion device project: management summary
Centralisation advice: Solution 3
Developing a business case for equipment centralisation facilities
Infusion device project – products developed:
Decision-making checklist
Two baseline assessments
Usability questionnaire
Centralisation advice (business case scoping)
Economic appraisal indicator (spreadsheet)
Patient information leaflet
NHS PaSA-hosted website
Six pilot sites willing to share their experiences with others
E-learning (in development)

www.pasa.nhs.uk/infusiondevices
Developing a business case for equipment centralisation facilities

Background

The number of infusion device adverse incidents reported to the Medicines and Healthcare products Regulatory Agency (MHRA) is increasing yearly. This has been recognised by the National Patient Safety Agency (NPSA) who have sponsored a project to establish the root causes of infusion device incidents and identify solutions to prevent their recurrence.

What solutions have been identified?

Four solutions have been identified to collectively assist Trusts to Buy Right, Use Right and Manage Right infusion and other medical devices. The solutions can be accessed via a ‘one stop’ website along with other relevant information to provide easily accessible and comprehensive information. The four solutions that comprise the overarching toolkit are:

1. a purchasing process checklist and baseline assessment;
2. an infusion device (usability) evaluation questionnaire;
3. centralisation – developing a business case for centralisation facilities;
4. interactive knowledge training (web, CD and hard copy).

Manage it right

This document addresses solution 3: centralisation advice

The philosophy of this advice is to provide guidance to assist organisations in determining their potential to develop the business case for an equipment library or other method of centralisation. Many organisations are aware of the benefits that an equipment library can bring but fail to develop this concept because of potentially high set-up costs.

What does this centralisation advice promote?

The advice contained in this document sets out a methodology to help organisations identify their potential for developing a centralisation facility. It promotes national recommendations and guidelines, such as those found in the Medical Devices Controls Assurance Standards (CAS 152), Clinical Negligence Scheme for Trusts (CNST) and MHRA.

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1 On April 1st 2003 the Medical Devices Agency and Medicines Control Agency merged into a single agency: the Medicines and Healthcare products Regulatory Agency (MHRA).
2 Trusts in Wales are covered by the Welsh Risk Pooling Scheme.
publications. The advice also promotes learning from organisations that have successfully developed equipment library facilities.

How will centralisation advice help organisations?

Solution 3 assists Trusts to ‘manage right’ by:

- facilitating the introduction of standardisation as promoted in the toolkit solutions 1 and 2;
- reducing stock holdings and their associated costs and maximising economies of scale;
- managing and controlling stock more effectively and reducing the risk of patient harm;
- contributing to planning for future replacement requirements by monitoring usage;
- minimising the training requirement and associated costs;
- reducing maintenance costs through increased monitoring and on-the-spot quality assurance (QA) checks by equipment library management;
- provide evidence to support Controls Assurance Standard 15 and CNST scores.

Who will manage the solution?

The solutions will become part of an information toolkit that will be managed through a website on the NHS-net. This toolkit is a collaboration between the NPSA, the NHS Purchasing and Supply Agency (PaSA), MHRA and the Bath Institute of Medical Engineering (BIME). The solutions website will be coordinated and managed by PaSA: http://www.pasa.nhs.uk/infusiondevices/
Advice on developing a business case for centralisation facilities

Purpose of this advice

This document sets out practical guidance to support the development of a business case to establish centralisation systems for managing infusion devices. It pulls together the experiences and learning of organisations that have successfully established similar facilities. Detail underpinning this guidance is also taken from the NHS Controls Assurance Standards. The primary goal is to ensure that associated risks that could lead to patient harm are reduced.

Rationale for centralisation

Infusion devices are used extensively in a wide range of health care settings to support treatments, from simple intravenous rehydration of patients to the infusion of complex drug regimens. The continued technical advancement of infusion devices is in response to clinical need and a requirement to manage the infusion risks associated with drug administration. The technical advancement in device design has led to them having multi-function specifications, which in turn can complicate use and increase risks.

The National Audit Office report in 1999 *The Management of Medical Equipment in NHS Acute Trusts in England*: ‘...identified considerable variations between Trusts, in terms of practices adopted, also in terms of medical equipment held in relation to size of trusts and also in respect of maintenance expenditure.’ This report concluded that the benchmarking of costs and management practices could yield the benefit of quality improvements, lower costs and reduced safety risks.

As yet most of the evidence to support medical equipment centralisation is anecdotal. Those sites with established centralisation systems (equipment libraries) now have other organisations attempting to learn from their experiences and establish equipment centralisation facilities of their own. Over 100 visitors from Trusts around the UK have visited one such site to gain insight and learn. A common area of enquiry inevitably centres around the business case development and preparation. Once the principles of a successful business case had been shared, visitors returned to their organisations with greater insight to develop a more robust business case.

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3 Centralisation could include equipment libraries or neighbourhood equipment stores.
4 NHS LA(Litigation Authority) Controls Assurance Standards.
5 The Freeman Hospital Equipment Library, Newcastle upon Tyne.
The benefits of equipment centralisation focus around:

- Improved efficiency of device management by:
  - reducing stock holdings currently held in wards and departments;
  - reducing the financial burden on Trusts to replace devices;
  - facilitating standardisation and rationalisation;
  - availability of devices is improved with less time spent by staff sourcing devices from other areas;
  - devices can be tracked and usage identified which in turn can inform future procurement needs.

- Improved housekeeping:
  - Devices are inspected, checked and cleaned/decontaminated after each use by library staff.
  - Infusion device batteries are regularly charged.
  - Reported ‘faults’ by staff are now dealt with and usually resolved by library staff. In approximately 80% of these no fault is ever found with the device. Prior to this, devices would have gone directly to the Electronics Department and would have required a technician to inspect them. More time is now available for the technicians to resolve ‘real’ faults. Training needs are also identified through this process.

The above also impact on a number of risk areas including:

- Financial cost:
  - by reducing the requirement to replace stock;
  - reduced technician time on ‘fault finding’ where no faults were ever found\(^6\);
  - a significant reduction in consumables cost (IV administration sets) through optimising economies of scale by standardisation.

- User errors:
  - a reduction in the range of infusion devices available for use improved familiarity and reduced confusion\(^7\);
  - fewer serious infusion device adverse incidents likely to be reported.

- Practice Issues:
  - Devices are available at short notice and can efficiently cover episodes of increased activity within an organisation.

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\(^6\) This was the experience of the Electronics Dept at Freeman Hospital, Newcastle, where a significant reduction of “no fault found” episodes has been identified following the introduction of the library.

\(^7\) See attached example business case to illustrate this.
It is clear from those organisations that have developed equipment centralisation facilities that positive experiences and outcomes outweigh the negatives. The advice contained in this document is designed to establish and emphasise the positive benefits and assist organisations to explore their own potential for change.

**Controls Assurance Standards**

It is important to understand existing guidance that underpins risk management in the medical devices area. The advice in this document embraces much of the information contained in the NHS Controls Assurance Standards guidance. The standard on medical devices management (CAS 15) within this framework is clear as to what is required to enable organisations to reduce risk. The standard promotes that:

- ‘There is a system in place, which ensures that all risks associated with acquisition and use of medical devices are minimised.’

The standard also states:

‘Medical device purchasers and providers should develop and implement suitable device management procedures. The aim is to ensure that whenever a medical device is used, it should be:

- suitable for its intended purpose;
- properly understood by the professional user;
- maintained in a safe and reliable condition...’

**Business plan development**

The content, structure and presentation of a business plan are all vital when presenting a case to the senior management team. Content should follow logical steps and provide an objective review of existing service provision. The advice steps below pull together the experiences of those organisations who have established a centralisation facility.

This guidance is not designed to replace existing business planning practice. The way that a business case is developed and presented should follow local arrangements. An example business case is also presented in Appendix 1 to illustrate one approach that followed steps similar to those below.
Step-by-step guide

It is accepted that many organisations will have successfully developed and implemented a business case for centralisation. This guide attempts to ‘point the way’ for those who have not yet addressed centralisation and provides knowledge and learning to assist you in this process.
Step 1: Setting out the business case

The following bullet points set out one way of addressing the business case:

- management summary;
- purpose;
- background and rationale;
- options appraisal;
- cost/benefits;
- time scale.

Management summary

A management summary is recommended at the beginning of your business case. The purpose of this is to make it clear to the reader precisely what is proposed and how this will be achieved. It is important that the benefits of the business are emphasised. Information is likely to include:

- A brief overview of the reasons and main drivers for developing an equipment library. These could include reducing patient risk, cost reduction, quality improvements, and so on. It should also emphasise national influences such as Controls Assurance Standards (CAS 15).
- Key findings of any audit/review carried out in support of the change. This could include device usage/utilisation, device range, infusion device incident review, device failure/maintenance reports and staff trained.
- How centralisation will help improve patient safety and improve the quality of device management and practice.
- Costs/benefits summary.

The important emphasis on the summary is that it is concise.

Purpose

The purpose sets the scene for the development of the business case. It should state the key recommendations for change including reference to Controls Assurance Standards and Medicines and Healthcare products Regulatory Agency recommendations and the reasons why the facility is being proposed.

Background and rationale for change

This section is your opportunity to set out in greater detail the reasons for change. You should consider starting by referring to national initiatives and recommendations – then focusing on raising your local issues. Trust risk issues relating to infusion devices will help to consolidate and support the case to develop a centralisation facility. You should include information such as:
- national risk initiatives (CNST and CAS or the Welsh Risk Pooling Scheme), you may use your current position to see what improvements, including centralisation, can be made to improve your CNST level/discount and demonstrate how it may improve your CAS score;
- current costs associated with infusion and other medical devices (including consumables) likely to be used in your equipment library;
- risk reviews (infusion device incidents) may persuade management that action is required;
- infusion device audit outcomes;
- findings from what other Trusts have achieved.

Again, it is advisable to keep the narrative as brief as possible. You should insert appendices where more detailed items of work are referred to.

**Options appraisal**

This section should provide a range of options and their costs to be considered by the management team (see example business case: Appendix 1). It is also appropriate to recommend your preferred option. It is probably better to present financial detail and numbers in a table format. It is recommended that you propose up to four options including a ‘do nothing’ option.

**Cost/benefit review**

This section should provide a balanced discussion of the key findings within the business case development. You should provide compelling evidence to support your case. Information may include:

<table>
<thead>
<tr>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of infusion device incidents.</td>
<td>Reduction of infusion device incidents.</td>
</tr>
<tr>
<td>Cost of current non-standardised stock.</td>
<td>Stock reduction through centralisation.</td>
</tr>
<tr>
<td>Training.</td>
<td>Reduced training requirement due to standardised stock (fewer devices).</td>
</tr>
<tr>
<td>Maintenance.</td>
<td>Reduced device down-times through improved management/centralisation.</td>
</tr>
<tr>
<td>CNST/Welsh Risk Pool costs.</td>
<td>Contributes to reducing CNST/Welsh Risk Pool premiums.</td>
</tr>
<tr>
<td>Set-up costs of building equipment library/centralisation facilities.</td>
<td>Potential to offset these costs through greater efficiencies.</td>
</tr>
<tr>
<td>Costs of staffing/running the facility.</td>
<td>Potential to offset these costs through greater efficiencies.</td>
</tr>
</tbody>
</table>
It is good to argue from a wide range of areas, not just the financial costs.

**Time scale**

The timescale to implement and develop the equipment library should be proposed for each of your options, with a description of the development required and realistic deadlines (see options appraisal example in example business case).

**Step 2: Gathering information to support the business case – audit**

It is important that information is gathered to support the purpose and aims of the business case. This is the most important step in developing the business case. The audit of existing practice should provide objective evidence from which the business case argument can be put forward. It is appropriate to refer to audit findings in the business case but the detail should be located in the appendices.

There are a number of audits recommended by exemplar sites to highlight risk areas and provide strong evidence for change, these include:

- Review (audit) of infusion device stock should:
  - provide information on the range of infusion devices available;
  - provide information on the numbers and costs of devices available;
  - provide information on the age of devices available;
  - establish device replacement requirement (assuming a ten-year lifecycle).

- The inherent risks of a wide range of stock include:
  - Many devices available leading to confusion and misuse.
  - It is difficult to provide skills training on every device in a wider range of products.
  - Large numbers of devices available places an increase of workload on the Electronics department. Non-centralised management of devices means that these could be scattered across many areas and be difficult to track. Maintenance could be missed.
  - Although a Trust may have large numbers of devices available these may be aging or obsolete and inappropriate for many applications. The risk to the patient could be significant in specific areas such as Critical Care where highly potent drugs are often infused.
  - Many hospitals who have had equipment bought in bulk, either for its
entire organisation or specific areas, face the prospect of having to replace this device population as they reach the end of their lifecycle.

- As a general rule the greater the range and numbers of infusion devices available for use the greater the risk.

**Review of use of infusion devices**

One organisation carried out a specific audit where an audit of infusion device ‘idle time’ identified that they were not being used for 60% of the time. The main points from this were that:

- The asset register identified almost 1,000 infusion devices.
- The cost range of each device was £1,000–£3,500 (the lowest cost device price was used for the purpose of this exercise to provide a minimal estimate).
- The total replacement cost of the stock holdings would be a minimum of £1m.
- Therefore it was estimated that 60% of infusion devices were not used, equalling £600k.

- The inherent broad risk areas established with this were:
  - inefficient management of devices;
  - identified recurrence of similar adverse incidents;
  - high yearly capital replacement costs for infusion devices;
  - poor control over purchasing.

By establishing potential financial inefficiencies you are more likely to influence your financial director to support your business case.

**Consumable usage and costs**

- By establishing the range and cost of IV-giving sets (consumables supporting the range of infusion devices used within an organisation) it should be easy to identify where savings can be made through standardisation.

- It should be emphasised that organisations should avoid the temptation to standardise on the device with the cheapest administration set. This is not always cost effective. Some administration sets are designed to be used for longer than 24 hours, others are not.
Risk assessment

Establishing risk areas in the use of infusion devices is another significant driving force in obtaining business case approval. There are two key areas that should be identified through audit.

- Clinical risk related to the number of infusion device related adverse incidents. It may be possible to:
  - establish trends such as the types and range of devices that are involved;
  - determine whether training is available and/or has been carried out appropriately;
  - whether serious harm or injury has occurred.
- Financial risk related to missed opportunities in maintaining and using a non-standard stock. Standardisation can affect greater economies of scale in terms of:
  - reducing the unit cost of the infusion device;
  - reducing the cost of the administration set consumables (IV sets).

Centralisation will facilitate standardisation more efficiently than a department-by-department equipment management system.
Acknowledgements

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Bath Institute of Medical Engineering
Medicines and Healthcare products Regulatory Agency
National Patient Safety Agency
NHS Purchasing and Supply Agency
Royal College of Nursing
The National Patient Safety Agency

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.