Standardising and centralising infusion devices – a project to develop safety solutions for NHS trusts
Full evaluation report
### Infusion device publications

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Summary

1.0 Purpose
A report on the evaluation of findings from the infusion device project pilot work. The report includes:

Section 1: An evaluation of the impact of solutions in pilot sites.

Section 2: An evaluation of the infusion device project pilot process.

2.0 Background
The infusion device project was sponsored by the National Patient Safety Agency (NPSA) to identify the root causes of infusion device incidents associated with user error and establish solutions to prevent their recurrence. The project identified that uncontrolled purchasing and device management, in the absence of competency-based training, were contributing factors in causing incidents with infusion devices.

A range of solutions have been developed to assist trusts to Buy Right, Manage Right and Use Right infusion devices. The purpose of these solutions is to promote standardisation, centralisation and competency training, which will over time improve patient safety. Three solutions have been tested and evaluated in six pilot sites across England and Wales and focus on the Buy Right and Manage Right issues.

A fourth solution focusing on competency-based training (Use Right) is also being developed separately in collaboration with the NHS University and will be ready by late autumn 2004.

A patient information leaflet, the content of which was proposed and agreed by patients, has been developed. This product evaluated very well in pilot sites and is available as part of the solutions toolkit.

3.0 Baseline assessments and solutions evaluation in pilot sites
Six pilot sites were recruited from an ‘expression of interest’ list of 93 in response to an advert placed in the Department of Health Chief Executive Bulletin. The pilot sites were chosen to represent configuration, size and (where possible) geographical spread. Another consideration was that the pilot sites should not be involved in any other work being promoted by the NPSA.

The following NHS trusts were chosen:
- Hull and East Yorkshire;
- Leeds Teaching Hospitals;
- North Cheshire;
• Blackpool Fylde and Wyre;
• Cardiff and Vale;
• Epsom and St Helier.

Two baseline assessments (Appendix 1) were carried out to establish the need for solutions. Comprising 22 specific evaluation criteria, the assessments took place in each pilot site to provide a benchmark against which action could be planned and progress measured.

Baseline assessment 1 focused pilot sites on the process for making purchasing decisions. It promotes national recommendations such as Controls Assurance Standards (CAS) and Clinical Negligence Scheme for Trusts (CNST).

Baseline assessment 2 helped pilot sites to establish data that reflected existing infusion device safety, maintenance and purchase related practice; and also identify the scope for development work in these areas.

4.0 Solutions description

Three solutions were tested and evaluated and two further solutions are being developed. The solutions are designed to assist trusts to work within the scope identified through baseline assessments. The solutions are:

Solution 1: Purchasing decision-making checklist – promoting standardisation

Solution 2: Usability evaluation questionnaire – sharing evaluation information

Solution 3: Developing the business case for centralisation

Solution 4: E-learning: a collaboration with the NHSU (Currently in development).

5.0 Solutions testing and evaluation

Solutions 1, 2 and 3 were tested and evaluated between May and November 2003. Appendix 2 provides detail on the evaluation criteria used, the baseline assessments and evaluation findings.
Section 1

6.0 An evaluation of the progress made in pilot sites following the establishment of baseline assessment data and implementing NPSA solutions

Pilot sites completed baseline assessments against which action plans were developed. These action plans provided the focus for pilot sites to develop their purchasing and management systems. A web-based toolkit of solutions (Appendix 3) was used to facilitate this process.

All pilot sites have submitted a report on the impact of project solutions measured against initial baseline assessments. The following summarises the impact of solutions following testing.

6.1 Baseline assessment 1: personnel involved in decision making

All pilot sites could identify the board member responsible for medical devices management, although this person’s contribution to the process ranged significantly. A similar picture emerged for purchasing committees. Only two of the pilot sites had committees that met on a regular basis. Stakeholder involvement in purchasing was also variable. Two pilot sites had not involved stakeholders at all and, at best, the other pilot sites only involved stakeholders when infusion devices were being purchased for specific areas.

Evaluation

All pilot sites can now identify the role and function of their board member responsible for medical device management. They also had clear stakeholder membership and terms of reference for their purchasing committee. All had held at least one meeting to discuss the project and explore ways of taking the solutions and action plans forward.

6.2 Baseline assessment 1: policies/national directives (CAS, CNST)/ information used to support decision making

Three pilot sites had a medical devices policy but only two of these provided guidance on purchasing, standardising and replacing devices. Three policies recommended centralisation but only one pilot site actually had an equipment library. Four of the pilot sites had made progress in improving their Controls Assurance Standards (CAS) score over the previous three years although scores now appear to have reached a plateau despite scope to improve. Five of the pilot sites had not carried out an audit on existing infusion device stock utilisation.
Evaluation

Five pilot sites had used information from the Medicines and Healthcare products Regulatory Agency (MHRA) and Bath Institute of Medical Engineering (BIME) to inform purchasing decisions. All pilot sites felt that general infusion device information was difficult to access and time consuming as it was in many different locations. The ‘one stop’ website and toolkit of solutions was evaluated to be an extremely useful resource. All felt that the baseline assessments, which were not part of the web-based solutions toolkit, should be made available because of their usefulness.

All of the pilot sites have since carried out a device utilisation audit (baseline 2) as recommended in solution 3. These audits established the following averages across the six pilot sites:

- 65% of available stock in each site was under-utilised;
- the range of infusion devices available for use was 31;
- infusion device stock was 1065;
- the cost of this stock was £1.6m.

These findings reflected an inefficient system in which infusion devices are purchased, managed and used. This is probably a national issue supported by the fact that 93 trusts initially expressed an interest in participating in this pilot work (implying that they needed help).

Appendix 4 summarises the pilot data from baseline assessment 2 in greater detail. All anticipated that the principles embodied in the solutions would help to improve their Controls Assurance Score.

6.3 Baseline assessment 2: risk considerations

All pilot sites had been able to access incident reports related to infusion device use. Not all had linked this data to the purchasing process. All pilot sites could identify a designated person with responsibility for circulating MHRA safety notices and bulletins but could not be certain if recommendations had been actioned and therefore were not closing the loop.

Evaluation

Pilot sites reviewed their infusion device incident data reported during the previous year. Across the sites, 321 incidents were reported revealing the following:

- range of incidents reported per site was 12 and 196;
- 96 over infusion episodes (30%).
• 21 under infusion episodes (6.5%);
• 59 user error episodes (18.4%);
• 12 device failures (3.7%);
• 10 tampering (all patients) (3%);
• ‘other’ episodes included:
  - prescription error;
  - wrong prescription/wrong patient;
  - incorrectly mixed drugs;
  - patient interfering/tampering;
  - staff not trained;
  - housekeeping.

Significantly, the two largest trusts identified 196 (60%) and 70 (22%) of all pilot incidents. Four pilot sites’ incident reports were below 20. Low reporting could indicate a poor reporting culture, although two of the pilot sites noticed an increase in reporting following commencement of the pilot work. This is possibly related to the profile that the project has brought within the trust. All pilot sites are now committed to monitoring and evaluating this trend.

All pilot sites are also working to ensure that MHRA safety notices are dealt with appropriately and followed up.

6.4 Baseline assessment 1: tender development

Five pilot sites had not carried out a trust-wide tendering process within the last seven years. Trust standardisation was not a priority and the development of an organisation-wide device specification had not been developed. The 6th pilot site (exemplar site) had developed their systems using the tender process.

Evaluation

As a consequence of the project work, four of the pilot sites are committed to carrying out a trust-wide tender review. All are accessing the solutions website for tendering advice and guidance and are committed to the goal of standardisation.

6.5 Baseline assessment 1: infusion device usability evaluation

No national evaluation process or documentation existed for infusion devices to establish usability evaluation data. Local evaluation was carried out but was not consistent.

Evaluation

Pilot sites have started to use the questionnaire (solution 2). This has
been developed and will be managed by MHRA and BIME. BIME will monitor the situation and publish reports when evaluations are received. They will also provide feedback to manufactures.

6.6 Baseline assessment 2: infusion device management issues

Pilot sites were asked to carry out a maintenance review of ten randomly-selected infusion devices from their stock. This established that:

- 60 infusion devices were reviewed across the six pilot sites;
- 120 faults were reported;
- 30 episodes of no fault were found.

In relation to the use of ageing and/or damaged devices (from entire pilot site stock):

- 250 episodes of ‘devices damaged’ were reported in the six pilot sites;
- over 1,200 infusion devices were more than ten years old (19% of total stock).

The purpose of this review is to highlight the relationship between the numbers of faults reported (120) and the episodes where no fault was found (30). The findings highlight that in 25% of the episodes the device was wrongly reported as faulty. The data for the remaining 75% did not reveal the nature of the fault and it is likely that the device ‘fault’ was not a failure issue but more probably a user/handling problem. This is indicative of poor training and device management.

The data also highlighted that the incidence of devices being damaged is extremely high. This is indicative of poor device management systems such as non-standardised stock and decentralisation. It was also highlighted that nearly one-fifth of all infusion device stock, across all pilot sites, was more than ten years old. This could have serious patient safety implications if such devices are used for applications that require a high specification device.

Evaluation

It will only be possible to evaluate the impact of solutions on standardisation and centralisation once device management systems have been scoped, developed and implemented (that is Buy Right, Manage Right and Use Right). This could take at least a year and probably longer. The exemplar pilot site (Cardiff and Vale), well advanced in device management, has reviewed the proposed solutions and indicated that if they had had access to solutions earlier they would have certainly expedited their work.
It has also emerged from the pilot work that the basic yearly absorption costs (the cost of running a device as rather than device cost) including maintenance, training and management ranged from £20 to £200. Pilot site data indicates that the average number of devices per trust is 1,065. Of these 65% (692) are idle at any one time. Assuming an absorption cost of £30 a device per year, then the overall cost for devices that are not used could be around £20,000 per trust, £124,000 for the six pilot sites or £3,700,000 for the 189 NHS acute trusts in England and Wales.

These findings will be taken forward to a health economist who will advise on the production of an economic appraisal. The absorption cost figure is an assumption based on discussions with a number of trusts from around the UK. It should be noted that the figure of £30 used in the illustration is probably an under-estimate.
Section 2

7.0 An evaluation of the infusion device project pilot process

The following section summarises pilot site responses to a questionnaire designed to evaluate the project process (Appendix 5). A recommendation is requested following each question and a number of questions prompted the pilot lead to apply a ranking, ranging from (the solutions) ‘made the situation worse’ to ‘excellent improvement’. A summary of the recommendations can be found in Appendix 6. The ranking results for these questions (1 to 11) have been tabulated in Appendix 7.

The overall impact of the infusion device project ranked 4.61 (moderate to good). The need for senior management ‘buy in’ was highlighted as vital to the success of solutions implementation. The solutions website design ranked 4.2 (moderate to good), with web information content ranking 4.6 (moderate to good).

How helpful were solutions in identifying what ‘needed to be done’ ranked 5.7 (good to excellent). In particular the business case for the equipment library was singled out as most helpful. Baseline assessments were ranked 5.4 (good to excellent).

Solution 1 ranked 4.4 (moderate to good) and was felt to be very good in identifying strengths and weaknesses. Solution 2 ranked 3.75 (minor to moderate) this had less of an impact, possibly due to the design of the form and web access problems during testing. The evaluation has been fed back to BIME who are managing this element. Solution 3 ranked 4.0 (moderate to good) and was felt to be very useful.

The following highlights the responses and recommendations from pilot sites in relation to each evaluation question.

Q1: State the overall impact that the infusion device project has had on the trust’s ability to purchase and manage infusion devices:

The ranking for this question was 4.61 (moderate to good) in range 1–6.

Responses

- Project raised the profile on buying the right equipment and made the trust realise that they are buying equipment that is not required.
- Project has had a great impact and it has backed up the direction the trust has been going over the last eight years.
- Members of staff are 100% behind setting up an equipment library, however there is a lack of leadership and support from board level.
• The project provided guidance needed to develop a structured view of the entire process.

• Providing the business care proposal is accepted for the equipment library, the overall impact will improve the trust management of medical devices.

• Provided the impetus to get standardisation of infusion devices higher on trust agenda.

Recommendation 1

• The need for senior management ‘buy in’ and support for the process will be vital when the solutions are rolled out to the wider NHS. Where this was lacking in the pilot sites, development work struggled. Chief executives, finance directors and risk management leads should therefore all be targeted as part of the project launch strategy.

**Q2: How helpful was the solutions website?**

The ranking for this question was **4.2** (moderate to good) in range 1–6.

**Responses**

• Provided a great deal of information, sometimes difficult to access, but seems much clearer now.

• Would be helpful if a specific goal was defined and a step-by-step approach with clear steers would also be helpful.

• Easy to navigate with good information and links.

• Introduction and interactive knowledge bring great benefits.

• Useful in preparing a trust’s business case.

• Still not detailed enough.

Recommendation 2

• A step-by-step flow chart should be developed to guide website users through the solutions process.

• A review of the website layout should be carried out with the NHS PaSA web designers to ensure ease of access and usability. This should incorporate any changes made as a consequence of this evaluation.

**Q3: How would you rate the information and content presented on the website?**

The ranking for this question was **4.5** (moderate to good) in range 1–6.

**Responses**

• Excellent, clear and met all needs.
• Step-by-step guidelines and flow charts would be useful.
• Little to criticise, perhaps the omission of user evaluation from BIME.
• Easy access, well presented and understandable. Needs more content.
• Need to make it a lot easier to access.

Recommendation 3
• Step-by-step guidelines as for Q2.
• Introduce a frequently asked questions (FAQ) document into toolkit.

Q4: How helpful were solutions in identifying what needs to be done?

The ranking for this question was 5.17 (good to excellent) in range 1–6.

Responses
• Device centralisation advice (business case development) and decision-making checklist were most helpful.
• Business case development and user assessment were helpful.
• The usability questionnaire is too lengthy.

Recommendation 4
• Feedback should be provided to BIME regarding the length and format of the evaluation questionnaire. BIME should revisit this and review format.

Q5: How would you rate the baseline assessment tools used at start of project?

The ranking for this question was 5.4 (good to excellent) in range 1–6.

Responses
• This started the ball rolling in identifying weak areas. Good way of identifying areas for development.
• Useful, but baseline assessment 2 more useful.
• Helped to show how much equipment in the trust was not being used. Also showed that we do not need to order more equipment and demonstrated the need for an equipment library.
• Following this structure reduces individual workload and eliminates wasted effort.
• Most useful aspect of this project, it gave structure and allowed you to see the bigger picture.
• Focused project team on the main issues and the number of equipment in the trust was a surprise.

**Recommendation 5**

• Baseline assessments 1 and 2 should be incorporated into the website toolkit. These have been merged into the existing solution 1.

**Q6: How helpful was solution 1?**

The ranking for this question was 4.4 (moderate to good) in range 1–6.

**Responses**

• Useful to locate and engage the decision makers to audit, initiate and improve.
• Very useful. Project lead set up stakeholders and the purchasing manager would like centralised purchasing to ensure *Buy Right*.
• Quickly establishes where you are and what needs to be done.
• Not particularly useful for trust which was already following procedure (exemplar site).
• Very useful in identifying strengths and weaknesses.
• Very useful as the decision-making checklist pointed out that there were many people making many decisions.

**Recommendation 6**

• As for Q5.

**Q7: How helpful was solution 2?**

The ranking for this solution was 3.75 (minor to moderate) in range 1–6.

**Responses**

• The evaluation of equipment used will help to assist with future purchasing.
• Results obtained were broadly similar for each device evaluated.
• Yet to use this, but will be using a shorter version.
• Not useful as staff do not complete the comments section.
• Recognised that many features were not necessary.

**Recommendation 7**

• Feedback should be provided to BIME regarding the length and format of the evaluation questionnaire. BIME should revisit this and review format.
Q8: How helpful was solution 3?

The ranking for this question was 4 (moderate) in range 1–6.

Responses

• Would have been of great help, however a library business case for our trust was already completed.

• Was very helpful, especially for those people who have no experience of developing a business case.

• Provides a complete overview of what needs to be done and can be easily adapted to local protocols.

• Use of the sample business case was helpful.

• Found our own trust’s business case more useful.

• Still in progress.

Recommendation 8

• The solution should remain as presented. However, in light of the pilot feedback it should be made clear in the explanatory notes within the documents that this solution is not designed to replace existing practice; but should be viewed as guidance that can be used as appropriate to meet specific needs. Trusts with well-developed systems will probably not gain much, whereas trusts who have under-developed systems will have their guidance optimised.

Q9: How useful was the project in bringing together key stakeholders within your organisation?

The ranking for this question was 4.67 (moderate to good) in range 1–6.

Responses

• Extremely helpful – raised the profile of a particular clinical area, clinicians speaking about their purchasing practices.

• Having outside influence will always concentrate minds.

• Had great difficulty in getting senior trust members to participate, no one came forward to assist the project.

• Absolutely no doubt this project was a key factor in focusing management and gaining board-level support for a strategic view.

• It’s been useful in gaining the attention of senior managers within the trust.

• The project team, with the help from NPSA, was able to engage the trust board in trying to find solutions.
Recommendation 9

- Senior management must be engaged, involved and support the solutions development process.

**Q10: How do you rate the level of support provided by NPSA project manager?**

The ranking for this question was **5.5** (good to excellent) in range 1–6.

**Responses**

- Very enthusiastic. Enthusiasm should be graded for the agenda for change.
- Very supportive and did his best to meet with executive directors and service directors.
- Site visits immensely valuable, support provided at an appropriate level. The enthusiasm alone would engage the sceptical and persuade the dissident.
- Outstanding support and enthusiasm, organisation of the project was excellent.
- Always available to advise. Visits to the trust demonstrated NPSA commitment to trust board and staff.
- Approachable and always provided advice.

Recommendation 10

- The involvement of a person from outside the pilot organisations appears to have added value and credibility to the work undertaken. This should be a key consideration when rolling out the solutions to the wider NHS. The use of the NPSA patient safety advisers and their team to act as a catalyst, as well as providing a national support mechanism, should be considered.
- The utilisation of the ‘experiences’ of the pilot sites should be developed to provide ‘real life’ advice and support to those organisations wishing to develop their systems.

**Q11: How do you rate the help received from other NPSA staff?**

The ranking for this question was **4.5** (moderate to good) in range 1–6.

**Responses**

- Contact with both finance and communications – no complaints.
- Good support from communications regarding press announcements.
• Very little involvement, though they have appeared very efficient and obliging.
• Minimal contact.
• All dealings have been very good.

**Recommendation 11**

• Feedback positive responses to appropriate NPSA staff.

**Q12: What is your organisation’s biggest achievement as a consequence of this project?**

**Responses**

• Helped to publicise our achievements, crystallising what has been saved in financial terms, reduction in number of clinical incidents.
• Project has raised profile of device management, enquiries are underway for future equipment library.
• A fundamental and somewhat radical change.
• The development of a business case for an equipment library.
• Clinical directors recognise that procurement and EBME need to be involved in the purchasing process from the start.
• The trust has a development group to open an equipment library by April 2004.

**Recommendation 12**

• Pilot site achievements should be published as one of the success factors of the project. This should illustrate what was achieved and the timescale within which progress has been made.
Q13: List all organisational achievements following participation in the project

Responses

• Creation of an all-Wales training group to standardise generic training. Initiation of objective type training on other types of equipment. Equipment purchasing has moved up the political agenda.

• Increased knowledge of risk management and patient safety issues, training issues, experience in developing business case.

• Engaging interest and strategic support at board level, assessing what we do and don’t do well.

• Big impression on senior level, working with agency has provided sense of increased status, raised profile.

• Support from board level for equipment library, clinical directorate support.

• Clearer understanding of issues relating to infusion device purchases, training and management, helped us realise trust needs standardisation of all IV equipment.

Recommendation 13

• As for Q12.

Q14: What do you see as the top five success factors?

Responses

• Good communication from NPSA; on-line information available; opportunity to establish key areas for work; trust genuinely want to make improvements; baseline assessment was able to show how much money the trust spent.

• [Device management] team established, chief executive support, directorate support; maintaining focus; networking with other pilot sites.

• Support from senior management; enthusiastic and hardworking team; support from project manager; successful internal publicity.

• Support and involvement from executive level, identifying space for equipment library; raising the profile through trust.

• Enthusiasm, personnel, ideas, deadlines, finance to run project.

Recommendation 14

• As for Q12.
**Q15: What were the main barriers experienced when developing the project?**

**Responses**

- Not enough slack time available in front-line clinical areas; and a procurement department which seems too large.
- Lack of support from senior managers. Verbal agreement of equipment library was given and it was looked at as a good idea, involvement and endorsement was not forthcoming.
- Business case unable to progress without sufficient space.
- Time to carry out project whilst carrying on with day-to-day work, spent double time working and allocated four days a week instead of two.
- Getting key people to make this a high priority; the existing workload of the team.
- Auditing all clinical areas.

**Recommendation 15**

The need to develop organisational systems is dependent on, and constrained by, two fundamental issues:

- support from senior management;
- time and appropriate leadership to focus on and develop the solutions.

It is therefore recommended that trusts appoint a person with responsibility to develop solutions. This person should link into the chief executive or finance director. The need to identify, as early as possible, the scope within a trust for development, is crucial.

**Q16: How did you overcome these barriers?**

**Responses**

- Rolled my sleeves up!
- Commitment from chief executive which was communicated to all staff; regular meeting of the project team.
- Working as a team.
- Standard response; tact, diplomacy and reassurance.
- Discussion, being available to them, enthusiasm and willingness to help.
- Accommodation committee has been asked to put project on their agenda to assist with identifying space.
• It was requested that the director of nursing nominate a senior trust member to pursue the project solutions.

Recommendation 16

• As for Q15.

Q17: How best do you think the NPSA can communicate the solutions to the wider NHS when they are ready for national implementation?

Responses

• Direct to chief executives, publicising in the nursing and medical press.
• Provide solution in bite-size pieces with information on what to expect from audits and the direction to take, website to include flow chart with project management guidelines. Pilot sites should be listed on website.
• Publish a final report widely. CEO bulletin and nursing press obvious routes for promulgation.
• Publications, journals and website.
• Conference, toolkit.
• Provide results to media, refer other trust who may wish to follow this model.

Recommendation 17

• The solutions roll out should be a part of a communication strategy which incorporates the above suggestions.

Q18: Is there anything else you would like to add and share?

Responses

• Thank you to the project manager, we enjoyed participating in this project.
• The original timescale was too short as it took three to four months to realise the workload involved.
• Senior management’s attention was influenced by photos taken of poor storage of infusion devices and other equipment.
• Will national implementation include access to mentors as the pilot site had access to project leads?
• Shows that for patient care to be improved many people, professions and departments need to work together; any one of these groups can break the chain of bad practice.
Recommendation 18
There is no doubt that the use of photography in presentations and reports grabbed the attention of senior management in both pilot presentations and reports. A digital camera is recommended for use as part of the gathering of information to add weight to reports and influence the decision-making process.

All above recommendations are summarised in Appendix 5

Pilot sites identified five success factors
1. Support from senior management (including chief executive and finance director);
2. Stakeholder representation in the process;
3. The baseline assessments and solutions;
4. A single focus (pilot lead) in trusts to coordinate solutions development;
5. The national profile of the project and support from NPSA.

8.0 General comments and quotes from pilot sites
The following comments were taken from the pilot responses:
‘Being a part of the project has added impetus to developing our system, something we have been trying to do for years.’ (Hull)
‘The solutions website provides all the information and links you could want to support purchasing.’ (Epsom)
‘The infusion device utilisation audit really opened my eyes to what our problems were. When I presented to the board, these findings really engaged them and now I feel I have good support to develop and improve our system.’ (Leeds)
‘The baseline assessments should be a part of the solutions toolkit on the website, they really help you to focus.’ (Cardiff)
‘I knew things weren’t perfect but I hadn’t realised how imperfect we were.’ (Cheshire)
‘When we presented our infusion device utilisation audit to the CEO (highlighting significant inefficiencies) he immediately decreed that no more infusion devices would be bought until the problem was sorted.’ (Blackpool)
9.0 Recommendations for roll out of solutions to NHS

This evaluation has confirmed that solutions have had a positive impact by assisting pilot sites to carry out structured reviews; develop and improve their systems; and identify opportunities to make significant financial savings. The ultimate aim of the solutions is to improve patient safety.

9.1 Integration of pilot learning from evaluation

The recommendations and learning from the pilot evaluation have been incorporated into the existing solutions.

In response to baseline assessment 2 findings, work has been conducted, in collaboration with the Department of Health, to illustrate the economic impact that the solutions have had on pilot sites. This will provide the financial evidence to encourage others to review and develop their systems. A spreadsheet has been designed to assist trusts in developing their own local economic appraisal and is available as part of the solutions toolkit.

9.2 Rollout and sustainability

An area on the PaSA website has been made available to host the solutions toolkit.

The toolkit comprises:

1. A checklist to ensure objective purchasing decisions and promotion of standardisation.

2. An infusion device usability evaluation questionnaire for submission to the MHRA Device Evaluation Service currently provided by the Bath Institute of Medical Engineering.

3. Advice on how to develop a business case for centralisation.

In order to communicate the benefits of the solutions and the evidence underpinning their development, the NPSA will also issue advice to trusts on centralising and standardising infusion devices. This guidance will be targeted at key influencers such as chief executives and finance directors. Key implementers such as clinical engineering managers, clinical governance and risk management leads, board members and others will also be engaged to promote the uptake of solutions.

Many of the recommendations contained within the solutions already form part of a number of national inspection schemes such as Controls Assurance Standards and CNST.
9.3 Evaluation of the impact of solutions on trusts

Due to the long-term nature of solutions, and the measurement of their full impact being unlikely for at least two years, it is recommended that evaluation is carried out in two ways:

- **Evaluation 1:** Carry out a review on the uptake of solutions following the launch of the infusion device solutions. This can be achieved quickly and would require only high level information. This is recommended to be carried out within the first year.

- **Evaluation 2:** A reappraisal of baseline assessments 1 and 2 to be carried out, at yearly intervals post-implementation.

10.0 Conclusion

The project has evaluated extremely positively. The solutions clearly identified device management issues and have assisted pilot sites to develop and improve their systems.

Predicted common issues emerged to provide evidence to confirm that infusion device management is probably a national issue. The solutions will certainly assist other NHS trusts to improve the way that infusion devices are managed.
Appendix 1

Baseline assessments 1 and 2.
### Baseline assessment 1

**A decision-making checklist: Establishing purchasing processes and systems**

<table>
<thead>
<tr>
<th>1.0 Personnel</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a trust board member with responsibility for medical device management?</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a medical devices purchasing committee?</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all stakeholders involved in the purchasing decision-making process?</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.0 Framework/directives</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a medical devices policy or a set of guidelines covering the purchasing process?</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the policy recommend standardisation?</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the policy provide guidance on device replacement?</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the policy recommend centralisation?</td>
<td>4, 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your organisation have a limited list of approved infusion devices?</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your organisation have standardised infusion device documentation and procedures?</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has your organisation improved its score over the last three years in addressing the Medical Devices Controls Assurance Standard?</td>
<td>1.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3.0 Information review</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is information supplied by the following organisations used to inform the purchasing process?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines and Healthcare products Regulatory Agency (MHRA) or Bath Institute of Medical Engineering (BIME)</td>
<td>3, 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchasing and Supply Agency (NHS PaSA)</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has an audit of existing stock been carried out to establish infusion device sufficiency and utilisation?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 4.0 Applying risk assessment principles

<table>
<thead>
<tr>
<th>Question</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are infusion device adverse incident report summaries, from within the organisation, used to highlight areas of risk and inform purchasing?</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a process to circulate MHRA incident reports within the organisation and would all staff be aware of such and take appropriate action?</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is competency-based training available to clinical staff within the trust and are they actively being trained and assessed?</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are clinical engineering personnel trained prior to the commissioning of infusion devices?</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.0 Tender development

<table>
<thead>
<tr>
<th>Question</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has there been a tendering exercise for infusion devices within the last seven years?</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your organisation use a pre-purchase questionnaire (PPQ) when buying new devices?</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does your organisation use a device specification that considers infusion device safety features when purchasing devices? There may be more than one specification (e.g. critical use or general use criteria)</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6.0 Device usability

<table>
<thead>
<tr>
<th>Question</th>
<th>Note</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are infusion devices evaluated by clinical staff prior to purchase? This involves clinicians using a device in practice for a short period of time (one or two months) and providing an evaluation at the end of this period.</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have a structured evaluation process?</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have a standard evaluation form?</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are results of the evaluation made available to manufacturers?</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you share evaluation information with other organisations?</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7.0 Establish the number of YES, NO and UNSURE answers in each column. The totals will give an indication of areas that need addressing and will help you develop an action plan. (Review score after 6 months.)

<table>
<thead>
<tr>
<th>Score</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Review score (+ 6 and 12 Months)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All **Unsure** and **No** scores will provide the basis for your action plan.
Notes

1. NHSLA Controls Assurance Standard: Medical Devices Management, Criterion 1.
2. NHSLA Controls Assurance Standard: Medical Devices Management, Criterion 2.
4. The agencies mentioned above provide information and guidance on various aspects of device management and use. Device Evaluations and Bulletins (MHRA) are available free to trusts via the internet and as hard copy. On behalf of the MHRA, the Bath Institute of Medical Engineering (BIME) have produced a website to display all infusion device evaluation information the link for which can be obtained via the NHS PaSA infusion device website.
5. NHS PaSA also provide a range of purchasing/tendering advice on their website.
6. Audit needs to be an integral part of the purchasing process. It is important that organisations understand what the sufficiency of their stock is (is the stock appropriate for its purpose?). It may be that a high percentage of stock is more than seven years old. This could be inappropriate for the required use – eg low-specification devices being used in a neonatal intensive care unit.
7. Organisations should have an appointed MHRA liaison person whose responsibility it is to coordinate the circulation and appropriate actions to MHRA incident reports. You should be satisfied that clinical staff can gain access to these reports (as for note 3).
8. Competency training should be formalised and certificated. Training and attendance records should be available (as for note 1).
9. Technical training for clinical engineering staff should be incorporated as part of the tendering specification and provided by the supplying company (as for note 1).
10. If there has not been a tendering exercise within this time it is possible that a non-standardised stock of infusion devices is available for use. Non-standardised stock increases the risk of user error.
11. The PPQ provides technical information and will inform the tendering/purchasing process. You are directed to the NHS PaSA website which provides advice and a specimen PPQ form.
12. It is important for organisations to have a device specification that meets their need. This will prevent the purchase of over-specified devices that have the potential to be confusing and lead to user error. You are directed to the NHS PaSA website which provides advice and a specimen PPQ form.
13. Infusion devices should be tested and evaluated by users prior to purchase. It is important that devices are intuitive as well as meeting the specification requirements of the organisation. Evaluation does not always occur, leading to evaluation information not being used and shared effectively. User views should also be fed back to manufacturers to provide them with information to influence future design. You are directed to the NHS PaSA website which where you can access a standardised evaluation form and device specification advice.

There are a series of web links to all the information sites identified above these can be found on the infusion device front page on the NHS PaSA web page: www.pasa.nhs.uk/infusiondevices
Baseline assessment 2

Establishing infusion device usage

Purpose of baseline assessment 2:

To establish data that can provide an evaluation benchmark against which the impact of solutions can be measured. Assessment will cover areas including infusion device stock, device range, maintenance, incidents review (risk management) and cost. A baseline must be determined prior to solutions implementation. Data collected from this assessment should also be used to inform solution 3.
### Assessment

Please record the model and number of each infusion device, as well as their costs, within your organisation. This should include all syringe, volumetric, PCA and ambulatory devices.

**Information source:** trust asset register, engineering asset register or supplies department.

<table>
<thead>
<tr>
<th>Infusion device description by type</th>
<th>Model</th>
<th>Total available</th>
<th>Unit cost when bought (£)</th>
<th>Total cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>eg Anyone’s syringe pump</td>
<td>Ex C1ent 1</td>
<td>100</td>
<td>1300</td>
<td>1300,000</td>
</tr>
</tbody>
</table>

**Other notes and additional comments:**
**Assessment**

Please record the make, number and cost of infusion device administration sets used within your organisation. Because more than one administration set can be used with one infusion pump you are directed to record the consumable support for the three most commonly used sets for a specific device. You should include sets used with both syringe and volumetric pumps.

**Information source:** supplies department; clinical engineering (EBME).

<table>
<thead>
<tr>
<th>Infusion administration sets: description</th>
<th>Manufacturer code</th>
<th>Total used</th>
<th>Unit cost (£)</th>
<th>Total cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>eg Anyone’s volumetric pump</td>
<td>ABC 23456</td>
<td>10,000</td>
<td>1.00</td>
<td>10,000</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>1</td>
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<tr>
<td>2</td>
<td></td>
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<tr>
<td>3</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reprint this sheet to continue if required

**Other notes and additional comments:**
**Assessment**

Identify the total number of adverse incidents involving an infusion device during a one-year period. You should break this down further by emerging common themes.

**Information source:** risk management: adverse incident database.

<table>
<thead>
<tr>
<th>Adverse incidents</th>
<th>Number</th>
<th>Notes/additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The total number of trust infusion device adverse incidents reported over a one-year period</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nature of incidents (breakdown of above)</th>
<th>Number</th>
<th>Notes/additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over-infusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under-infusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>User error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe)</td>
<td></td>
<td>(eg tampering)</td>
</tr>
<tr>
<td>Other (describe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other notes and additional comments:**
Assessment

As part of the assessment you should carry out an audit to establish reliability and maintenance issues associated with infusion devices. The audit should review a snapshot of ten randomly selected infusion devices which are at least one year old. The data recorded should be from over a one-year period for the first two areas identified below. One of the reasons for doing this is that data from the MHRA identifies that in over 53% of infusion device incident reports they receive, no cause or fault is identified. Infusion devices are frequently cited as the cause of incidents, but the devices are rarely found to be at fault. The next two sections require data from the entire stock.

Information source: clinical engineering/EBME/EME departments

<table>
<thead>
<tr>
<th>Fault log/maintenance issues</th>
<th>Number</th>
<th>Additional notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of faults/ failures reported in ten randomly-selected infusion devices over a 12-month period.</td>
<td></td>
<td>For the purpose of this snapshot audit focus on volumetric and syringe pumps only, as these are most commonly used.</td>
</tr>
<tr>
<td>Total number of NO FAULTS FOUND (following a reported “failure”) in the ten randomly-selected devices identified above.</td>
<td></td>
<td>For the purpose of this snapshot audit focus on volumetric and syringe pumps only, as these are most commonly used.</td>
</tr>
<tr>
<td>Number of damaged devices (from being dropped etc) requiring new parts. Identified from all maintenance records.</td>
<td></td>
<td>This reflects management issues such as poor storage facilities and handling (in wards/ departments.) and housekeeping practices (cleaning devices, battery charging etc).</td>
</tr>
<tr>
<td>Total number of infusion devices that are over ten years old. Include syringe, volumetric and ambulatory infusion devices. Identified from entire trust stock</td>
<td></td>
<td>This could indicate a risk if such devices are used to infuse high-risk drugs.</td>
</tr>
</tbody>
</table>

The data gathered from baseline assessment 2 above should indicate the scope for development of management systems within your organisation. It should also be used in conjunction with the economic appraisal spreadsheet supplied within the toolkit. This will assist you to develop the business case argument for centralisation and related device management issues.
Appendix 2

Detailed baseline assessments and an evaluation of progress.

Baseline assessment criteria and evaluation – The following summarises 22 baseline assessment criteria findings with an evaluation of progress. Criteria cover performance in the following areas:

- personnel involved in decision making;
- policies and directives used to support decision making;
- information utilisation review;
- risk considerations;
- tender development issues;
- infusion device usability issues;
- infusion device management issues.
<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
</table>
| Personnel involved in decision making | 1  Is there a trust board member with responsibility for medical device management? | • Five pilot sites could identify the board member.  
• One wasn’t sure. | All pilot sites now have an identified board member with responsibility for medical devices procurement. |
|                               | 2  Is there a dedicated medical devices purchasing committee?             | • Five pilot sites had a purchasing committee but their function was variable. (Two had not met for a considerable time; another committee had not met at all; Role/ function not clear etc.)  
• One pilot site did not have a committee. | All pilot sites have established/reconvened a purchasing committee. Terms of reference and membership have been developed. |
|                               | 3  Are all stakeholders involved in the purchasing decision-making process? (Senior officers, staff, patients, electronics staff, etc.) | • Two pilot sites did not involve stakeholders.  
• Three weren’t sure. | All pilot sites now ensure stakeholder representation within the purchasing committee. Does this include patients? |
| Policies / Directives to support decision making | 4  Is there a medical devices policy or guidelines covering the purchasing process? | • Three pilot sites had a policy. All recognised that their policy could be improved.  
• Two were in the process of developing a policy.  
• One did not have a policy. | All pilot sites have developed (or improved) a medical devices policy. |
|                               | 5  Does the medical device policy provide guidance on device replacement? | • Only two pilot sites provided guidance on device replacement. | All pilot sites now include in their policies advice on device replacement issues. The advice and guidance provided via PaSA/NPSA solutions website was felt to be extremely useful. |
All pilot sites have accessed the solutions toolkit via the PaSA website during the course of the solutions testing.

- Five of the pilot sites used information supplied by the above organisations.

9 Is information supplied by the MHRA/BIME and PaSA used to inform the purchasing process?

Information utilisation review

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Does the policy recommend centralisation?</td>
<td>• Three pilot sites recommended centralisation.</td>
<td>All pilot sites have included in their policy advice on centralisation and are working to develop a business case to support centralisation.</td>
</tr>
<tr>
<td>7</td>
<td>Does the policy recommend standardisation?</td>
<td>• Two pilot site policies recommended standardisation.</td>
<td>All pilot sites have included in their policies advice on device standardisation.</td>
</tr>
<tr>
<td>8</td>
<td>Has your organisation made progress in addressing the Medical Devices Controls Assurance Standard over the past three years?</td>
<td>• Four of the pilot sites had made progress in improving their CAS score although initial progress has now slowed down. • One pilot site felt that their scores had reached a plateau.</td>
<td>This aspect cannot be evaluated until individual CAS inspections. It is predicted that the evidence provided through this development work will support an improved CAS score.</td>
</tr>
</tbody>
</table>

Information utilisation review

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Is information supplied by the MHRA/BIME and PaSA used to inform the purchasing process?</td>
<td>• Five of the pilot sites used information supplied by the above organisations.</td>
<td>All pilot sites have accessed the solutions toolkit via the PaSA website during the course of the solutions testing.</td>
</tr>
</tbody>
</table>
All pilot sites have successfully completed an audit of infusion device use (see Appendix 4 summary table). The following summarises the findings:

- Across the six pilot sites 65% of infusion devices not used.
- Infusion device numbers ranged from 402 to 2,900.
- Range of available infusion devices per trust, 31.
- Average stock, 1,065.
- Average cost of stock per pilot, £1,616,667.

This data has provided compelling evidence for business plan and equipment management strategy developments. Five of the pilot sites are in the process of developing their business case for an equipment library.

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Has an audit of existing stock been carried out to establish infusion device sufficiency? (Sufficiency should be viewed as the use of devices that are appropriate for a specific application, eg General, Critical care or Paediatric/Neonatal use)</td>
<td>• Five of the pilot sites had not carried out any infusion device audit.</td>
<td>All pilot sites have successfully completed an audit of infusion device use (see Appendix 4 summary table). The following summarises the findings:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Across the six pilot sites 65% of infusion devices not used.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Infusion device numbers ranged from 402 to 2,900.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Range of available infusion devices per trust, 31.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Average stock, 1,065.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Average cost of stock per pilot, £1,616,667.</td>
</tr>
</tbody>
</table>
Each of the six pilot sites now has an appointed MHRA liaison person. Pilot sites are continuing to develop their systems to ensure appropriate actions are taken (to close the loop) in response to safety or hazard notification.

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
</table>
| Risk considerations with infusion device use | 11 Are infusion device adverse incident reports used to highlight areas of risk and inform purchasing? | • Five pilot sites had previously been able to review infusion device adverse events as part of their existing risk management strategy. Not all had linked adverse events to the purchasing process. One pilot site had great difficulty in accessing adverse incident information from their trust database. | Pilot sites established the following incident data:  
• Reported infusion device incidents ranged between 12 and 196 per year.  
• 321 adverse incidents reported in total.  
• 96 ‘over-infusions’.  
• 21 ‘under-infusions’.  
• 59 user errors (44 in one pilot site).  
• 12 device failures.  
• Ten tampering (all patients).  
• ‘Other’ failures included: - prescription error; - wrong prescription; - wrongly mixed drugs; - patient interfering/tampering; - staff not trained.  
Data collection was obtained from paper-based and electronic data storage systems. Significantly two trusts identified 196 (largest pilot) and 70 (second largest pilot) incidents respectively. Four pilot sites ranged below 20 incidents per year. This raises the issue of a poor reporting culture in low reporting pilot sites. Two sites have noticed an increase in reporting following commencement of the pilot work and the profile that has brought within the trust. This situation will be monitored at the end evaluation. |
<p>| | 12 Are MHRA incident reports circulated within the organisation and would all staff be aware of such and take appropriate action? | • All pilot sites stated that MHRA notices are circulated within their organisations. Most could not be certain that recommended actions had been taken. | Each of the six pilot sites now has an appointed MHRA liaison person. Pilot sites are continuing to develop their systems to ensure appropriate actions are taken (to close the loop) in response to safety or hazard notification. |</p>
<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13 Is competency-based training available to clinical staff within the trust? (This should include knowledge and skills training with assessment.)</td>
<td>Two pilot sites have assessed competency training.</td>
<td>Training is currently carried out intermittently using a range of methods. Only two pilot sites have competency-based training. Of the remaining pilot sites there is a commitment to develop formalised training using the proposed NPSA/NHSU e-learning system. In the interim pilot sites are to ensure that basic training is provided through manufacturers.</td>
</tr>
<tr>
<td></td>
<td>14 Are clinical engineering personnel trained prior to the commissioning of infusion devices?</td>
<td>Three pilot sites ensured their staff were trained.</td>
<td>Pilot sites recognise the need to include technical training as part of the overall tendering/purchasing process. The proposed solutions promote this.</td>
</tr>
<tr>
<td></td>
<td>15 Has there been a tendering exercise for infusion devices within the last five years?</td>
<td>Three pilot sites had not carried out a trust-wide tender. Two had carried out limited tenders for small projects.</td>
<td>Four pilot sites have started the tendering process aimed at rationalising and developing their existing systems trust-wide. One has just completed a tendering exercise and one has committed to embark on the process before the project end.</td>
</tr>
<tr>
<td></td>
<td>16 Do you use a Pre-Purchase Questionnaire (PPQ) when buying new devices?</td>
<td>All pilot sites routinely use PPQs as part of the purchasing process.</td>
<td>The use of PPQs is common practice in all pilot sites and usually sent out through the clinical engineering/EBME departments.</td>
</tr>
</tbody>
</table>

**Tender development issues**

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Starting point</td>
<td>Following evaluation</td>
</tr>
<tr>
<td>------</td>
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<td>---------------------</td>
</tr>
<tr>
<td>17 Do you use a purchasing specification that considers infusion device safety features when purchasing devices? (There may be more than one set of criteria, e.g. critical care or general use criteria.)</td>
<td>• Three weren’t sure if they used a specification for purchasing and no evidence of such could be presented. • Two had not used a specification for purchasing.</td>
<td>All pilot sites have accessed the PaSA infusion device website and have obtained information on specification development. This was felt to be useful and will be incorporated into ongoing/future tendering.</td>
<td></td>
</tr>
<tr>
<td>Infusion device usability</td>
<td>18 Is infusion device usability evaluated by clinical staff prior to purchase? This should involve clinical staff using the device for a short period of time (1–2 months) and providing an evaluation at the end of the trial.</td>
<td>• Three pilot sites had involved staff in evaluating infusion devices.</td>
<td>All six pilot sites have commenced/completed evaluation of their commonly-used infusion devices using the evaluation tool (solution 2). Evaluations will be submitted to BIME for publication on their website.</td>
</tr>
<tr>
<td></td>
<td>19 Do you have a structured evaluation process (as part of the purchasing committee tendering exercise)?</td>
<td>• Four pilot sites did not have an evaluation (usability) process for infusion devices. • One was not sure (could not provide evidence).</td>
<td>All six pilot sites have incorporated an evaluation process into future purchasing procedures.</td>
</tr>
<tr>
<td></td>
<td>20 Do you have a standard evaluation form? (Covering the ergonomics/usability of the infusion device.)</td>
<td>• Five pilot sites did not have a standard form</td>
<td>Five of the pilot sites are using the usability evaluation form on the BIME website. One pilot site uses their own evaluation format. A formal evaluation of the BIME form will take place at project end.</td>
</tr>
</tbody>
</table>
It will only be possible to evaluate the impact of solutions once device management systems have been developed and introduced. This could take at least a year, probably longer. The exemplar pilot site (Cardiff and Vale) has reviewed the proposed solutions and indicated that had they had access to solutions earlier it would have expedited their work. They particularly highlight the baseline assessments as being good tools to providing focus for developments. Cardiff has been through a tendering process and developed a good systems approach to infusion device management. They have recently opened an equipment library and are well advanced in standardising their stock. Incident reports have increased as the profile of their system increased.

<table>
<thead>
<tr>
<th>Area</th>
<th>Criterion</th>
<th>Starting point</th>
<th>Following evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.1 Do you share evaluation information with other organisations or manufacturers?</td>
<td><strong>No pilot sites shared information.</strong></td>
<td>All pilot sites agree that information should be shared and will be submitting data to BIME for publication.</td>
</tr>
<tr>
<td>Infusion device management issues</td>
<td>2.2 Pilot sites were requested to carry out a maintenance review of ten randomly-selected infusion devices from their stock.</td>
<td><strong>Total number of faults found in these devices over a one year period.</strong></td>
<td>It will only be possible to evaluate the impact of solutions once device management systems have been developed and introduced. This could take at least a year, probably longer. The exemplar pilot site (Cardiff and Vale) has reviewed the proposed solutions and indicated that had they had access to solutions earlier it would have expedited their work. They particularly highlight the baseline assessments as being good tools to providing focus for developments. Cardiff has been through a tendering process and developed a good systems approach to infusion device management. They have recently opened an equipment library and are well advanced in standardising their stock. Incident reports have increased as the profile of their system increased.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Total number of no faults found in these devices over a one year period.</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Total number of damaged devices received within a one year period</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Total number of obsolescent infusion devices (older than ten years)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>60 infusion devices reviewed across the six pilot sites;</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>120 faults detected in the 60 infusion devices;</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>30 episodes of no fault found.</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>250 episodes of ‘devices damaged’ in the six pilot sites;</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1,200 + infusion devices more than ten years old (19% of total stock).</strong></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2:
Illustration – solution website:
www.pasa.nhs.uk/infusiondevices/
### Appendix 3:

**Summary data – pilot site baseline assessment 2**

<table>
<thead>
<tr>
<th>Pilot sites</th>
<th>Infusion device stock</th>
<th>Total cost</th>
<th>Average unit cost £</th>
<th>Range</th>
<th>Under-utilised %</th>
<th>10% reduction in stock</th>
<th>Cost reduction £</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH NHS Trust 1</td>
<td>2,900</td>
<td>3,500,000</td>
<td>1,206.90</td>
<td>35</td>
<td>70%</td>
<td>290</td>
<td>350,000</td>
</tr>
<tr>
<td>EH NHS Trust 2</td>
<td>562</td>
<td>860,000</td>
<td>1,530.25</td>
<td>30</td>
<td>65%</td>
<td>56</td>
<td>86,000</td>
</tr>
<tr>
<td>HEY NHS Trust 3</td>
<td>1,156</td>
<td>2,050,000</td>
<td>1,773.36</td>
<td>37</td>
<td>70%</td>
<td>116</td>
<td>205,000</td>
</tr>
<tr>
<td>BFW NHS Trust 4</td>
<td>581</td>
<td>1,100,000</td>
<td>1,893.29</td>
<td>48</td>
<td>70%</td>
<td>58</td>
<td>110,000</td>
</tr>
<tr>
<td>CV NHS Trust 5</td>
<td>782</td>
<td>1,460,000</td>
<td>1,867.01</td>
<td>13</td>
<td>40%</td>
<td>78</td>
<td>146,000</td>
</tr>
<tr>
<td>NC NHS Trust 6</td>
<td>406</td>
<td>730,000</td>
<td>1,798.03</td>
<td>25</td>
<td>73%</td>
<td>41</td>
<td>73,000</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>6,387</strong></td>
<td><strong>9,700,000</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Average for six pilot sites</strong></td>
<td><strong>1,065</strong></td>
<td><strong>1,616,667</strong></td>
<td><strong>1,518</strong></td>
<td><strong>31</strong></td>
<td><strong>65%</strong></td>
<td><strong>106</strong></td>
<td><strong>161,667</strong></td>
</tr>
<tr>
<td><strong>All NHS Acute trusts (189)</strong></td>
<td><strong>201,191</strong></td>
<td><strong>305,550,000</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4:  
Process evaluation questionnaire

Dear Colleague,

The infusion device project pilot work is nearing completion and to help us learn as much as possible from your experiences I have prepared an evaluation questionnaire for you to complete. Evaluation aims to:

- Highlight whether the solutions tested have made a difference/or will make a difference in the pilot sites.
- Identify any improvements to the solutions/or how they are presented, that will add rigor to any recommendations made to the wider NHS.
- Review and learn from the process of pilot site testing to inform future work of the NPSA.

The questionnaire will ask you to evaluate key aspects of this work AND provide a brief narrative on how the project has helped you and your organisation. You will also be asked to give your view on process issues as well as the content.

The deadline for submission is the 20th November 2003. This also happens to be the final pilot site meeting at the NPSA, London, and you should be prepared to give a brief presentation on your findings at this meeting.

Could I also ask that you complete and submit this evaluation electronically.

You should also complete a ‘re do’ of the baseline assessment carried out at the beginning of the project and submit this at the same time.

I will also be writing to your chief executives to formally thank you all very much for your hard work during this project. I feel confident that much will be achieved in your individual trusts and the wider NHS as a result.

Chris Quinn  
Project Manager  
Infusion Devices Project  
NPSA
Please answer the questions and provide supporting narrative where either prompted or appropriate. The ranking range is as follows:

Please ✔ appropriate box

6 = excellent improvement
5 = good improvement
4 = moderate improvement
3 = minor improvement
2 = no change
1 = worsened situation

1 How would you rate the overall impact that the infusion device project has had on your organisation’s ability to purchase and manage infusion devices?  1 2 3 4 5 6

Explain

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

2 How helpful was the solutions website www.pasa.nhs.uk/infusiondevices in providing clear and appropriate information?  1 2 3 4 5 6

Explain

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

3 How would you rate the information/content areas presented on the website? Were they helpful, easy to access and understand?  1 2 3 4 5 6

What improvements would you suggest?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
4 How helpful were the solutions in identifying organisational weaknesses and establishing what needs to be done?  
1 2 3 4 5 6
Please indicate which solutions you found to be the most helpful in order of preference and why with the best first.
1
2
3

5 How would you rate the baseline assessment tool used at the start of the project?  
1 2 3 4 5 6
Explain

6 How helpful was solution 1 (decision-making checklist)?  
1 2 3 4 5 6
Explain

7 How helpful was solution 2 (usability questionnaire)?  
1 2 3 4 5 6
Explain
8 How helpful was solution 3 (developing a business case for centralisation)?

Explain

9 How helpful was the project in bringing together the key stakeholders within your organisation to address the project issues?

Explain

10 How do you rate the support provided by NPSA project manager?

Explain

11 How do you rate the help received from other NPSA staff (eg, finance, communications)?

Explain
12 What is your organisation’s biggest achievement as a consequence of the project?
Explain

13 List below all of your achievements from participating in the infusion device project.
Explain

14 What do you see as the top five success factors in making the project work?
   1
   2
   3
   4
   5

15 What were the main barriers you experienced when developing the project?
Explain
16 How did you overcome these barriers?

Explain

17 How best do you think the NPSA can communicate the solutions to the wider NHS when they are ready for national implementation?

Explain

18 Is there anything else you would like to add/share?

Explain

Date submitted:

Trust

Chris Quinn
Project Manager
Appendix 5:
Process evaluation

Table summarising the data from questions where a ranking was requested.

<table>
<thead>
<tr>
<th>Question</th>
<th>Blackpool, Fylde and Wyre NHS Trust</th>
<th>Cardiff and Vale NHS Trust</th>
<th>North Cheshire NHS Trust</th>
<th>Hull and East Yorkshire NHS Trust</th>
<th>Leeds Teaching Hospitals NHS Trust</th>
<th>Epsom St Helier NHS Trust</th>
<th>Average score</th>
</tr>
</thead>
<tbody>
<tr>
<td>How would you rate the overall impact that the infusion device project has had on your organisation’s ability to purchase and manage infusion devices?</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>4</td>
<td>4.67</td>
</tr>
<tr>
<td>How helpful was the solutions website in providing clear and appropriate information?</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>4.17</td>
</tr>
<tr>
<td>How would you rate the information/content areas presented on the website? Were they helpful, easy to access and understand?</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>4.50</td>
</tr>
<tr>
<td>How helpful were the solutions in identifying organisational weakness and establishing what needs to be done?</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>5.17</td>
</tr>
<tr>
<td>How would you rate the baseline assessment tool used at the start of the project?</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>Not part of initial work</td>
<td>5.40</td>
</tr>
<tr>
<td>How helpful was solution 1 (decision making checklist)?</td>
<td>5</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>Not part of initial work</td>
<td>4.40</td>
</tr>
<tr>
<td>How helpful was solution 2 (usability questionnaire)?</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>?</td>
<td>Not part of initial work</td>
<td>3.75</td>
</tr>
<tr>
<td>How helpful was solution 3 (developing a business case for centralisation)?</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>4.00</td>
</tr>
<tr>
<td>Question</td>
<td>Blackpool, Fylde and Wyre NHS Trust</td>
<td>Cardiff and Vale NHS Trust</td>
<td>North Cheshire NHS Trust</td>
<td>Hull and East Yorkshire NHS Trust</td>
<td>Leeds Teaching Hospitals NHS Trust</td>
<td>Epsom and St Helier NHS Trust</td>
<td>Average score</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
<td>---------------------------</td>
<td>--------------------------</td>
<td>----------------------------------</td>
<td>----------------------------------</td>
<td>------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>How helpful was the project in bringing together the key stakeholders within your organisation to address the project issues?</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>4.67</td>
</tr>
<tr>
<td>How do you rate the support provided by NPSA project manager?</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>5.50</td>
</tr>
<tr>
<td>How do you rate the help received from other NPSA staff, eg finance, communications?</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>4.50</td>
</tr>
</tbody>
</table>

**Key:**
6 = excellent improvement  
5 = good improvement  
4 = moderate improvement  
3 = minor improvement  
2 = no change  
1 = worsened situation
Publications issued by the NPSA

A patient safety alert requires prompt action to address high risk safety problems.

A safer practice notice strongly advises implementing particular recommendations or solutions.

Patient safety information suggests issues or effective techniques that healthcare staff might consider to enhance safety.
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.