

The Management of Medical Equipment in NHS Acute Trusts in England



Contents

Executive summary and recommendations	1
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Part 1: Background	11
Medical equipment and patient care	11
The role of the NHS Executive, the Medical Devices Agency, the NHS Supplies Authority, and medical equipment suppliers	13
The MDA have issued guidance on medical equipment management	14
Why the NAO examined the Management of Medical Equipment	16
Scope of our examination	16
Methodology	17
<hr/>	
Part 2: Strategic management of medical equipment	18
Introduction	18
Management arrangements	18
The information infrastructure	20
Improving the strategic management of medical equipment	24
<hr/>	
Part 3: Acquisition and use of medical equipment	26
Introduction	26
Planning the acquisition of medical equipment	26
Selecting medical equipment	32
Medical equipment standardisation	34
Provision and use of medical equipment	36
<hr/>	
Part 4: Medical equipment maintenance	43
Introduction	43
Trusts spend over £120 million a year on maintenance of medical equipment	43
Medical equipment maintenance is carried out in a variety of ways	44
The majority of maintenance spending is on external provision	44
Almost all trusts use some form of planned preventative maintenance	45
There may be scope to increase standardisation of planned preventative maintenance schedules between trusts	46

The balance between in-house and external maintenance needs to be carefully considered	46
Cost savings may be possible from better management of external maintenance contracts	48
Reasons for variations across trusts in maintenance costs	49
Maintenance costs are strongly associated with trust size, and this explains about three quarters of maintenance cost variations	49
There are other factors that explain some of the variation in maintenance costs	50
Savings of up to 15 per cent of total annual maintenance costs may be possible	50
Cost-effectiveness of insurance maintenance is not yet proven	51
Quality Standards for maintenance work	52
Twenty eight per cent of internal NHS maintenance suppliers are externally accredited	53
Improving the cost effectiveness of maintenance in trusts	54
Part 5: Medical equipment safety	55
Introduction	55
Extent of adverse incidents	55
User training	61
Action to improve medical equipment safety	65
Appendices	
1. Audit methodology used by the National Audit Office	66
2. Statistical analysis of provision of medical equipment and maintenance costs at NHS trusts in England	70
3. Medical equipment suppliers and manufacturers consulted by the NAO	81
Glossary of terms	82

Executive summary and recommendations

Overview

1 Medical equipment includes all medical devices connected to patients as part of their treatment and care in hospital, and medical devices used for diagnostic and laboratory purposes. Medical equipment therefore represents a substantial asset for the NHS that needs to be managed efficiently. Moreover, the way in which medical equipment is purchased, managed and used can influence the quality of care delivered to patients. Medical equipment can also involve risks to both patients and staff, particularly if used improperly, although the risks are small compared with the number of medical procedures carried out.

2 This report considers the strategic management of medical equipment in NHS acute trusts in England, its acquisition and use, how it is maintained, and how safe it is in use. The report examines the performance of trusts in managing medical equipment against good practice guidelines, particularly those promulgated by the Medical Devices Agency (MDA), highlighting the examples of good local practice we found.

3 The report concludes that, although there are examples of good practice, overall more needs to be done by trusts to allocate clear responsibility for medical equipment at board level. Trusts need to ensure that inventory information is comprehensive and used fully in decision making. Procurement of medical equipment needs to be better co-ordinated across trusts, with more involvement of technical personnel. They can also usefully contribute to non-clinical aspects of user training. We also recommend action that should help to improve the standards of reporting of adverse safety incidents, and to reduce their occurrence.

4 The report recommends that the NHS Executive and NHS trusts should investigate unexplained variations in the value of medical equipment holdings to see whether some trusts are under-provided with medical equipment compared to similar trusts. There may be good reasons why some trusts appear to have higher than expected amounts of medical equipment and maintenance costs, and we cannot make estimates of what economies will be possible following further investigation. We cannot therefore make an estimate of what savings can be achieved, but there is scope for investigating holdings of medical equipment to see whether economies of up to a maximum of £400 million are possible.

Medical equipment in NHS acute trusts

5 NHS trusts hold a vast array of medical equipment, ranging from less expensive items, such as stethoscopes and blood pressure gauges, to complex and costly medical equipment such as magnetic resonance imaging scanners, which typically cost £1 million and involve substantial ongoing revenue costs.

6 In total, in 1996-97, we estimate that NHS acute trusts in England held medical equipment with a replacement value of some £3 billion. They spent some £220 million on acquiring new and replacement medical equipment, and a further £120 million on maintenance. The value of medical equipment held and the scale of expenditure remained at a similar level in 1997-98. Although not specifically addressed in this report, charitable donations also contribute funding, particularly for medical equipment related to high profile conditions and services, such as coronary care, cancer and children's services.

Main findings on the strategic management of medical equipment

7 In January 1998 the MDA introduced revised guidance on the management of medical devices, including medical equipment. The revised guidance was less prescriptive than the previous guidance and its scope extended to medical devices used in the community. However, neither this guidance nor its predecessor set out the broader principles of good practice underlying the proper governance of medical equipment, including the role of trust boards. While the current guidance contains some examples of good practice, these could usefully be supplemented, particularly with regard to medical equipment organisation and management arrangements.

8 Clear leadership at board level is desirable if a trust's medical equipment is to be managed in a strategic manner. There were differences in the way responsibilities for medical equipment matters were allocated at trust board level, and at 12 per cent of trusts there was no clear lead at board level. In these circumstances it is difficult for trusts to be confident, and to demonstrate, that they are taking an acceptable approach to the strategic management of what is a substantial asset.

9 The MDA guidelines recommend that the manager of technical servicing (technical supervisor) should be involved in the purchase, acceptance testing, installation, and repair and maintenance of medical equipment, and the training

of users. However, a substantial number of technical supervisors did not include the procurement of medical equipment or the training of users as one of their main responsibilities.

10 The MDA guidelines also recommend that there should be a person in each hospital department nominated to represent all aspects of the use of medical equipment, but only a quarter of trusts had departmental user representatives in all hospital departments. The lack of user representation at departmental level can result in poor co-ordination between departments over the use and sharing of medical equipment, and between user departments and the technical department, for example over maintenance needs and scheduling. It may also impact on safety in the event that the MDA issues a Hazard or Safety Notice, as there is an increased risk that it takes longer to locate and identify specific medical equipment.

11 One in three trusts did not have an equipment procurement committee as recommended by the MDA. Furthermore, 60 per cent of the committees that did exist did not have responsibility for the procurement of all medical equipment, although in each case the proportion of a trust's expenditure on medical equipment not covered was unclear. In these circumstances the scope for effective strategic planning, co-ordination and procurement of medical equipment is limited, thereby risking value for money.

12 Good quality information is a prerequisite for effective management of medical equipment. At some of the trusts we visited medical equipment inventories were either out of date, inconsistent with other records, or lacking important detail. Poor inventory management and information can constrain a trust's ability to make rational long term planning decisions on the basis of the existing stock of medical equipment. It may also limit the efficient utilisation of medical equipment and effective planning of maintenance, and there may be safety implications if medical equipment cannot be located promptly via an inventory.

Main findings on the acquisition and use of medical equipment

13 A properly planned approach to the acquisition of medical equipment, taking into account the needs and preferences of professionals and end-users whilst retaining consistency and control, is needed if value for money is to be obtained. Some trusts demonstrated good practice by, for example, involving technical personnel in the acquisition process and using lifecycle costing to inform acquisition decisions. However, not all trusts we visited had a formal business planning process in place for the acquisition of medical equipment, and while business cases were often prepared they were of variable quality. The variable

quality of business cases applied equally to the acquisition of more costly medical equipment, such as magnetic resonance imaging (MRI) scanners, which can each cost up to £1 million in capital costs alone and can have a strategic impact beyond the boundaries of the purchasing trust.

14 Trusts made good use of available information in selecting medical equipment for purchase, including information on products provided by manufacturers or suppliers, and from the MDA and NHS Supplies. Some medical equipment suppliers told us, however, that they considered NHS medical equipment procurement procedures to be inconsistent between trusts and overly complex, resulting ultimately in higher prices being charged to their NHS customers.

15 On average, in 1996-97 trusts completed 40 per cent of medical equipment purchases in the last quarter of the year. And a fifth of trusts spent more than 50 per cent of their medical equipment budget in the final quarter. This pattern of spending, which was repeated in 1997-98, might reflect prudent financial management by some trusts, but where it is not planned there is a risk that trusts spend at the year end to use up their budgets, without due regard to value for money and longer term strategic priorities.

16 Clinical requirements will dictate that a minimum number of makes and models of the same item of medical equipment is needed in a hospital. But, where appropriate, standardisation of medical equipment can save costs on acquisition and maintenance, improve flexibility in the use of medical equipment for patient care, and reduce some of the potential for serious incidents. Standardisation of medical equipment by type, in conjunction with the operation of medical equipment libraries, can also lead to more efficient utilisation of medical equipment.

17 For selected items of equipment, we found a wide range in the number of makes and models held by different trusts. Standardisation to a limited number of makes and models of medical equipment can produce substantial savings and we found examples of where this had been achieved, but only a small minority of trusts had a documented policy on the standardisation of medical equipment.

18 The size of a trust and the nature of services provided are important determinants of the amount of medical equipment held, but allowance for these and a range of other factors explained only three quarters of the variation in medical equipment holdings across trusts in 1996-97. Some trusts had less equipment than expected, and this may reflect either efficiency in use, or under-provision in comparison to similar trusts. Some trusts are highly specialised

and require more, or more expensive, medical equipment. In some cases, equipment may be fully depreciated and kept in reserve, overstating the unexplained level of medical equipment. We cannot therefore make an estimate of what savings can be achieved, but there is scope for investigating holdings of medical equipment to see whether economies of up to a maximum of £400 million are possible.

Main findings on medical equipment maintenance

19 Most medical equipment maintenance is carried out by suppliers or by third parties, who together accounted for about two-thirds of total maintenance costs across all acute NHS trusts in England in 1996-97 and in 1997-98. Trusts vary in the relative amount of maintenance carried out in-house and externally. Although there can be advantages from contracting with external suppliers of maintenance, particularly for more complex items of medical equipment, we found that some trusts had reduced their overall maintenance costs through the increased use of in-house maintenance. However, in each case the balance of provision needs to be weighed carefully to make sure that any change offers value for money. Some trusts had also produced savings through the rationalisation and improved monitoring of external maintenance contracts.

20 Almost all trusts have adopted planned preventative maintenance, taking into account manufacturers' recommendations on maintenance frequencies, in line with MDA guidance. Some trusts strictly follow maintenance schedules set by medical equipment suppliers. Others have developed their own schedules in the light of operating experience, to save costs without jeopardising safety. Trusts, however, need to take account of the potential increased exposure to liability should they vary maintenance schedules from those recommended by medical equipment manufacturers.

21 Total maintenance costs in 1996-97 varied widely across trusts. Allowance for the value of medical equipment held and a range of other factors explained nearly 80 per cent of the variation. Trust specific factors may well account for some of the remaining variation, and further investigation by trusts is needed. We cannot make an estimate of the savings that can be achieved, but the potential is for savings up to a maximum of £18 million a year.

22 Maintenance cover arranged through insurance companies is becoming increasingly popular. On the basis of international experience that we reviewed, we caution that this route may not offer savings in the long term, and in each case the benefits of maintenance insurance need to be assessed carefully.

23 Thirty per cent of in-house maintenance departments had external accreditation to a recognised quality standard. Apart from the greater assurance accreditation gives to medical equipment users, based on examples of best practice we saw it leads to higher quality of work and the scope for efficiency savings.

Main findings on medical equipment safety

24 More than 2,000 adverse safety incidents involving medical devices, including medical equipment, were reported to the MDA by NHS trusts in England in 1997-98. Although the number of adverse incidents is low in relation to the total number of procedures carried out in NHS trusts, there has been an upward trend in incidents reported since 1993-94. The MDA believes this is due, at least in part, to improved reporting by trusts and the introduction of mandatory reporting of some types of incidents by manufacturers. Over the three financial years 1995-6 to 1997-8, nine deaths and 55 serious injuries have been directly related to medical devices, including medical equipment, or their misuse.

25 We found a wide range in the number and proportion of adverse incidents involving medical equipment reported by NHS trusts to the MDA under its voluntary reporting scheme. The variations suggest that the safety record of some trusts may be worse than in others. Also, or alternatively, some trusts may have a poorer record than others in reporting incidents.

26 We found in some trusts visited examples of good practice in reporting adverse incidents and in disseminating safety information issued by the MDA. However, other trusts had ineffective systems for reporting adverse incidents or ensuring that an adverse incident involving an individual item of medical equipment would not be repeated.

27 While trusts find MDA Hazard and Safety Notices useful, some were unable to act on them effectively, particularly where their inventories are incomplete or out of date.

28 It is essential that all users of medical equipment are properly trained. User error is a frequent cause of adverse incidents, and good quality training is probably the most important factor in reducing the level of user error. Medical engineering departments are well placed to play a more active role, than they do at present in some trusts, in the non-clinical aspects of training in medical equipment use.

Recommendation 1: Improving strategic management of medical equipment

29 We found examples of good practice that could be adopted more widely. Strategic management could be improved by implementation of the following recommendations:

- The MDA guidance to trusts should be supplemented to address some higher level strategic issues, including the role of trust boards, and good practice in the management of medical equipment;
- trusts should ensure that there is clear and effective oversight at board level of all aspects of medical equipment, and consider whether this responsibility might be exercised more effectively by vesting it in a single director;
- all trusts should establish procurement committees, with medical engineering and finance department representation, and ensure that medical equipment user representatives are established in all hospital departments;
- trusts should review their inventory management arrangements against the principles of good practice set out in MDA guidance, and look at the potential for modern information systems to facilitate consolidation into a single inventory where practicable.

Recommendation 2: Improving value for money from the acquisition and use of medical equipment

30 In the light of our findings, we recommend that trusts should:

- review their business planning arrangements for medical equipment, in particular the quality of business cases developed for the acquisition of more expensive items of medical equipment;
- review their medical equipment procurement procedures to ensure they are based on full life costing, are only as complex as is needed to ensure value for money, and encourage a consistent approach. The NHS

Executive should provide a lead by identifying and promulgating good procurement practice taking account of the outcome of the 1998 Cabinet Office review of NHS procurement;

- seek to reduce the number of different models of each type of medical equipment in use and, accordingly, introduce a replacement strategy that promotes standardisation of medical equipment, to save money and minimise the staff training burden while ensuring that all clinical needs are covered. Benchmarking between trusts has an important role to play in facilitating this work;
- examine whether the pattern of expenditure over the financial year in procuring medical equipment is conducive to ensuring good value for money;
- benchmark their holdings of medical equipment against those of similar trusts to examine how cost effective they are and identify good practice.

Recommendation 3: Increasing the value for money obtained from maintenance

31 We found many good examples of innovation, cost saving and quality of work improvements in connection with medical equipment maintenance. To learn from this, and taking account of our other findings, we recommend that trusts should:

- examine whether they can reduce maintenance costs through sharing maintenance with external suppliers, or by taking over some work altogether;
- review external contracts, to seek cost savings through better contract co-ordination and monitoring of their need. When considering insurance based maintenance, trusts should assure themselves that long term savings are possible;
- develop and review planned preventative maintenance schedules, in the light of experience and manufacturers' recommendations on maintenance frequencies, and sharing information and experience with other trusts, with a view to saving costs without reducing medical equipment safety or increasing exposure to liability;

- benchmark their maintenance costs against those of other trusts, in order to introduce best practice and explore the potential for financial savings;
- evaluate the benefits of, and where appropriate take steps to obtain, external accreditation of their in-house maintenance departments.

Recommendation 4: Improving safety of medical equipment

32 The upward trend in the number of medical equipment safety incidents reported may stem in part from more reliable reporting by trusts, and we welcome the MDA's work to improve the standards of reporting. We recommend that:

- the MDA and the NHS Executive should investigate variations in the levels and proportions of incidents reported, and consider whether the voluntary system that requires trusts to report incidents, when taken together with other reporting systems, leads to a sufficiently comprehensive knowledge of medical equipment safety risks in NHS trusts;
- trusts should have effective systems and fully documented procedures for recording and reporting medical equipment safety incidents, and ensuring that adverse incidents occurring within a trust are not repeated;
- the MDA and the NHS Executive should consider how best practice related to safety of medical equipment generally can be monitored, disseminated and put into effect in order to reduce the overall level of adverse incidents;
- trusts should consider how to make best use of medical engineering department and other expertise in user training.

Overall conclusions

33 Our examination has identified many examples of good practice in the management of medical equipment, from strategic overview, to day to day activities such as maintenance, and in the field of medical equipment safety.

34 There is considerable variation between trusts, however, in terms of practices adopted, and also in the amount of medical equipment held in relation to size of trust and other factors, and also in respect of maintenance expenditure. In

many instances we believe there may be potential for financial savings and we have attempted to quantify this. We believe that the benchmarking of costs and management practices, as used by many public and private sector organisations, could yield the benefits of lower costs, quality improvements and reduced safety risks.

35 The Accounts Commission for Scotland have adapted some of our methodology to review the management of medical equipment by trusts in Scotland. And we have discussed with the Audit Commission the scope for them to undertake local audits of NHS trusts in England and Wales, drawing on our findings, in order to help realise these benefits.

Part 1: Background

Medical equipment and patient care

1.1 Medical equipment represents a substantial asset for the NHS and is central to patient care. Ongoing increases in the sophistication of medical equipment provide benefits to patients in terms of new and advanced techniques, improved clinical outcomes and less time in hospital. For the NHS there are additional benefits of higher patient throughput and lower costs of diagnosis and treatment. However, medical equipment can involve risks to both patients and staff, particularly if used improperly, although the risks are small compared with the number of medical procedures carried out.

1.2 For the purpose of this report we have defined medical equipment to include all medical devices connected to patients as part of their care in hospital, and medical devices used for diagnostic or laboratory purposes. Medical equipment may also be used to support research and teaching. Medical equipment therefore represents a sub-set of medical devices, which also include items such as hospital beds, replacement joints and surgical appliances.

1.3 NHS trusts hold a vast array of medical equipment, ranging from small, inexpensive items such as stethoscopes and blood pressure gauges each costing less than £100, to complex and costly medical equipment such as magnetic resonance imaging scanners which typically cost £1 million and involve substantial ongoing revenue costs. We estimate that in 1996-97 acute NHS trusts in England held medical equipment with a total replacement value of some £3 billion (for items individually valued at more than £500), spent £220 million acquiring new and replacement medical equipment, and more than £120 million maintaining their stock of medical equipment¹. The value of medical equipment held and the scale of expenditure remained at a similar level in 1997-98.

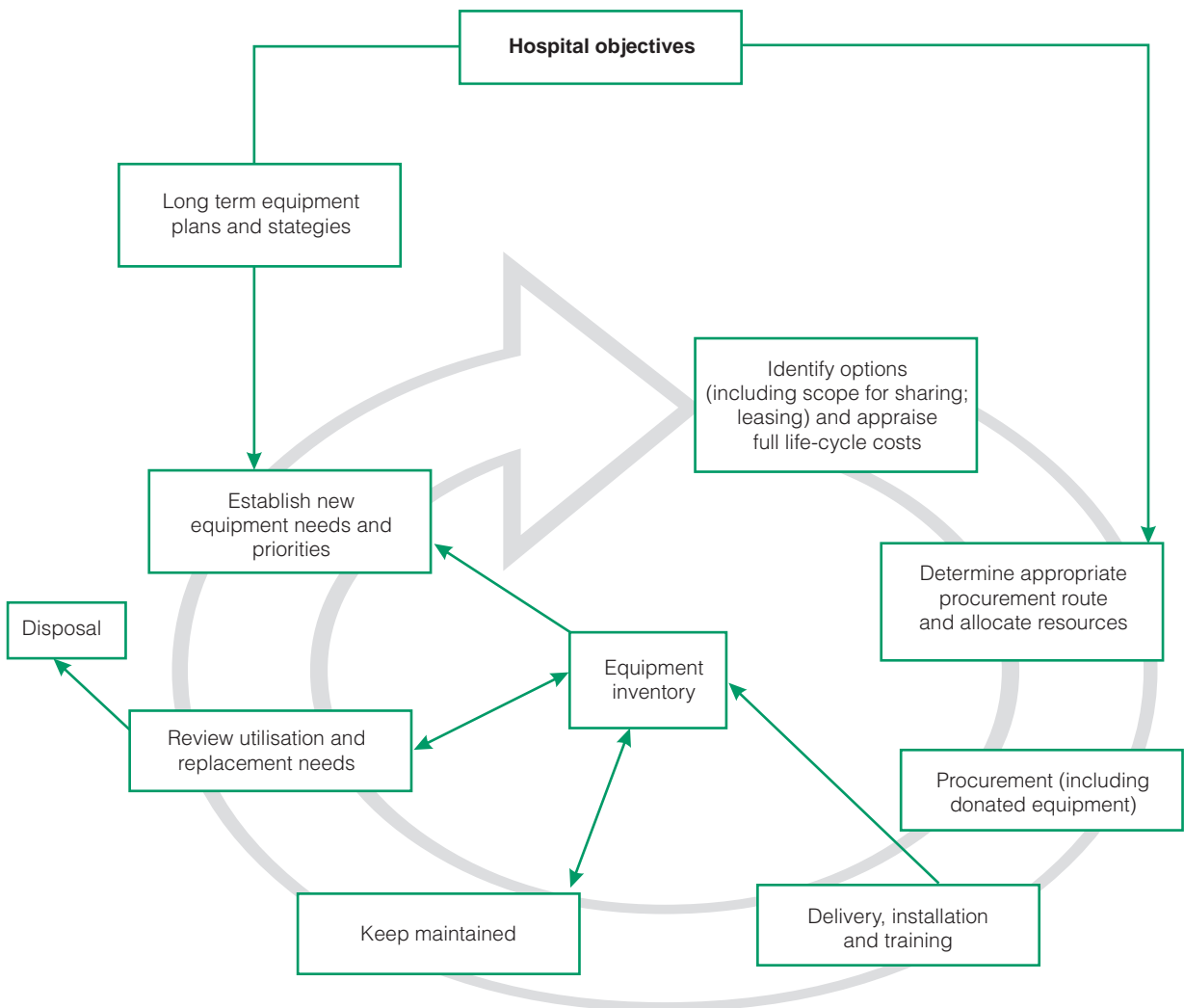
The nature of medical equipment management

1.4 For a trust, medical equipment represents a substantial asset that has significant running costs. Trusts therefore need to exercise a strategic approach to medical equipment management. This requires both long term planning, control and review at a corporate level, and effective management at the operational level.

1 NAO survey of all acute trusts carried out for this Report.

And mechanisms need to be in place to ensure that medical equipment is acquired on the basis of assessed and prioritised need and cost effectiveness criteria, and is used efficiently and effectively. Trusts' decisions on medical equipment acquisition, use, maintenance and replacement need to be made on the basis of complete and reliable information, including life cycle costs and up to date inventories. Figure 1 illustrates the main aspects of medical equipment management.

Figure 1 The management cycle for medical equipment



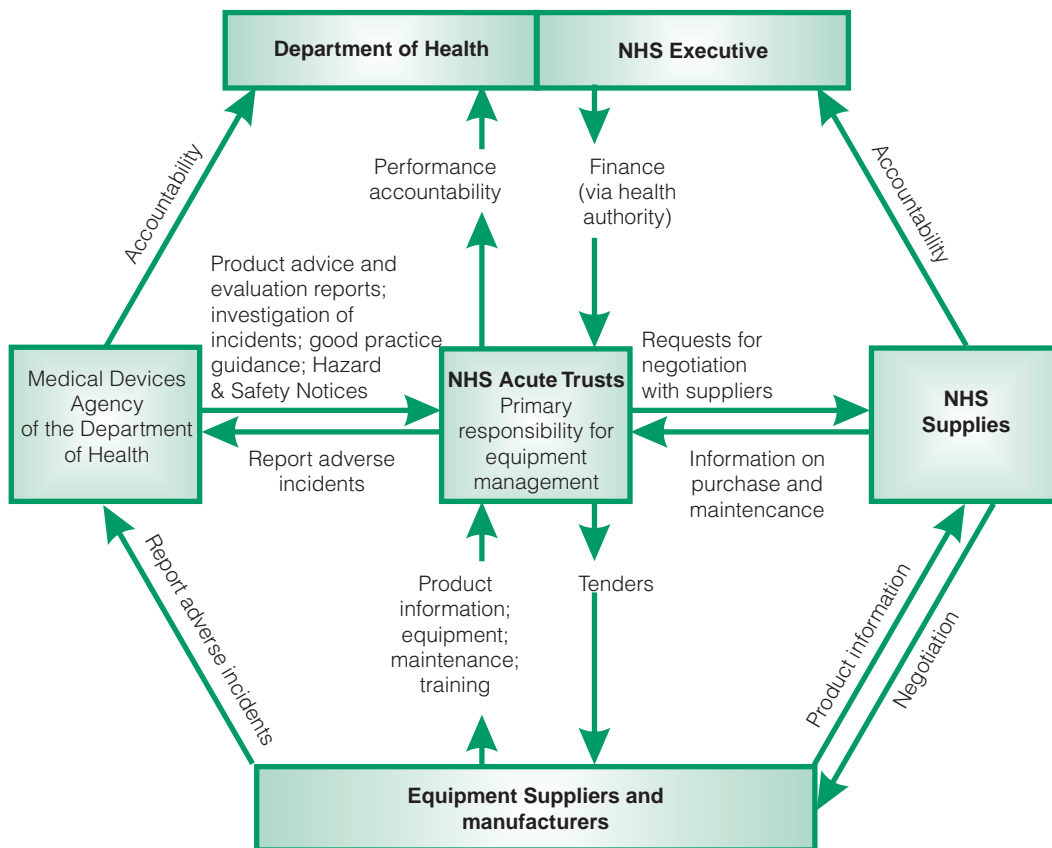
Source: National Audit Office

The role of the NHS Executive, the Medical Devices Agency, the NHS Supplies Authority, and medical equipment suppliers

1.5 Figure 2 sets out the roles of, and relationships between, the parties involved with medical equipment. The NHS Executive has no direct responsibility for medical equipment. However, they are required to approve capital expenditure on certain items of expensive medical equipment, such as MRI scanners which can each cost in excess of £1 million.

Figure 2

The organisational relationships, roles and accountabilities for medical equipment strategy and management



Source: National Audit Office

1.6 Each NHS trust is responsible for managing their own medical equipment portfolios and taking decisions about acquisition, replacement, maintenance arrangements, training and disposal. Trusts receive revenue and capital allocations from the NHS Executive out of which they fund the purchase and

running costs of medical equipment. Trusts are accountable to Parliament for this expenditure, through the NHS Executive. Trusts are also responsible for the safety of medical equipment under the EU Directive on Health and Safety at Work.

1.7 The primary role of the Medical Devices Agency (MDA), established in 1994 as an executive agency of the Department of Health, is to ensure that medical devices meet appropriate standards of safety, quality and performance². It also provides advice to trusts on medical equipment performance and selection, and it has issued guidance on the management of medical equipment. If adverse incidents occur in connection with medical devices, including medical equipment, there is a voluntary reporting system for trusts to notify the MDA, which in turn investigates. Suppliers and manufacturers are also required to notify adverse incidents to the MDA.

1.8 Some trusts choose to use the services of the NHS Supplies Authority when acquiring medical equipment. These services can include the provision of specialist advice on items of medical equipment, and negotiating prices and contracts with medical equipment suppliers. Trusts gain access to these services by paying an annual fee to NHS Supplies. The purchasing fee is based on a trust's non-pay spend that is influenced by NHS Supplies. The maximum annual fee paid by the largest acute trusts is £22,000.

1.9 Medical equipment suppliers and manufacturers provide advice on medical equipment prior to acquisition. They also provide maintenance services and training for users. Trusts negotiate maintenance contracts with manufacturers, suppliers or third parties, where less expensive than carrying out in-house maintenance, or where there are very specialised technical requirements.

The MDA have issued guidance on medical equipment management

1.10 The Department of Health first issued guidance to the NHS on the management of medical equipment in 1982. Periodically updated, this guidance remained extant until January 1998. It recommended a system of medical equipment management to help ensure that all medical equipment used in the NHS was not only understood by users and suitable for its intended purpose, but also

2 MDA Annual Report 1997-98.

maintained in a safe and reliable condition and could be used with confidence. The guidance also addressed issues related to obtaining value for money from medical equipment

1.11 The MDA issued new guidance in January 1998, during the course of our examination. The primary reason for the new guidance was to take account of developments in medical equipment usage, including the increased use of medical equipment by community as well as acute trusts. The new guidance also reflects recent changes in legislation, relating in particular to the establishment of the single European market and the impact of European Union Directives on procurement and safety. However, the principles of good practice embodied in the new guidance generally reflect those set out in the earlier guidance. These cover:

- organisation and allocation of responsibilities for medical equipment management;
- inventory management;
- acquisition and replacement of medical equipment;
- acceptance and testing;
- user training;
- medical equipment servicing and maintenance; and
- accident and medical equipment defect reporting.

1.12 Using this guidance, the main responsibility rests with individual NHS trusts to ensure that the acquisition, maintenance and use of medical equipment comply with relevant health, safety and environmental standards, and achieve value for money.

Cabinet Office review of NHS procurement

1.13 The Cabinet Office completed a review of NHS procurement in November 1998. Ministers are considering the review's recommendations. Although this report does not take account of the review's findings, we note that in

many areas they are consistent with the findings and recommendations, in respect of the procurement aspects of medical equipment management, set out in this report.

Why the NAO examined the management of medical equipment

1.14 We examined the management of medical equipment in NHS acute hospital trusts because:

- medical equipment represents a substantial asset for hospitals - £3 billion replacement cost, and £340 million on purchase and maintenance in 1996-97;
- during preliminary work we found wide variations in the amount of medical equipment employed by trusts, after taking account of their size, and in maintenance expenditures in relation to the amount of medical equipment employed. These variations suggested there might be scope for improved value for money and financial savings;
- although the use of medical equipment involves small inherent risks, there are additional risks to patients and staff from its misuse. It is important to establish how trusts manage these risks; and
- the study provided an opportunity to identify good local practice to help trusts and the NHS Executive to improve the management of medical equipment across all trusts.

Scope of our examination

1.15 Against this background, we examined how NHS acute trusts managed their medical equipment portfolios to ensure that risks to value for money and patient safety are minimised. In particular, against the principles of good practice embodied in MDA and other guidance we examined:

- trusts' arrangements for the strategic management of medical equipment (Part 2);
- how trusts acquire and use medical equipment, (Part3);

- medical equipment maintenance, (Part 4); and
- medical equipment safety and how this might be improved, (Part 5).

1.16 We did not examine year 2000 issues, which potentially affects medical equipment that relies on software or has in-built electronic chips, as these issues have been covered in earlier reports³.

1.17 Although most medical equipment purchases are funded by the NHS, charitable donations also contribute significantly, for example for coronary care, cancer and children's services. We did not examine issues arising from the nature of funding of medical equipment.

Methodology

1.18 Our report is based on a survey of all 227 acute NHS hospital trusts in England relating to 1996-97; visits to 10 trusts; discussions with key stakeholders including medical equipment suppliers; and benchmarking the performance of 12 trusts. We also carried out a limited follow up survey of trusts to determine the overall position on expenditure in 1997-98. However, unless otherwise stated, the analyses in this report are based on the original survey of trusts which relates to 1996-97.

1.19 During the examination we were assisted and advised by the Emergency Care Research Institute (ECRI). Details of the methodology employed are at Appendix 1.

1.20 Except where we specifically use the term "medical devices", the report applies to medical equipment in accordance with the definition in paragraph 1.2.

Part 2: Strategic management of medical equipment

Introduction

2.1 Medical equipment represents a substantial asset that needs to be managed efficiently and effectively. We examined two strategic aspects of medical equipment management, looking at whether trusts have:

- proper management arrangements in place; and
- an adequate information infrastructure to underpin the management of medical equipment.

Management arrangements

MDA guidelines should be supplemented by the dissemination of good practice

2.2 MDA guidelines set out responsibilities for purchasing, deploying, maintaining and repairing medical devices, including medical equipment⁴. The MDA told us that they designed the most recent guidelines, issued in January 1998, to cover essential management principles in a less prescriptive way than the previous guidelines, and extended their scope to cover medical devices used in the community as well as in hospitals.

2.3 Discussions with the 12 trusts whose performance we benchmarked revealed that they made extensive use of MDA guidelines but, by being less prescriptive about management issues, the current guidance was of less practical use to them than its predecessor. For example, the benchmark trusts believed that the current guidance is less clear than its predecessor on certain good practices that could be employed by trusts to manage medical equipment efficiently and effectively.

4 MDA, Health Equipment Information Bulletin (HEI98)

2.4 Although MDA guidance sets out the roles and responsibilities for some key players involved in day to day medical equipment management, it does not set out the broader principles of good practice underlying the proper governance of medical equipment. For example, the guidance does not suggest a role for trust boards. Given the value of medical equipment within the NHS in England, at some £3 billion, we consider that the MDA guidelines should be supplemented by the identification and dissemination of good practice in this area.

Lead responsibility for medical equipment management varies across trusts and in 12 per cent of trusts there was no clear lead at board level

2.5 Clear leadership at executive level is required to ensure that effective medical equipment management policies and procedures are in place across a trust. Our survey showed that 70 per cent of trusts had a board director with a lead role in medical equipment management, although in all but one case this was part of broader responsibilities. In some trusts chief executives assumed a leadership role, but 12 per cent of trusts told us that there was no clear lead at board level. In terms of size of medical equipment holdings, we could find no pattern to these findings. A lack of a clear lead on medical equipment matters at board level was as likely in large trusts as in trusts with small medical equipment inventories.

2.6 Where leadership on medical equipment matters at trust board level is unclear, there is an increased risk that Boards are unable to assure themselves, or otherwise demonstrate, that proper governance and management arrangements are in place, and that they are obtaining good value for money from expenditure on, and the use of, medical equipment.

Technical personnel and departmental user representatives are not involved in medical equipment management to the extent recommended by MDA guidance

2.7 The MDA guidelines recommend that the manager of technical servicing (technical supervisor) should be involved in the purchase, acceptance testing, installation, and repair and maintenance of medical equipment, and the training of users. Our survey showed, however, that only 55 per cent in-house maintenance managers saw procurement, and only 46 per cent saw user training, as one of their main responsibilities.

2.8 The guidelines also recommend that each department of a hospital should have a person nominated to represent all aspects of the use of medical equipment from a user's viewpoint.⁵ The nominated person may be a clinician, a nurse, or other professional, depending on the department concerned. Their purpose is to represent all aspects of the use of medical equipment within their particular field of activity, including acceptance of medical equipment into service, day to day supervision of use and user training. Our survey showed that only a quarter of trusts had such personnel in all departments or clinical directorates. A half of trusts said that some departments or clinical directorates had such a designated person. However, a quarter of trusts told us that they did not have departmental or clinical representatives.

68 per cent of trusts had procurement committees to advise on purchasing but less than half of these influenced all acquisition decisions

2.9 Many trusts have found it helpful to have purchasing advisory committees, that include clinical engineering and finance expertise, to inform purchasing^{6 7}. Benefits include better informed decisions based on the capabilities of new medical equipment and the merits of new models, fuller consideration of the revenue consequences of capital acquisitions, and a forum for deciding on acquisition priorities. Our survey showed that 68 per cent of trusts had such a committee with specific responsibility for selecting and procuring medical equipment for the whole trust. However, 60 per cent of these committees did not have responsibility for advising on the procurement of all medical equipment, although in each case it is unclear what proportion of a trust's expenditure on medical equipment was not covered. We consider, therefore, that some acquisition decisions in some trusts were likely to have been made without the benefit of the full range of expertise, increasing risk to value for money.

The information infrastructure

2.10 Trusts need an appropriate information infrastructure to plan and manage medical equipment efficiently and effectively. Without adequate records about medical equipment held, value for money can be compromised in a number of ways including:

5 MDA, Device Bulletin (DB9801), 1998

6 MDA, HEI98,1991

7 MDA, DB9801, 1998

- risk of undetected theft;
- poor basis for knowing whether new or additional medical equipment is needed;
- poor priority setting in acquisition;
- risks arising from lack of records that medical equipment has been acceptance tested;
- less scope for flexible deployment of medical equipment;
- inefficient utilisation of medical equipment;
- difficulties in organising appropriate maintenance and repairs and monitoring its costs;
- difficulties in locating medical equipment; and
- safety risks, for example if medical equipment subject to a manufacturer's recall cannot be identified and traced.

A complete and up-to-date inventory or inventories of medical equipment is therefore essential for efficient and effective medical equipment management⁸.

A half of trusts have a single medical equipment inventory, while most others have several

2.11 About half of the NHS acute trusts surveyed had a single inventory of medical equipment. At the sites we visited the typical number of inventories was four. Trusts maintained different inventories for a variety of reasons, including a lack of confidence in the accuracy of the information held on the central asset register and because medical equipment was managed and maintained by different departments. Most commonly, separate inventories were held by specialist departments whose activities used a lot of medical equipment of a particular type such as intensive care units, special care baby units, pathology and

**An electronic medical
equipment inventory data
input screen**



Source: Hammersmith
Hospitals NHS Trust

radiology. However, at three trusts out of the ten we visited, each ward maintained its own inventory of medical equipment, which resulted in considerable duplication of effort as similar data was held on the trust's central inventory.

2.12 There was no arrangement, therefore, common to all trusts that had a medical equipment inventory or inventories. Where planned, there might be good reasons for having more than one inventory. For example in some trusts there might be benefits in an intensive care unit or pathology department maintaining their own inventory because of the specialist nature of the medical equipment they

use. However, an excessive number of inventories within a trust limits the potential to readily cross-link information from different sources, increases the risk of gaps or duplication in coverage, and is likely to encourage different approaches to medical equipment management. It also makes the consolidation of information for strategic overview problematic. In these circumstances, NHS trusts should be encouraged to look at the potential for modern information systems to link centralised and decentralised inventories.

**Incomplete inventories that are not up to date can
constrain the efficient management of medical equipment**

2.13 Most trusts have established criteria for including items on medical equipment inventories, such as minimum value or medical equipment type. Our survey showed that about 40 per cent of trusts excluded items from the medical equipment inventory if their value fell below a specified threshold. Although there is no guidance on appropriate thresholds one third of trusts that applied a value threshold used a figure of £5,000.

2.14 By excluding items such as those valued below £5,000, however, and in the absence of alternative systems to manage such equipment, the usefulness of an inventory as a tool to efficiently and effectively manage the utilisation, maintenance and repair of medical equipment is limited. We found from our visits to trusts that difficulties often arose when medical equipment that was not recorded on an inventory was loaned between wards or departments. In these

circumstances details of medical equipment movements were not monitored. Often, items could not be located, or were kept for long periods even though not needed by the holder, thereby incurring cost penalties. In establishing criteria for the inclusion of medical equipment on inventories, trusts should also take account of routine maintenance needs.

2.15 It is also important that inventories are up to date. At some trusts we visited, medical equipment was not entered onto the inventory if it had been funded by charitable donation, or if it had not been acceptance tested. In the absence of alternative recording systems, this can again give rise to inefficient usage and potential safety problems.

Improving the quality of inventory information

However, we found some examples of good practice used by trusts to ensure the quality of information (see Box 1). These included:

- ensuring that all medical equipment is acceptance tested and recorded in the inventory at this point;
- using planned preventative maintenance programmes to verify and update details of medical equipment held on the inventory;
- establishing protocols for visits by technicians to check and update ward inventories;
- frequent cross-checking of different inventories and information sources; and
- ensuring there are efficient processes to record data and analyse it through the use of computerisation.

Box 1 **Examples of good local practices in inventory management**

Central Sheffield University Hospitals NHS Trust have established a single computerised inventory for medical, laboratory and radiology equipment. This inventory is accessible to all directorates via the hospital network. A local medical equipment management website is being set up to assist directorates with medical equipment management and will provide links to the medical equipment inventory, the Medical Equipment Management Manual, the Medical Devices Agency and other sources of information to assist with medical equipment management at directorate level. The central database makes it easier to identify medical equipment that is not held on any maintenance contract and establishes a framework for contract monitoring and risk management, with audit trails of service history.

York Health Services NHS Trust order all medical equipment with their medical engineering department as the delivery address. This enables the department to maintain a comprehensive and accurate inventory irrespective of the source of funding. The department is responsible for the goods received process and payment is only authorised following satisfactory commissioning.

City Hospitals Sunderland NHS Trust has a procedure whereby all orders are processed through a central purchasing department. This information was used to ensure all medical equipment purchased goes through the trust's centralised medical equipment acceptance testing procedure, and is entered on the trust's single inventory (which also fulfills the purpose of an asset register). The information is then used to plan maintenance programmes.

Improving the strategic management of medical equipment

2.16 We found a number of examples of good practice regarding the organisation of responsibilities for medical equipment management, and in compiling and exploiting medical equipment inventories. However, some trusts need to do more. We consider that:

- the MDA guidance to trusts should be supplemented by the identification and dissemination of the good practice exercised by some trusts in the management of medical equipment;
- trusts need to consider whether the allocation of responsibility for medical equipment at board level is clear, and whether there should be a single point of responsibility for all relevant medical equipment issues across the trust. The minority of trusts that have no clear lead on medical equipment issues at board level should examine if this is appropriate given the size and importance of the assets they have in their charge;
- the third of trusts without a purchasing advisory committee should establish one as advocated in MDA guidelines, or take other appropriate steps to ensure that procurement is co-ordinated effectively across the trust;

- all trusts should review and, where appropriate, take action to update and complete their medical equipment inventories, where practicable using available information technology to facilitate consolidation into a single inventory; and

- trusts should consider the extent to which their inventories are being fully exploited by management as a source of information for drawing up medical equipment strategy, deciding priorities and making rational acquisition, maintenance and disposal decisions.

Part 3: Acquisition and use of medical equipment

Introduction

3.1 Trusts spent £120 million on new and £97 million on replacement medical equipment in 1996-97. Manager and clinician responsibilities for medical equipment include selection, acquisition and commissioning, maintenance and, ultimately, replacement. Work on NHS supplies management and purchasing has already been carried out by the National Audit Office⁹ and by the Audit Commission¹⁰. This report looks at trusts' arrangements for:

- planning the acquisition of medical equipment;
- selecting medical equipment;
- standardising medical equipment by type; and
- the provision and use of medical equipment.

Planning the acquisition of medical equipment

3.2 A properly planned approach to the purchase of medical equipment, taking into account the needs and preferences of professionals and end-users whilst retaining consistency and control, is needed if value for money is to be obtained^{11 12}. We consider that all trusts should have planning systems in place for the purchase of medical equipment. Benefits include:

- a co-ordinated trust wide approach to medical equipment issues;
- better communication between all parties involved in the acquisition and use of medical equipment;

9 National Audit Office, National Health Service Supplies in England, HC 457, Session 1995-96, June 1996

10 Audit Commission, Goods for Your Health - Improving Supplies Management in NHS Trusts, November 1996

11 MDA, DB9801, 1998

12 Her Majesty's Treasury, Appraisal and evaluation in central government 1997 and NHS Executive, Capital Investment Manual 1994

- costed programmes for medical equipment acquisition, maintenance and replacement;
- a consistent approach to acceptance testing and user training; and
- potential for greater standardisation of types of medical equipment.

We found some weaknesses in business planning arrangements at some trusts we visited

3.3 Five of the trusts we visited had no documented procedures for purchasing all medical equipment. Three of the trusts that did have documented systems in place were able to assess the need to acquire and replace medical equipment, by analysing demand and usage information from medical equipment inventories and other sources of information, including records kept in a medical equipment library.

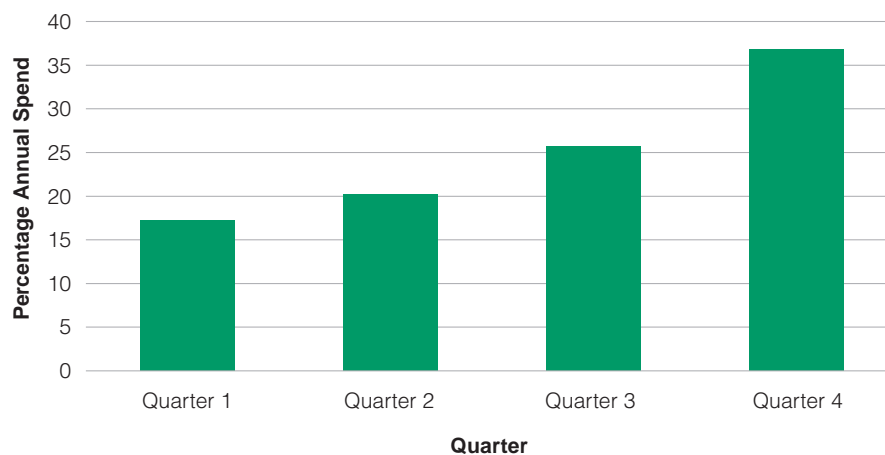
Nearly 40 per cent of medical equipment purchases are made in the last quarter of the financial year

3.4 MDA guidance pre 1998 states that trusts “should avoid the hurried or unstructured purchase of medical equipment at the end of a financial year since this often precludes rational selection”¹³. Our survey showed that 38 per cent of expenditure on purchasing medical equipment in 1996-97 occurred in the final quarter of the year (Figure 3). A similar pattern featured in 1997-98. Medical equipment suppliers considered that this pattern had persisted for some years, and they had seen no change since 1996-97. The pattern represents the average expenditure by trusts across the year. About a fifth of the trusts surveyed had spent half of their annual budget in the final quarter of 1996-97 and two trusts that made all their purchases in this quarter.

Average Percentage Quarterly Spend on Medical Equipment in NHS Acute Trusts 1996/97, England

Figure 3

Figure 3 shows that 38 per cent of expenditure on medical equipment occurred in the final quarter.



Source: National Audit Office Survey

3.5 There are risks to value for money where the pattern of expenditure has not been planned. For example, in one trust that required the production of business cases, often the procedure was not followed towards the end of the financial year, because there was insufficient time to draw up a business case if expenditure was to be made from that year’s budget. Some trusts visited told us that it was often a lack of certainty over funding that resulted in the purchase of medical equipment being delayed until late in the financial year. In our view this increases the risk of hurried purchases at the end of the year to use up available budgets, and a failure to maximise value for money.

3.6 The NHS Executive told us, however, that this pattern of expenditure was consistent with prudent financial management. For example, cautious purchasing early in the financial year would allow for later uncertainties such as a failure of critical equipment that was found to be uneconomic to repair. It also increased the opportunity for trusts to take advantage of supplier discounts that become available at the end of the financial year.

Business cases were widely used but of variable quality

3.7 A business case sets out for approval at the appropriate level the basis for a decision on the acquisition of medical equipment. It must convincingly demonstrate that an acquisition best meets the identified needs of users or patients, is economically sound and affordable. Business cases are particularly important for more expensive items of medical equipment, such as magnetic

resonance imaging scanners. These have a strategic function, require a substantial capital investment and have significant ongoing revenue expenditure implications. The length, and the level of detail of the analysis contained in, business cases should be commensurate with the size of the proposed investment.

3.8 Nine out of the 10 trusts visited produced business cases to justify the acquisition of medical equipment. Four trusts applied these procedures only to medical equipment costing over £5,000. In these circumstances lower cost items, such as infusion pumps, were purchased on a less formal basis. Nevertheless in total smaller value items may comprise a substantial amount in terms of initial capital outlay and subsequent running costs. Therefore, although business cases may not be appropriate for individual lower value items, their acquisition needs to be properly planned and co-ordinated, for example to take advantage of bulk discounts. One trust had no business case procedures in place.

3.9 In one trust business cases, for all medical equipment acquisitions irrespective of value, contained few details and were only two pages in length. Another trust had no guidance on the value and type of medical equipment that required the production of a business case.

3.10 We examined a sample of 15 business cases developed since 1994 for the acquisition by trusts of magnetic resonance imaging (MRI) services, including the purchase of MRI scanners. The acquisition of MRI scanners, which can cost more than £1 million to buy and install, and incur substantial maintenance and running

An MRI Scanner in use



Source: Hammersmith
Hospitals NHS Trust

costs, should be governed by principles set out in the NHS Capital Investment Manual¹⁴. These include a step by step guide on the preparation and content of business cases. Our examination, however, showed a considerable variation in the quality of business cases and significant departures from the guidelines set out in the NHS Capital Investment Manual. Common failings we identified included:-

- insufficient or inadequate estimates of the volume or nature of clinical demand;
- poorly defined objectives and an inadequate technical specification of the requirement;
- inadequate appraisal of funding options;
- failure to adequately assess revenue and income streams.

Few of the trusts we visited evaluated full lifetime costs before the acquisition of medical equipment

3.11 The initial purchase price of medical equipment is only part of the total cost of medical equipment ownership. Other costs over the lifetime of medical equipment include maintenance, training and operating costs. Full cost, or life cycle costing, is therefore an important aspect of medical equipment selection and acquisition^{15 16}, but only three trusts out of the 10 visited used the life cycle approach to evaluate the cost implications of medical equipment purchase. As an example of the size of savings that are possible, the Royal United Hospital Bath NHS Trust told us that life cycle costing had led to a change in infusion pumps across their site, with a saving on consumables of £35,000 a year.

14 NHS Executive, Capital Investment Manual 1994

15 MDA, HEI98, 1991; DB9801, 1998

16 HM Treasury guidance note on life cycle costing, 1992

✓ **There is best practice that can be adopted more widely to improve acquisition decisions**

3.12 We did however find good practice in business planning and preparing business cases at some of the trusts visited and through our survey of trusts. Examples included:

- precise definition of user need, and the identification of a range of suitable medical equipment rather than one make or model;
- use of standard business case forms to ensure consistency;
- use of life cycle costing;
- risk management strategies included in business cases where appropriate;
- full and clear analyses of different options to meet user needs for medical equipment;
- production of a best buy guide by the medical engineering department.

Some suppliers of medical equipment consider that different purchasing procedures used by different NHS bodies lead to increased prices

3.13 We interviewed twelve medical equipment suppliers, who together cover a substantial portion of the market for medical equipment, to gather their views on the way the NHS purchases five items of medical equipment that are in common use (Appendix 3). Half the suppliers expressed concern about NHS purchasing procedures. They stated that they had to deal with a wide range of different procurement procedures whilst selling identical medical equipment to different trusts. They said also that compared to their other customers there was sometimes insufficient continuity in terms of contacts at trusts and they often needed to contact several individuals to discuss the supply of a single piece of medical equipment. The suppliers considered that these factors increased their cost of submitting tenders and therefore resulted in a higher price charged to NHS customers.

There is scope for technical personnel to be involved more in purchasing

3.14 Our survey showed that 45 per cent of trust technical supervisors did not have procurement as one of their main responsibilities. However, we found a number of examples of good management practice where the expertise of medical engineering departments had improved the process of buying of medical equipment and related services. An example that produced significant cost savings is given in Box 2. Technical advice in procurement is important to provide an assessment, independent of clinical users, of the need for, and effectiveness of, the technology being proposed. Trusts told us that other benefits included:

- improved processes for medical equipment procurement;
- fuller assessment of which medical equipment best meets user needs; and
- wider use of whole life costs in decision making.

Box 2 How involvement of medical equipment engineering departments in purchasing can produce significant cost savings and other benefits

At the Oxford Radcliffe Hospital NHS Trust the Medical Equipment Engineering Department provides services and co-ordinates purchasing for several trusts. This Department places orders directly with suppliers. Requests for medical equipment from a single supplier from different trusts are amalgamated on one order. Discounts are negotiated on the value of the order as well as the number of items ordered over a period of time. This has resulted in combined orders for items such as patient monitoring, infusion devices and anaesthetic equipment, with financial savings of approximately £500,000 from expenditure of about £3.8 million.

The involvement of the Medical Equipment Engineering Department has enabled the development of a detailed knowledge of items of inventory, complete with their costs. It has also led to better informed medical equipment selection, the assurance that medical equipment is purchased with appropriate accessories and that future maintenance and running costs are identified. Additionally it has facilitated the standardisation of medical equipment by make and model, so that repairs and staff training are easier.

Selecting medical equipment

3.15 Technical considerations are particularly important in the selection of medical equipment, which has to meet patients' and clinicians' needs in a reliable and safe manner. The main source of technical information about new medical equipment is suppliers, and we found that all trusts made use of suppliers' technical information. Such information on its own, however, is not generally sufficient to determine the right choice of medical equipment, as an individual

supplier has an interest in presenting information in a way designed to encourage a purchase. It is therefore important that trusts make use of a wider range of advice.

3.16 The MDA also provide advice on choosing the most suitable medical equipment.¹⁷ Our survey showed that more than 92 per cent of trusts were using MDA evaluations to gather information about competing products. These evaluations provide information about particular products or groups of products, and some include descriptions of the market for products and the individual products available, who supplies them and their specific purpose. In 1997/98 the MDA published 118 evaluation reports for the NHS¹⁸.

3.17 Three quarters of trusts also made use of information from NHS Supplies about products, terms of service, spares and support service available from suppliers and on compliance with safety standards. NHS Supplies work with some trusts to negotiate deals with suppliers at advantageous prices. In June 1997 NHS Supplies, in collaboration with the NHS Confederation, produced a boardroom briefing document that contained practical advice to trusts on the purchase of medical equipment and the issues that a trust should consider regarding the future management of the equipment and post-purchase requirements.

3.18 NHS Supplies have also produced a pre-purchase questionnaire, which can be used by trusts directly or as a model to develop their own questionnaire. Nine of the ten trusts visited used a pre-purchase questionnaire that had a set of standard questions about each item of medical equipment being considered for purchase. The questionnaire was used to check on compliance of equipment with safety standards, the supplier's support for maintenance and spare parts. Trusts visited found the use of a questionnaire to be a thorough means to gather comparable information on different items and models of medical equipment.

17 MDA, DB9801, 1998

18 MDA 1997/98 Annual Report

Medical equipment standardisation

There is scope for much wider implementation of MDA guidance on standardising makes and models of medical equipment

3.19 MDA guidance recommends consideration of standardisation of medical equipment as a means to reduce costs of service, spares and training. Although there are risks from relying on too few suppliers of medical equipment, “considerable savings and benefits result if a single product model is used for a given application throughout the organisation”¹⁹. Safety is also enhanced because user errors resulting from confusion between similar devices are reduced. In addition, medical equipment standardisation gives greater flexibility in the clinical setting, allowing patients to be transferred between medical departments if necessary, facilitated by the availability of the same medical equipment in different locations.

3.20 Our survey showed however that only 12 per cent of trusts had a documented policy on standardisation of medical equipment. Furthermore, for the 70 per cent of trusts that had purchasing advisory committees, only a half of them had responsibility for the formulation of policy on medical equipment standardisation.

We found considerable variation in the extent to which similar medical equipment had been standardised

3.21 Our survey asked trusts how many makes and models they held of five items of medical equipment that were in common use and where at least some degree of standardisation is possible: infusion devices, endoscopes, defibrillators, anaesthetic machines and neonatal incubators. The analysis shows a wide variation between trusts in the diversity of medical equipment held (Figure 4).

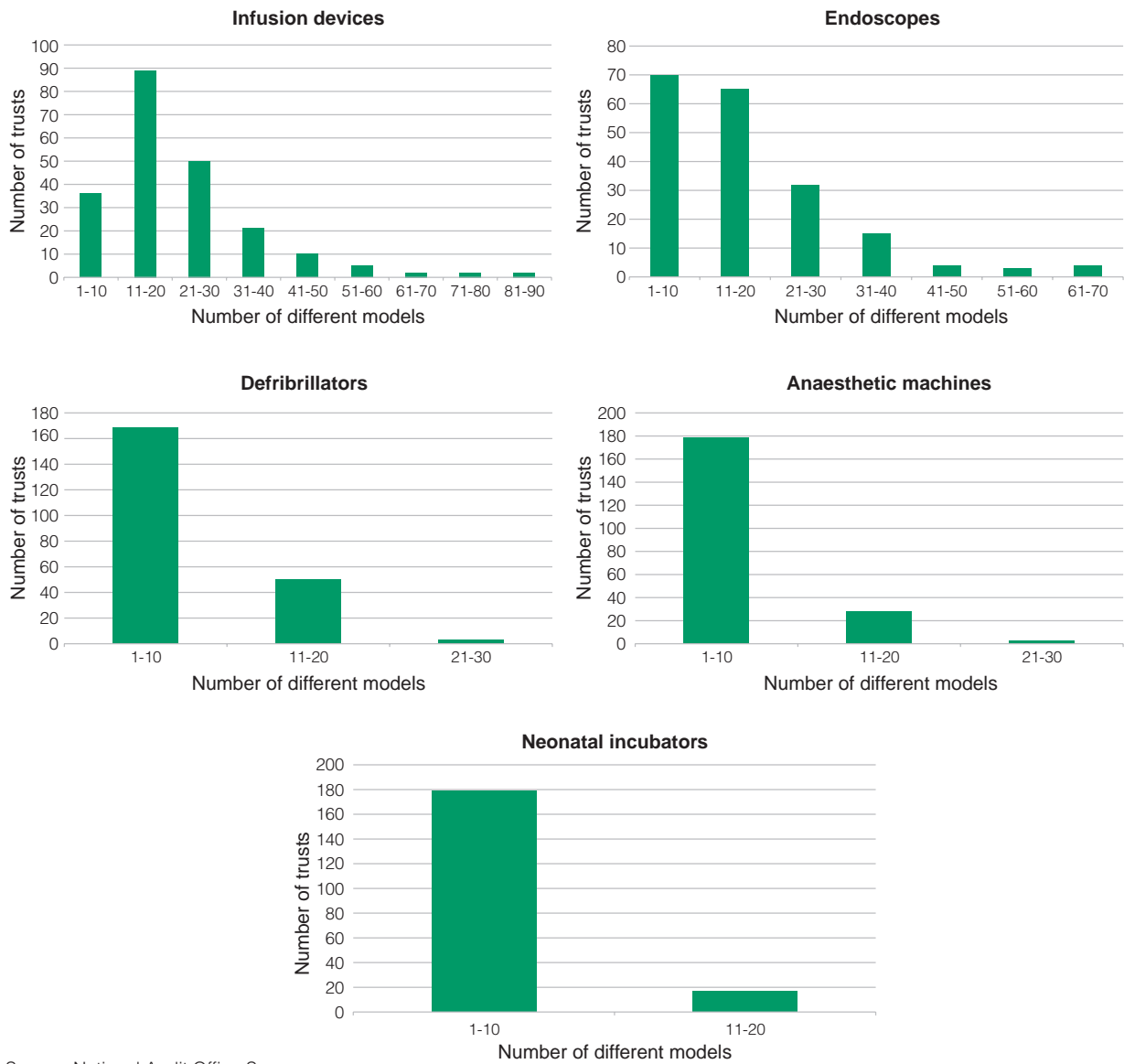
3.22 The variation reflects, in part, the volume of each item held and the number of makes and models of different items of medical equipment available on the market. The number of makes and models in use is also likely to increase as new, improved models are introduced to the market. Further, clinical requirements will dictate that a minimum number of makes and models are needed in hospitals. For example, a trust providing a full range of services might be expected to have at

19 MDA, DB9801 ,1998

least six different models of infusion pump available, and many models of endoscope. Nevertheless, this wide range is of significance from both the point of view of cost efficiency and safety, and suggests considerable scope for standardisation.

Figure 4

Diversity of common items of medical equipment held by trusts



Source: National Audit Office Survey

We did, however, find some good practice on medical equipment standardisation

3.23 We found a number of trusts that had developed good practice approaches to standardisation which could be adopted more widely (Box 3).

Box 3 Increasing medical equipment standardisation in trusts

Poole Hospital NHS Trust has established a trust-wide Product Selection Group that has as one of its remits the selection and standardisation of clinical equipment. The Group, which has expertise from clinical users, medical engineering, finance and purchasing, has developed a standard list of clinical equipment for departments to use when purchasing equipment. Only products approved by the Group may be purchased and only in exceptional circumstances may an alternative product be ordered – providing it is authorised by the Chief Executive or a member of the Executive team.

Doncaster Royal Infirmary and Montagu Hospitals NHS Trust introduced standardisation and rationalisation of commonly used medical equipment including infusion pumps. This involved standardising on the basis of medical equipment already in use, to take advantage of existing user knowledge and maintenance experience. A Best Buy guide has been developed, and is revised every 6 months. If medical equipment contained in the Guide is not the preferred option, the reasons and a detailed specification of the medical equipment preferred are required prior to a decision to purchase. The Best Buy guide is based on full life costings, taking into account initial capital price, training, maintenance, warranty period and consumable costs.

Provision and use of medical equipment

Variations in medical equipment provision across acute trusts

3.24 Trusts need to have available sufficient medical equipment to support the efficient and effective delivery of patient care. Excessive provision is wasteful, while under-provision threatens the effective treatment of patients. We examined the provision of medical equipment, including both owned and leased equipment, in terms of its replacement cost value. In benchmarking across trusts it is necessary first to make allowance for differences in size, for example by adjusting the value of medical equipment to take account of trust income²⁰. In addition, the activity and casemix of a trust will have an influence on the type of medical equipment held, for example in a teaching hospital compared to a general hospital.

3.25 Figures 5 to 7 show the range in provision of all medical equipment in relation to trust income for three categories of trust: teaching, acute (non teaching) and other²¹. These figures show that there remains a considerable variation in the

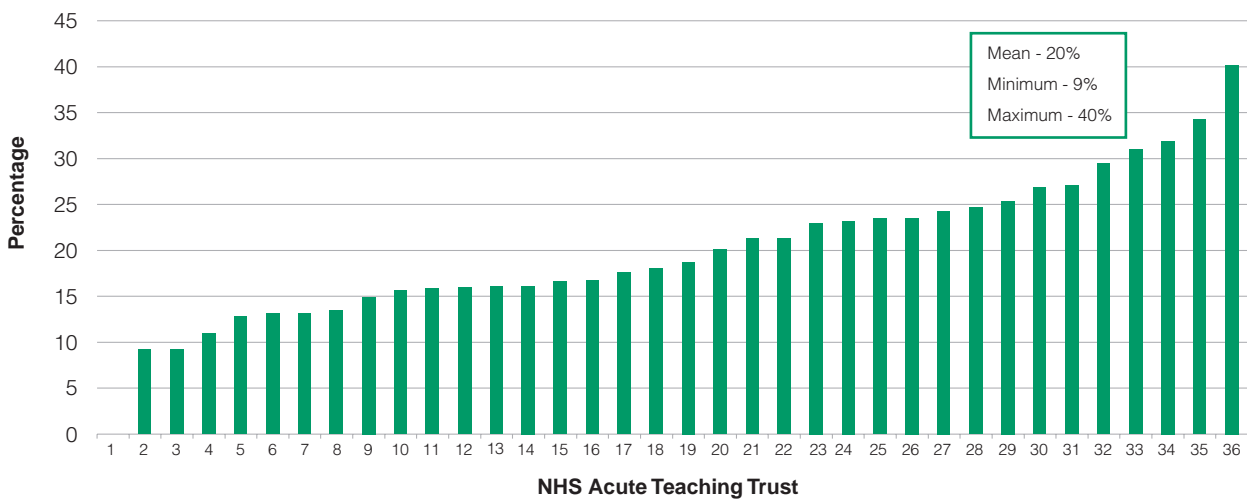
20 We also considered other measures of size, including number of beds. A correlation analysis showed that trust income provides a better explanation of the level of provision of medical equipment.

21 Other hospitals include combined trusts which provide acute and other services such as community health services

value of medical equipment held by trusts after allowing for income and trust type, although part of the variation, particularly at the top end of the distribution, might reflect the nature of the work undertaken at some trusts (such as those that are specialist referral centres).

Figure 5

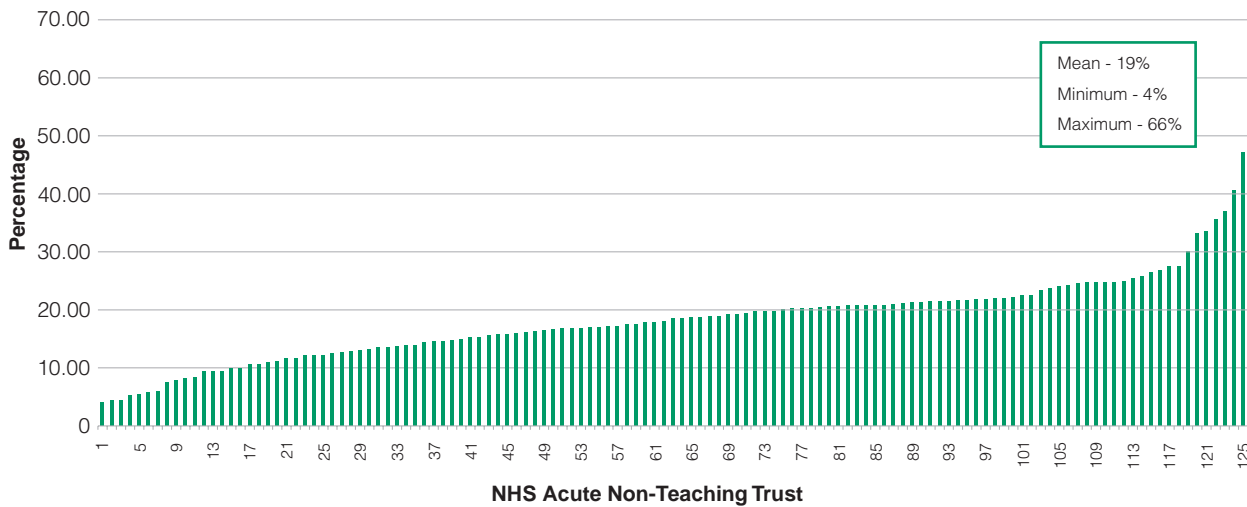
Medical Equipment Replacement Cost as Percentage of Trust Income for English NHS Acute Teaching Trusts 1996/97



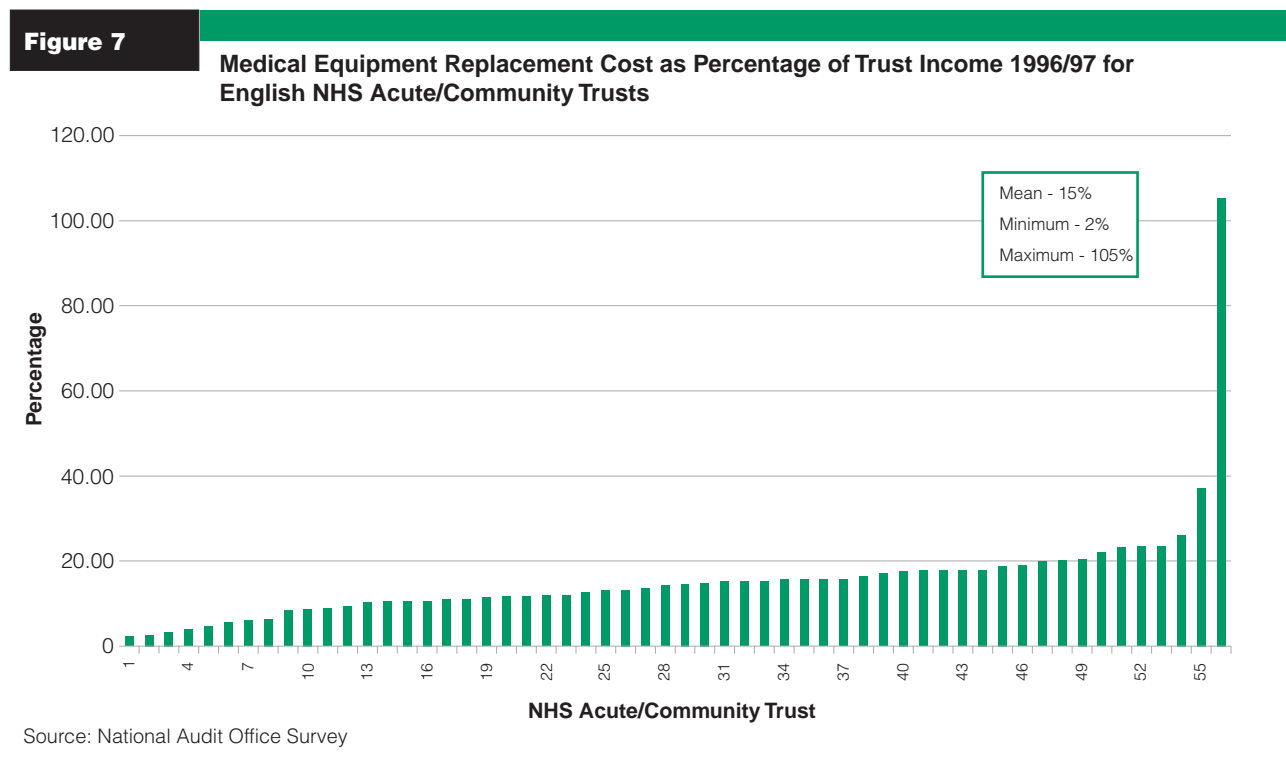
Source: National Audit Office Survey

Figure 6

Medical Equipment Replacement Cost as Percentage of Trust Income for English NHS Acute Non-Teaching Trusts 1996/97



Source: National Audit Office Survey



Accounting for variation in the provision of medical equipment

3.26 Our detailed discussions with trusts, together with suggestions made to us by our benchmarking club of NHS trust medical engineers, indicate that a wide variety of factors need to be taken into account to make meaningful comparisons of levels of provision across trusts. These factors fall into a number of groups (Appendix 2).

- size and throughput of trust;
- type of trust, in particular whether a trust has a teaching role;
- the mix of patients treated – casemix;
- activity of trusts in terms of procedures carried out, which affect the type of medical equipment needed and its value;
- medical equipment availability, for example the use of medical equipment libraries that allow more intensive use of medical equipment stock; and

- quality of management information about medical equipment, which can influence understanding of what medical equipment is already available within a trust.

We could explain three quarters of the variations in the value of medical equipment held by trusts

3.27 Using the statistical analysis detailed in Appendix 2, we found that a number of the factors were associated with value of medical equipment, although factors related to trust size were predominant. For example, teaching hospitals have on average more medical equipment than acute (non-teaching) hospitals, but teaching hospitals tend to be larger hospitals.

3.28 By itself, trust income explains just over 70 per cent of the variation in provision of medical equipment. Other factors increase this level of explanation slightly. The proportion of trust income spent on research, the number of day and ordinary cases handled in a trust, and the number of transfers into a trust - a measure reflecting the complexity of cases - increased the overall level of explanation of variation in trusts' medical equipment levels to 74 per cent. This indicates that there are substantial variations in medical equipment holdings, just over a quarter in total, which cannot be readily explained.

The unexplained variation in provision of medical equipment should be investigated further

3.29 It is important to bear in mind that there are trust specific factors which our statistical analysis cannot capture. For example, a number of trusts provide highly specialised treatment, and our data for case mix cannot take this fully into account. Nevertheless, the extent of unexplained variation is significant.

3.30 For some trusts the replacement cost value of their medical equipment inventory was less than expected, by an amount across these trusts equivalent to £400 million or 14% of the total replacement cost value of medical equipment, based on the total medical equipment inventory of £2.8 billion in 1996-97. This may reflect high efficiency in the use of medical equipment, though it might be a reflection of under-investment compared to other trusts with similar characteristics.

3.31 The same figure of £400 million applies in total to trusts that had more medical equipment than predicted. The NHS Executive pointed out to us that this may not reflect over-provision, either because of the factors we could not allow for

in our statistical analysis, or because some of the equipment may be heavily depreciated. Such equipment could be kept as stand-by, and measurement of its replacement rather than actual value may inflate its financial significance.

3.32 We stress that our statistical benchmarking, even though it has taken account of a wide range of influences, should not be used as the basis for estimates of possible savings in trusts with apparent over-provision, or as a direct measure of efficiency or under-investment in those with less than expected provision of medical equipment. But since a significant fraction of medical equipment holdings by NHS acute trusts in England cannot be readily explained, it is important that further work is carried out to establish the true position at each trust.

Medical equipment libraries offer the potential for more efficient utilisation of medical equipment

3.33 Although some staff use specialist medical equipment, many items are common between departments. One possible way to utilise medical equipment more efficiently is through a medical equipment library. A medical equipment library is an area where medical equipment is stored and staff from different departments can share in its use. Typical items of medical equipment suitable for holding in a library include infusion pumps, nebulisers and other portable devices. Medical equipment libraries have features such as dedicated library staff, control over the issue and receipt of items, and carry out activities such as cleaning, recharging and other maintenance work.

3.34 Our survey showed that 51 trusts (22 per cent) had a medical library. Trusts with libraries told us that the establishment of a library had led to benefits such as:

- reductions in rental costs;
- helping to standardise medical equipment and optimise its use;
- improving access to medical equipment for maintenance;
- providing safe storage, and thereby reducing breakages;
- ensuring that medical equipment is complete with accessories; and
- facilitating training in the use of medical equipment as it is loaned out.

3.35 Box 4 illustrates how a medical equipment library can be organised. A number of trusts told us that libraries can achieve significant savings, for example by holding pressure relieving devices that would otherwise have to be rented at greater cost. The benefits here are likely to extend beyond acute hospitals into community trusts.

✓ **Box 4**

Establishing a medical equipment library

Oxford Radcliffe Hospital

The hospital has a medical equipment library used by 18 general wards. There are 460 items in the library including infusion devices, ECG monitors, pulse oximeters and nebulisers. A nurse practitioner manages the library supported by a clerk. The hospital porters provide a key to allow access out of normal office hours. The clerk of the library:

- issues and records medical equipment used;
- follows up medical equipment to ensure it is returned; and
- checks the condition and function of returned medical equipment.

The information gathered includes the frequency that items are used and which departments use them. This data is used to evaluate the need for additional items of medical equipment and to plan for staff training.

Benefits have included:

- saving in nursing time looking for medical equipment (estimated financial savings of over £4,000 each year); and
- more efficient use of medical equipment.

Oxfordshire Community Health NHS Trust

A similar system has been organised for the Oxfordshire Community Health NHS Trust involving over 1,200 items of pressure relieving equipment. A comparison of the cost of this arrangement with the cost of rental from commercial organisations has shown an annual saving of over £900,000.

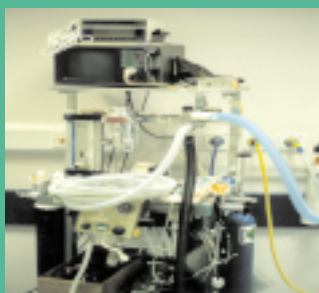
More cost effective purchase and use of medical equipment

3.36 Some trusts have adopted MDA recommendations regarding the purchase of medical equipment and, in relation to their size and activity, some trusts may be efficient in their use of the medical equipment they hold. There is, however, considerable scope to achieve greater cost effectiveness on the basis of our findings and the best practice we observed. Measures that need to be taken include:

- trusts need to review, and if necessary implement improved, business planning for the purchase of medical equipment;



A new-born baby in intensive care in a neo-natal incubator attached to a heart monitor.
Source: Royal Brompton Hospital and Harefield NHS Trust.



An anaesthetic machine with cardiac monitoring equipment.
Source: Hammersmith Hospitals NHS Trust.



Clinician holding an endoscope used for internal investigation.
Source: Hammersmith Hospitals NHS Trust.



A defibrillator used to correct life-threatening heart rhythm and rate problems on a cardiac arrest trolley.
Source: Hammersmith Hospitals NHS Trust.

- trusts need to review their procurement procedures, taking account of the outcome of the 1998 Cabinet Office review of NHS procurement, and there is a clear role for the NHS Executive to take the lead in identifying and disseminating best practice;
- cost effectiveness and financial savings are possible by involving technical personnel more in the purchasing process, and trusts should take steps to do this;
- trusts should examine whether the pattern of expenditure over the financial year in procuring medical equipment is conducive to good value for money;
- trusts should introduce a medical equipment standardisation policy, if they do not have one, to help achieve improved medical equipment safety and financial savings;
- trusts should benchmark their holdings of medical equipment against those of similar trusts, to examine and understand how cost effective their holdings are and to identify good practice. Whilst we recognise that there will be specific factors applicable to individual trusts that will explain some of the variations in medical equipment holdings, techniques such as benchmarking could have considerable potential for validating the reasons for variations, including whether some potentially significant financial savings could be made; and
- trusts, particularly larger trusts, that do not have a medical equipment library should consider the benefits and costs of establishing one.

Some common items of medical equipment referred to in this report

Part 4: Medical equipment maintenance

Introduction

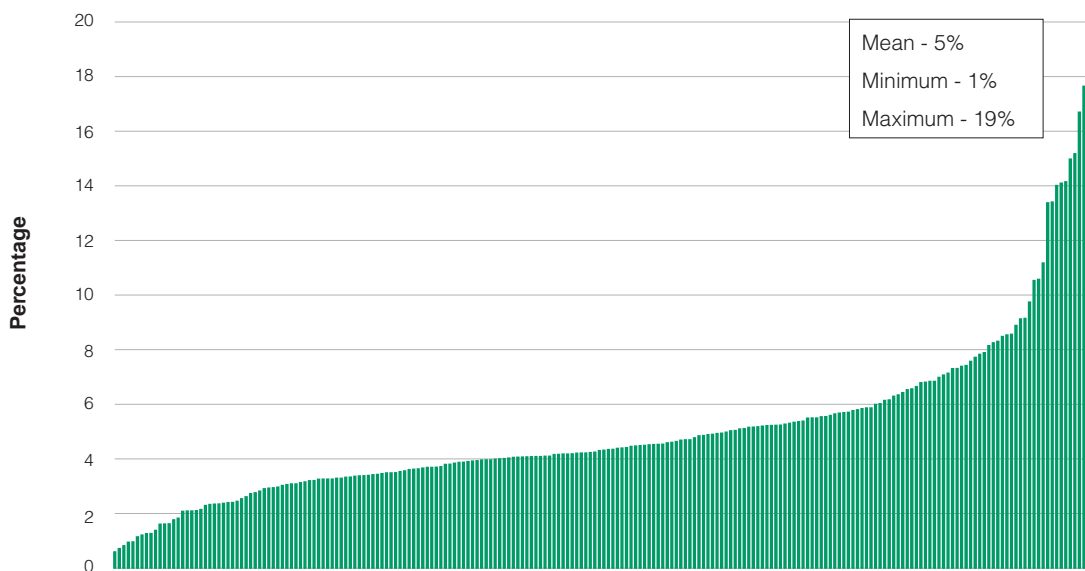
4.1 Effective maintenance is essential if medical equipment is to function as intended and to prevent breakdowns that could limit availability of care or be harmful to patients. We therefore considered how trusts obtain maintenance services, and the associated costs and value for money.

Trusts spend over £120 million a year on maintenance of medical equipment

4.2 Our survey of NHS trusts shows that spending on maintenance totalled £124 million in 1996-97. This is equivalent to about five per cent of the replacement value of medical equipment, although this proportion varies widely between trusts (Figure 8).

Figure 8

Maintenance expenditure by trust as a percentage of medical equipment replacement value



Source: National Audit Office Survey

Medical equipment maintenance is carried out in a variety of ways

4.3 The arrangements for maintaining medical equipment vary between NHS trusts. Generally an individual trust uses both external contractors and in-house maintenance departments. No standard name exists for in-house maintenance departments, but their functions are similar with regard to the management of maintenance of medical equipment, and in this report they are generically referred to as “Medical Engineering Departments”.

4.4 Nearly all trusts make some use of external contractors. These provide services covering planned maintenance, repairs and the replacement of parts, often for an inclusive price. The main types of external contractor are:

- another NHS organisation, such as a neighbouring trust;
- the supplier of the medical equipment; and
- a third party maintainer that did not supply the medical equipment but offers a specialist maintenance service.

An alternative is for maintenance to be provided on the basis of an insurance contract, though, in contrast to the USA where such an approach has been in use for more than a decade, its use in the UK is relatively recent.

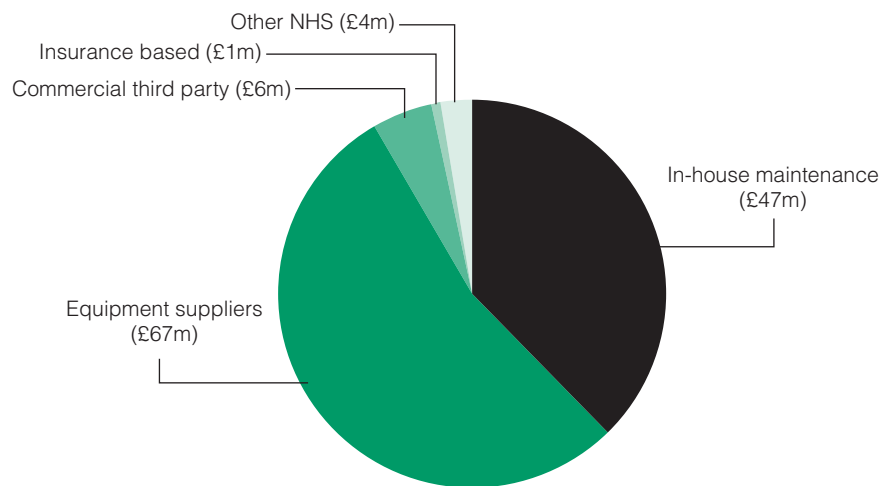
The majority of maintenance spending is on external provision

4.5 At the trusts visited there was diversity in the sources of maintenance used. Some trusts had a policy to increase the use of what was seen as a good performing internal department. At other trusts more maintenance was carried out externally because of shortages of medical engineering staff. However, we were told that, generally, maintenance was carried out externally where medical equipment was complex, required frequent maintenance, or parts were difficult to acquire or expensive to carry as stock. Figure 9 shows expenditure by the trusts surveyed on the different sources of maintenance in 1996-97. This overall pattern was repeated in 1997-98.

Maintenance spending by type of provision

Figure 9

Figure 9 shows that medical equipment suppliers and in-house medical engineering departments accounted for over 90 per cent of £124 million a year expenditure on maintenance in 1996-97.



Source: National Audit Office Survey

Almost all trusts use some form of planned preventative maintenance

4.6 Planned preventative maintenance is a process whereby checks, adjustments and replacements are made to medical equipment on a planned basis before breakdown occurs. MDA guidance states that regular inspections and routine servicing should be carried out on a planned and controlled basis, taking into account manufacturers’ recommendations.²² Our survey showed that nearly all trusts adopted some form of planned preventative maintenance. The eight trusts that did not relied only on breakdown cover. In view of the MDA’s guidance we consider that all trusts should adopt planned preventative maintenance, as a means of maximising medical equipment availability and safety.

There may be scope to increase standardisation of planned preventative maintenance schedules between trusts

4.7 Half of the trusts surveyed carried out planned preventative maintenance on the basis of schedules determined by the trust; a third followed schedules recommended by medical equipment suppliers; and 13per cent of trusts used a mixture of their own and medical equipment suppliers' schedules. Box 5 illustrates some examples of good practice. The considerable experience within the NHS of the most commonly used items of medical equipment should allow a more consistent approach between trusts to planned preventative maintenance scheduling, through sharing information and good practice. This could lead to reduced costs without compromising safety, if maintenance in some trusts was carried out less frequently, although trusts need to take account of their increased exposure to liabilities should they vary maintenance schedules from those recommended by manufacturers.

✓ Box 5

Examples of good practice in NHS trusts setting maintenance schedules for medical equipment

✓ The **United Bristol Healthcare Trust** the medical equipment department follows the manufacturer's recommendations for the planned preventative maintenance of anaesthetic equipment, and for other items determines the planned preventative maintenance intervals based on a risk assessment. This selective and considered approach is estimated to have reduced maintenance costs for the radiology department alone by £18,000 a year.

✓ At **Pinderfields Hospital** the medical engineering department provides advice to departments and wards on the maintenance requirements of medical equipment. Maintenance schedules are determined on the basis of assessed risk and in-house experience. For some medical equipment this means longer intervals between maintenance than those recommended by suppliers. However, for some critical medical equipment maintenance is more frequent, in some cases after each use by a patient.

The balance between in-house and external maintenance needs to be carefully considered

4.8 Each trust should consider carefully the relative advantages and disadvantages of in-house maintenance, compared with maintenance that is carried out by external organisations, in line with MDA guidance²³ and taking account of any possible safety implications. Although there can be advantages from contracting with external suppliers of maintenance (such as predictable costs, assured access to spares), we found that some trusts had saved costs by

23 MDA DB9801, 1998

bringing the maintenance of some items of medical equipment in house, rather than relying solely on manufacturers or other external maintainers of medical equipment. Other trusts told us they had established arrangements to share the responsibility for maintenance with medical equipment suppliers. These often involved the trust providing front-line maintenance, while the supplier attended major failures that in-house staff were unable to handle. Trusts told us that the result was often a significant reduction in the costs of maintenance contracts, although the impact on internal maintenance costs was unclear, as well as improvements in the overall maintenance

✓ **Box 6** **Examples of good practice in sharing the maintenance of medical equipment between NHS hospitals and equipment suppliers**

✓ The **Freeman Group of Hospitals Trust** reached an agreement with one of its manufacturers to train two of its in-house staff. These staff provide first line maintenance for the Trust's radiology equipment. They are also involved in carrying out planned preventative maintenance jointly with the manufacturer. This resulted in the manufacturer reducing the annual cost of maintaining their equipment by 18 per cent, an annual saving of £39,200.

✓ The **University Hospital, Birmingham** annually negotiates shared arrangements with manufacturers. The Trust has found that this provides benefits such as quicker response times and improved maintenance of equipment through on-the-job training provided to in-house staff. The shared arrangements enabled the Trust to reduce maintenance contract costs from £203,143 to £108,109, realising annual savings of some £95,000.

✓ **Poole Hospital NHS Trust** has established co-operative contracts and "parts only" contracts with major equipment suppliers with maintenance responsibility split between the "in-house" department and the manufacturer, yielding a more effective support arrangement than could be achieved by either party alone. The main relationship involves the trust in providing first line and planned preventative maintenance support, with parts access for quickly resolvable faults and service engineer attendance for major failures. Co-operative contracts have realised the following benefits:

- downtime reductions of 15 per cent
- savings of 30 per cent on the costs of support contracts
- one phone call only needed for support/parts requests
- one order number only covering the contract
- priority access to supplier support organisation
- additional savings in the contract due to improved reliability
- no parts inventory kept due to same day despatch

"Parts only" contracts with equipment suppliers realise improvements in response to failure, minimise parts stockholding costs and yield typical financial savings of 10 per cent on the costs of parts. They are based on the previous year's parts usage and any adjustments in the year are reflected in the next year's contract. Other benefits include:

- one order number for the year (monthly invoice for fixed amounts)
 - known expenditure irrespective of activity
 - one phone call for same day parts despatch
 - reduction in internal paperwork of approximately 25 per cent
 - reductions in inventory and associated costs of approximately 25 per cent
 - improved relations with supplier who is more aware of needs and associated problems
-

Cost savings may be possible from better management of external maintenance contracts

4.9 Respondents to our survey provided examples of how they had been able to improve the management of external maintenance, often with cost savings (Box 7). Local good practice included:

- keeping computerised record systems of service maintenance schedules and maintenance carried out. This allowed better monitoring of the value of external contracts on the basis of work actually carried out;
- bringing maintenance contracts together to improve monitoring and to realise scale economies. A number of trusts told us this led to savings ranging from five per cent to 20 per cent of external maintenance costs;
- annual review of maintenance contracts. For example, one trust told us it had terminated a maintenance contract following review, saving over £25,000 a year;
- careful assessment of the need for fully comprehensive maintenance contracts.

✓ **Box 7** **Examples of good practice in management of external maintenance contracts by NHS hospitals**

✓ **The Oxford Radcliffe Hospitals NHS Trust** Medical Engineering Department co-ordinates external maintenance contracts for all the Oxfordshire Trusts. This enables the rationalisation of contracts and contractors and the sharing of information on quality of service, cost of parts, etc. This process has led to significant financial savings. For example, in the maintenance of radiology equipment there has been a saving of approximately £42,000 annually out of a total radiology equipment budget of £325,000.

✓ At the **Freeman Hospitals Trust** the number of all inclusive comprehensive maintenance contracts has been reduced to a minimum. This has been achieved through investing in the training of in-house technical staff, and has resulted in the amount spent on external maintenance contracts being reduced by £87,000, from £544,000 in 1993/94 to £457,000 in 1997/98. Over the same three year period the amount spent on internal maintenance has increased by £29,500. Further benefits of developing the in-house department include quicker response times, reduced downtimes and a reduction in costs incurred through external maintenance contract administration.

Reasons for variations across trusts in maintenance costs

4.10 Maintenance costs vary considerably in relation to the value of medical equipment held (Figure 8). According to trusts, influences on maintenance costs fall into a number of groups:

- size and throughput of trust;
- type of trust, in particular whether a trust has a teaching role;
- mix of patients treated, which requires different types of medical equipment with implications for maintenance costs;
- activity of trusts in terms of procedures carried out, which affect the type of medical equipment needed and its value;
- the extent to which standardisation has allowed a reduction in the number of makes and models of medical equipment, and thereby economies in maintenance;
- policies on medical equipment availability and use, which allow more intensive use of medical equipment stock;
- the quality of management information about medical equipment;
- the presence of items of medical equipment that are expensive to maintain, such as diagnostic imaging equipment;
- average age of medical equipment.

Maintenance costs are strongly associated with trust size, and this explains about three quarters of maintenance cost variations

4.11 We found a strong relationship between maintenance costs and trust size (Appendix 2). Trust income accounted for just over two thirds of the variation in total maintenance expenditure by trusts. The best measure of size was trust annual revenue income. The number of beds was a poorer measure, accounting by

itself for only about 38 per cent of the maintenance cost variation. Trust income and the amount of equipment held by a trust, another size indicator, explain three quarters of maintenance cost variations.

There are other factors that explain some of the variation in maintenance costs

4.12 We undertook a statistical analysis of the causes of maintenance costs that were not related to trust size (Appendix 2). The analysis allowed for the combined effect of factors likely to be important in determining trust maintenance costs.

4.13 We found, as expected, that a trust's maintenance costs are increased where it provides a maintenance service for another trust, and this needs to be allowed for when examining cost variations. Within a trust, maintenance costs are reduced slightly by greater use of in-house maintenance after standardising for other factors. This is consistent with good practice we found where costs had been saved by transfer of some maintenance in-house. However, before doing this, trusts must consider carefully all the financial and safety implications.

4.14 We also found that newer medical equipment resulted in higher maintenance costs. This may reflect greater adherence to manufacturers' maintenance schedules for more modern equipment, or the nature of newer medical equipment hardware, and requirements to keep associated software up to date. Our results show that an increase in the number of makes of medical equipment held by a trust also increases maintenance costs, all else being equal. This is consistent with the good practice we found where trusts had reduced costs by standardising makes and models, although trusts must ensure that they have available a range of makes and models of medical equipment to meet clinical needs.

Savings of up to 15 per cent of total annual maintenance costs may be possible

4.15 Overall, the influences we examined explained 77 per cent of maintenance cost variations across acute NHS trusts in 1996-97. There will be trust specific factors that can account for some of the remaining variation in costs, which we could not explain in terms of general influences on costs. For example, specialist centres are likely to have equipment with more complex and expensive maintenance requirements.

4.16 If the trusts that have higher than predicted maintenance costs could reduce expenditure to the level expected on the basis of their characteristics, we estimate that potential savings of up to £18 million a year, or 15 per cent, could be possible in relation to a total annual maintenance spend in all NHS acute trusts in England of £124 million. We stress for the reasons above that this figure is an indication of the scope for savings, rather than an estimate of the total savings that can be made. However, many trusts have maintenance costs that are lower than expected, given their size, activity and other characteristics. This may reflect good practice along the lines we have identified. Alternatively, some trusts may not be carrying out sufficient maintenance. It will be important, therefore, for trusts to examine their medical equipment maintenance costs closely.

Cost-effectiveness of insurance maintenance is not yet proven

4.17 Under the terms of an insurance maintenance policy, a trust has a contract with an insurance company whereby the company arranges and pays for medical equipment maintenance and repair services, when required, from the supplier or another third party. Our survey showed that 30 trusts were using some form of insurance maintenance, although this accounted for only a very small fraction of total expenditure on maintenance across all trusts. For an individual trust using insurance, typical expenditure was 10 per cent of the total maintenance budget. We found from our visits and contacts with other trusts, however, that many more trusts were considering this option.

4.18 The advantages and disadvantages of insurance based maintenance, based on experience of the approach in the USA, are shown in Box 8. The findings from the USA indicate that trusts need to be discerning in how they use insurance maintenance. One advantage is the consolidation of maintenance contracts, but this can be done without using the insurance option. A further advantage is that trusts can avoid the risk of incurring large maintenance bills on expensive items of medical equipment. The use of insurance for small value items of medical equipment, however, can result in high administrative charges that may outweigh any financial or other benefits.

Box 8 Experience from the USA of the use of insurance maintenance

Based on the experience of hospitals in the USA using insurance maintenance over the past 15 years:

Potential advantages

- Can reduce a trust's exposure to liability in the event of litigation
- Contract costs are capped meaning more certainty over maintenance costs
- Enables consolidation of maintenance contracts
- Centralisation of management of maintenance expenditure
- Reduced need for hospital resource to manage maintenance
- Service can evolve into asset management, with an employee of the insurance company based on-site to handle requests and manage administration

Potential disadvantages

- Higher maintenance charges per request, as the supplier charges on a time and materials basis rather than at a rate usually charged under a typical service contract
- Increased administrative costs, of staff to handle additional calls and invoices, particularly if many small items are covered

Potential costs and benefits

- Short term reductions in maintenance costs, typically for one to two years
- Increases in premium, when an analysis of cost history and insurance risks shows this is necessary to recover losses to the insurance company

Source: Emergency Care Research Institute (ECRI) - Health Systems Group USA

4.19 Long term savings may not be possible at all hospitals, but in discussions with trusts we were given examples of where cost savings had been achieved in the short term. For instance, at one trust savings of at least £15,000, or 20 per cent, had been made in the first year of an insurance maintenance contract for selected items of medical equipment. However, we also found examples where expected cost savings had not been achieved, and a comprehensive maintenance contract provided by the supplier would have been cheaper in the longer term. Therefore, although insurance maintenance may offer savings in the short run, typically during the first two years of the contract, trusts need to take considerable care to ensure that the approach offers savings in the longer term as well.

Quality standards for maintenance work

4.20 There is a need to ensure that medical equipment is maintained to an appropriate standard and by an acceptable process so that a trust can demonstrate that patients are not exposed to risks beyond those inherent in the clinical treatment they receive. The quality of medical equipment maintenance can be

enhanced through the adherence of maintenance organisations to a recognised quality standard. Accreditation to the standards promulgated by the International Organization for Standardization, for example, requires a maintenance organisation to develop a quality plan; define customers and their needs; document procedures; and monitor and improve the maintenance process on a continuous basis. It requires external certification and accredited bodies are subject to external audit on a regular basis.

4.21 Accreditation, therefore, provides assurance that maintenance processes are properly documented, and that clear procedures and a comprehensive system of record keeping are in place. Apart from the greater assurance that this gives to medical equipment users, based on examples of good practice we saw it leads to higher quality work and provides scope for efficiency savings, for example from a reduction in medical equipment downtimes.

Twenty eight per cent of internal NHS maintenance suppliers are externally accredited

4.22 Our survey showed that 28 per cent of trusts with internal maintenance departments were accredited under a recognised quality standard, most commonly a standard of the International Organization for Standardization. External accreditation may add to overhead costs, for instance because of the need to employ a quality control manager, but we found from the sites visited, and from examples of good practice given to us by other trusts, that accreditation had also brought a number of benefits, including:

- an assurance to users on the standards applied to in-house maintenance;
- confidence in bringing maintenance work in-house when cost justified;
- systems to monitor quality, and response and completion times;
- improved monitoring of planned preventative maintenance and evidence that it has been carried out;
- systematic feedback from users to help improve services;
- a reduction in medical equipment downtimes.

Improving the cost effectiveness of maintenance in trusts

4.23 We found many examples of good practice at trusts that has resulted in reduced maintenance costs and improved quality of service. These examples provide a basis for improvement more widely across NHS trusts. They should consider:

- the adoption of planned preventative maintenance in the very small number of trusts that do not use it;
- whether the schedules for the planned preventative maintenance of different types of medical equipment offer the best value for money, in the light of experience;
- the potential for savings through sharing or taking on work carried out by external maintainers of medical equipment, taking account of any possible safety implications;
- whether improved oversight of external contracts by medical engineering departments could bring economies of scale, better monitoring and evaluation, and cost savings, in line with the best practice we observed;
- benchmarking their maintenance costs with other trusts, to see what savings are possible and whether sufficient maintenance is being carried out;
- where insurance based maintenance is being considered, whether it will offer cost savings in the long term;
- external accreditation for in-house maintenance departments, taking account of the costs and potential benefits.

Part 5: Medical equipment safety

Introduction

5.1 Each year, a number of incidents related to medical equipment occur in hospitals that give rise to, or have the potential to, produce unexpected or unwanted effects involving the safety of patients, users or other persons. And over the three financial years 1995-96 to 1997-98 nine deaths and 55 serious injuries have been directly related to medical devices, including medical equipment, or their misuse. We have examined the extent of adverse incidents involving medical devices reported to the MDA by NHS trusts in England, and looked at user training which has an important bearing on the safe use of medical equipment.

Extent of adverse incidents

There is a voluntary system for trusts, and a mandatory system for manufacturers, to report adverse incidents to the MDA which carries out investigations

5.2 When an adverse incident relating to a medical device, including medical equipment, occurs there is a national but voluntary system for trusts to report it to the MDA. Under this system, hospitals are asked to report incidents that led to, or could have led to, death, life threatening illness or injury or a similar deterioration in health. Further, the MDA should be informed of any other incidents or faults related to a medical device that may have implications elsewhere in the NHS, or for other healthcare organisations²⁴. In addition to the voluntary system, there is also a mandatory obligation on manufacturers of devices that conform to the medical device directives of the European Union, to report to the MDA any adverse incidents which had led, or had the potential to lead, to death or serious injury. Figure 10 shows the action taken as a result of an adverse incident being reported to the MDA.

24 "Reporting Adverse Incidents Relating to Medical Devices", MDA Safety Notice 9801, 1998

Figure 10 The system of reporting and communicating adverse incidents



Source: Medical Devices Agency

The number of adverse incidents reported to the MDA, by NHS trusts in England under the voluntary reporting scheme, has been growing since 1994-95 and more than 2,000 adverse incidents relating to medical devices were reported in 1997-98

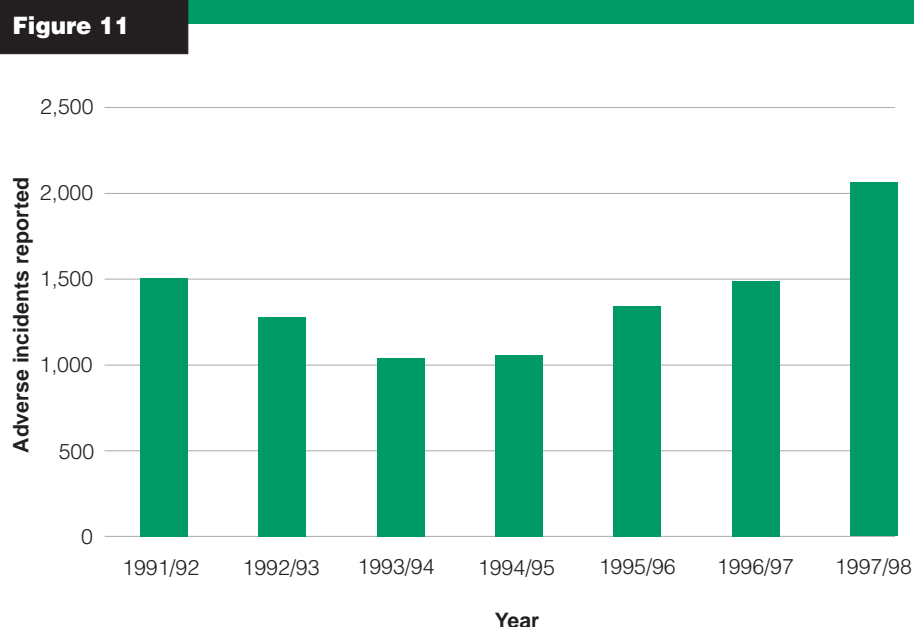
5.3 We sought data from NHS acute trusts in England on the number of adverse incidents relating to medical equipment occurring over time, but because of trust mergers and renaming this was not possible. Our analysis therefore covers all medical devices in all NHS trusts in England unless otherwise stated.

5.4 Figure 11 shows the trend in the number of adverse incidents involving all medical devices, including medical equipment, reported by NHS trusts in England to the MDA since 1991-92. In 1997-98 there were 2,056 adverse incidents reported, an increase of 38 per cent compared with the previous year. The MDA believes that the increase in reported incidents is due in part to more consistent reporting of incidents, for example, as a result of improved communication between the MDA and trusts.

There may still be inconsistency of reporting rates

5.5 Our survey of NHS acute trusts in England showed that on average trusts reported only 50 per cent of incidents involving medical equipment in 1996-97. This suggests that not all incidents associated with medical equipment are being

Number of Adverse incidents relating to medical devices reported by NHS trusts in England, 1991-92 to 1997-98



Source: Medical Devices Agency

reported to the MDA. We found that there was a wide variation in the rate of reporting by individual trusts that had recorded adverse incidents, from none reported to all reported. Even allowing for the variation in the type of incident that might occur during a year in a trust, this range suggests that reporting rates are not uniform. Trusts we visited told us that some incidents were not reported to the MDA when staff alleged that medical equipment was faulty, but subsequently no fault with the medical equipment could be found. This may indicate cases of user error that had not been reported to the MDA.

There are significant regional variations in the rate of reported adverse incidents

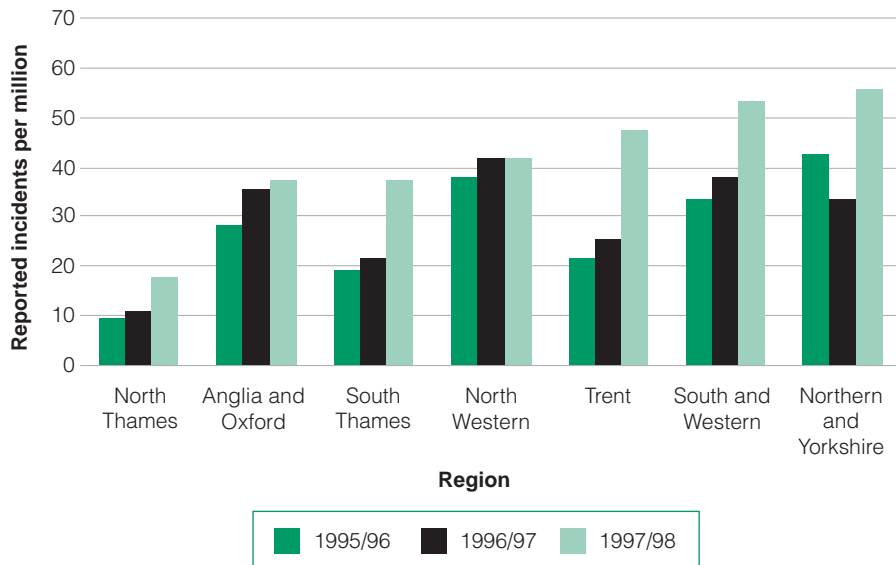
5.6 We examined the number of adverse incidents involving all medical devices per million population reported to the MDA in each NHS region in England. At this level factors that might affect the number of adverse incidents, such as the complexity of medical equipment, or case mix, tend to be evened out. The analysis shows wide variations, with three times the number of incidents per head reported in 1997-98 in Northern and Yorkshire region than in North Thames (Figure 12).

5.7 Apart from variations between regions in the prevalence of adverse incidents, the only other obvious explanation for the regional variation in incidents reported is differences in trusts' reporting rates. It is of concern if trusts in some regions report fewer adverse incidents than in others, or if trusts in some regions have a higher rate of adverse incidents.

The number of adverse incidents involving medical devices per million population reported to the Medical Devices Agency by NHS Region

Figure 12

Figure 12 shows wide variations in the number of adverse incidents reported by NHS regions, when account is taken of differences in populations.



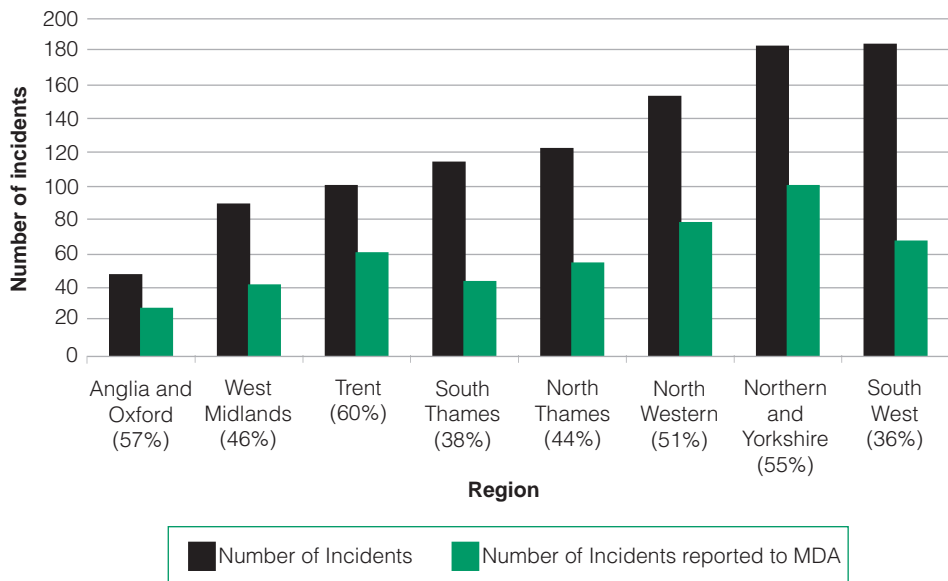
Source: Medical Devices Agency

5.8 For 1996-97, we analysed by region the number of adverse incidents specifically related to medical equipment, recorded and reported to the MDA by acute trusts only, using returns from our survey (Figure 13). This showed that there were nearly 1,000 incidents recorded by acute trusts, of which less than half were reported to the MDA. The percentage of incidents reported varied from 36 per cent in South and West region to 60 per cent in Trent region. While these variations may reflect the nature of incidents occurring in 1996-97, the extent of the range in incidents reported to the MDA may reflect different views as to what constitutes a reportable adverse incident under the voluntary reporting scheme.

Numbers of Adverse Incidents involving Medical Equipment by English region in 1996/97, in NHS acute trusts and the percentage reported to MDA

Figure 13

Figure 13 shows that acute trusts in England told us there were 992 incidents in 1996-97, of which 470 (47 per cent) were notified to the MDA. The percentage figure relates to the proportion of incidents reported to the MDA.



Source: National Audit Office Survey

There may be scope for improving procedures within trusts for reporting adverse incidents and reacting to MDA safety warnings

5.9 We examined adverse incident procedures at the ten trusts we visited. We found that nine trusts had a documented procedure for reporting adverse incidents, although at three trusts these had been instigated only recently. Only four trusts had a system to check that reporting procedures were actually followed on wards and in departments. Interviews with ward staff about the procedures in place and the actions necessary if an incident occurred revealed some deficiencies. At two trusts, for example, that there was no formal procedure for quarantining medical equipment after it had been involved in an incident.

✓ We found examples of good practice procedures relating to handling adverse incidents

5.10 We found from our visits examples of good practice in reporting adverse incidents and disseminating safety information issued by the MDA. These included:

- having a single person within a hospital responsible for reporting adverse incidents to the MDA and distributing Hazard and Safety Notices. This raises awareness centrally in a trust of the type of incident that may occur. The MDA told us that more than 80 per cent of NHS trusts in England had a MDA liaison officer;
- having a trust director taking the lead in formulating and implementing the policy for identifying, reporting, monitoring and acting on incidents. This enables analysis of incident reports, with the findings being presented to the trust board;
- keeping clear and concise records, which register adverse incidents and subsequent corrective action;
- distributing information on incidents to all staff in a monthly newsletter;
- circulating widely to all departments and wards a summary list of Hazard and Safety Notices so staff can check for themselves that they have received all those that may be relevant;
- incorporating the reporting of adverse incidents into an overall risk management strategy for the trust;
- having a written policy covering dissemination of MDA reports and notices, and procedures for handling such notices when received (see Box 9).

Box 9 Examples of practices to promote the safe use of devices

✓ At **City Hospitals Sunderland** all Hazard and Safety Notices are distributed throughout the trust via a central committee. On receipt of a notice by the committee a search is made on the asset register to check whether the Trust holds the device. Information is added to the notice to indicate whether the device requires technical modification or some other action, changes in the operating procedure or is for information only. Copies are then forwarded to the appropriate divisions through the network of business managers. If there is uncertainty about who would require copies then all business managers receive a copy.

✓ **Doncaster Royal Infirmary and Montagu Hospital NHS Trust** have produced a booklet to serve as a reference document for medical equipment controllers and others involved in medical devices. It centres around twelve common questions that frequently arise when dealing with medical devices such as: What is the MDA? What do I do if there is an adverse incident? What devices do I need formal training in?

Answers to these questions refer the reader to subsequent sections of the document that deal with specific areas including training issues, fault reporting procedures, adverse incident policy, decontamination protocols etc. The document also contains appendices containing the trust's overall medical equipment management strategy, a full list of current medical equipment controllers and a list of other publications relating to the use and handling of medical devices. The document is available on the Trust's computer network as well as being available in paper form for ward and department use.

Trusts found the MDA's warning notices useful in avoiding further incidents but could not always act on the information

5.11 The MDA issues a Hazard or Safety Notice when its investigations show there are wider implications for other patients or users. A Hazard Notice is issued where there is potential for death, serious injury or illness related to the use of a medical device. A Safety Notice is used to recommend or inform of actions to improve the safety of medical equipment, to repeat warnings on long standing problems or to follow up manufacturers' medical equipment modifications.

5.12 Nearly all trusts in our survey found MDA Hazard and Safety Notices to be helpful or fairly helpful. Trusts felt that MDA notices provided a wider picture than trusts could know from their own limited experience, made possible corrective action before the problem occurred in the trust, or gave a clear analysis of the problem and advice on appropriate action from an authoritative and independent source.

5.13 However, some trusts visited had problems in circulating notices to all relevant staff. The identification of departments that held a specific device was often constrained by incomplete inventories. There were also some difficulties in ensuring that action was taken in response to the issue of Hazard or Safety Notices.

User training

User error is a significant cause of incidents involving fatalities or serious injuries

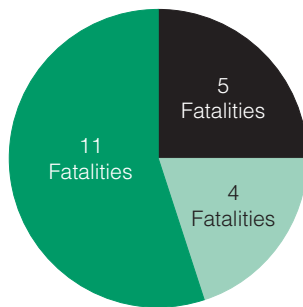
5.14 According to MDA data on adverse incidents related to medical devices, the majority of fatalities and reported serious injuries arise for a wide range of often complex reasons, but user error is a cause in a substantial number of cases. User error accounted for 25 per cent of fatalities and 33 per cent of serious injuries in the period 1995/96 to 1997/98 (Figure 14). For medical equipment only our survey of acute NHS trusts showed that infusion equipment, of which there are numerous makes and models that can lead to confusion and operator error, is the most common type of medical equipment associated with adverse incidents (Figure 15 and Box 10).

Causes of adverse incidents involving medical devices, including medical equipment, that resulted in fatalities and serious injuries, reported to the MDA 1995-98

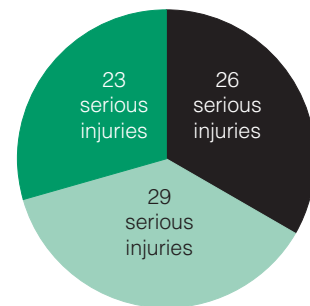
Figure 14

Figure 14 shows that user error was the cause of death and serious injury in a substantial number of cases

Causes of Reported Fatal Adverse Incidents 1995-1998: Total Fatalities 20



Causes of Reported Serious Injuries 1995-1998: Total Serious Injuries 78

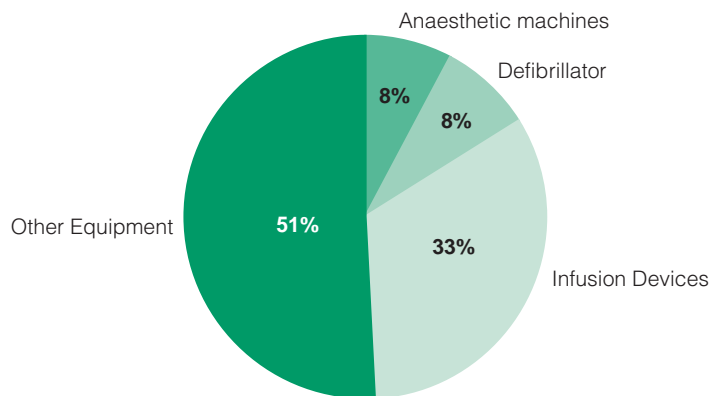


Source: Medical Devices Agency (all NHS Trusts in England)

Types of medical equipment involved in adverse incidents in English NHS Acute Trusts 1996-97, reported to the NAO

Figure 15

Figure 15 shows that infusion equipment (mentioned by 33 per cent of trusts), which includes infusion pumps, infusion devices and syringe pumps or drivers, is most commonly involved in adverse incidents. Anaesthetic machines (8 per cent) and defibrillators (8 per cent) also account for many incidents. The 51 per cent classified as "other equipment" covers a wide variety of different items



Source: National Audit Office Survey

Box 10 Confusion between different infusion pumps

Patients in hospital often require medication over a period of time, and this can be delivered via an electrically powered infusion pump. The level of medication required varies between patients and a variety of infusion pumps are needed to cater for this. Typically, an individual NHS trust will hold at least six different models of pump. Each type of pump has to be set to deliver the required medication over a specific time period.

Some pumps are set to deliver medication at an hourly rate; others are set at a daily rate. Giving a patient a daily dose within an hour can have serious consequences. In practice there has been confusion between models of pumps and patients have died as a result.

In response to this problem, in November 1995 the MDA issued a Hazard Notice (HN9506). This aimed to ensure that all users received adequate training to become familiar with the difference between two particular models of pumps where confusion had led to serious over-infusion and patient death, and that all such pumps were fitted with improved labelling.

Medical engineering departments could usefully be more involved in training for safe medical equipment use

5.15 MDA guidance emphasises the importance of training in the use of medical equipment in relation to patient safety²⁵. The medical engineering departments at trusts we visited told us that their personnel could make a significant contribution to training in the use of medical equipment. While they felt it was not their role to be involved in clinical aspects of medical equipment usage, it was desirable for them to be involved in the non-clinical aspects of training such as the operation of medical equipment, potential operating risks and general safety questions. However, our survey showed that only about half of trusts involve medical engineering staff in this role.

5.16 Our discussions at the trusts visited showed that the arrangements for training staff in the use of medical equipment were not as comprehensive as they should be. And 22 per cent of the trusts surveyed considered that the better training of medical equipment users and technical staff was one of the main ways in which the management of medical equipment could be improved. Often, user departments had either no training budget or a very limited one, and few trusts had formal policies or procedures in place for training staff to use medical equipment. These trusts placed reliance on individuals to identify their own training needs, leaving it to local managers to check with staff whether they had sufficient training before using medical equipment. Only one trust we visited kept a formal training log of the training received by their staff.

5.17 Problems with training can be exacerbated where staff turnover is high and there is substantial use of bank and agency staff. The MDA note in their guidance that “many adverse incidents in hospitals occur during the early hours of the morning, and that sometimes the staff involved (night staff and bank nurses especially) have not been able to complete relevant training”. These findings reinforce our conclusions that medical engineering departments can usefully play a wider role in medical equipment training than at present, while trusts should think carefully about how training in the use of medical equipment is provided in general in order to reduce risks to patients.

 **Improving training for safe use of medical equipment: good practice**

5.18 Our survey and discussions identified a considerable amount of good practice in training related to medical equipment usage. Examples include:

- having a professional lead training on how to use particular items of medical equipment;
- designating particular managers as responsible for ensuring that staff are trained;
- surveying users to assess their training needs and identify gaps in knowledge, and using the results to design training courses and target those staff who would benefit most from courses;
- standardising the training offered to staff to ensure consistency and save training effort;
- providing documents which certify that staff have been trained in using specific items of medical equipment;
- training new staff in the use of medical equipment as part of their induction;
- developing safety protocols especially aimed at bank and agency staff unfamiliar with their workplace.

Action to improve medical equipment safety

5.19 We recognise that the upward trend in adverse incidents may in part reflect better reporting of medical equipment related problems, and we welcome the MDA's work to improve reporting so that problems may be avoided in future and risks to patients and others minimised. However, it is important that further action is put in hand to further minimise risks. In particular, the NHS Executive and the MDA should consider:

- whether variations in the rates of adverse incidents that occur, and in the rates of adverse incidents that are reported, represent an unacceptable safety risk, and if so address the problem;
- steps to improve the consistency of reporting of adverse incidents, and whether the existing voluntary reporting scheme best serves the interests of safety;
- how best practice generally can be monitored, disseminated and implemented in order to reduce the level of adverse incidents in the future.

And trusts should consider:

- steps to ensure that they have documented procedures for dealing with and disseminating information about adverse incidents, based in part on the best practice we have found;
- how the expertise of engineering departments can be better drawn into non-clinical aspects of training for safe use of medical equipment.

Appendix 1

Audit methodology used by the National Audit Office

Introduction

1 We used a variety of techniques to examine the issues identified for the study. These comprised:

- issuing a self-completion audit programme to all NHS acute trusts in England for completion in respect of 1996-97 by the head of medical engineering departments;
- appointing a consultant to obtain the views of equipment manufacturers on the procurement process for medical equipment;
- appointing Emergency Care Research Institute (ECRI) as consultants to provide advice on equipment management.
- carrying out a literature search of research articles on:
 - equipment purchasing;
 - equipment maintenance;
 - equipment libraries;
 - training in the use of equipment;
 - adverse incidents involving equipment.
- consultation with the Royal College of Surgeons, the Association of Anaesthetists, the British Society of Gastroenterology, the National Performance Advisory Group, Glasgow Royal Infirmary University NHS Trust and the University of Strathclyde;

- carrying out in depth audit visits to:
 - Brighton Healthcare NHS Trust;
 - Freeman Group of Hospitals NHS Trust;
 - Kingsmill Centre for Healthcare Services NHS Trust;
 - Oxford Radcliffe Hospitals NHS Trust;
 - Pinderfields Hospital, part of Pinderfields and Pontefract Hospitals NHS Trust;
 - Royal Free Hospital, Hampstead NHS Trust;
 - Scunthorpe and Goole Hospitals NHS Trust;
 - Swindon and Marlborough Hospitals NHS Trust;
 - United Bristol Healthcare NHS Trust;
 - University Hospital, Birmingham NHS Trust.

- organising a benchmarking forum.

Issue of audit programmes

2 We carried out a census in England of 227 NHS trusts that provide acute services. The objective of the census was to obtain information not centrally available. We developed and piloted a specific self-completion audit programme for the census²⁶. We issued the audit programmes in November 1997 and gave a telephone contact help point to recipients. We achieved a 100 per cent response rate. We also carried out a follow up survey of trusts to determine the overall position on medical equipment expenditure in 1997-98.

26 A copy of the questionnaire is available on request to Health VFM Area, National Audit Office, 157-197 Buckingham Palace Road, Victoria, London SW1W 9SP.

Establishing the views of equipment suppliers

3 We appointed a consultant to establish the views of manufacturers who supply equipment to NHS acute trusts. The consultant carried out a series of structured interviews to determine ways in which hospitals can improve their approaches in purchasing medical equipment. The consultant developed and used an audit programme that was completed during the course of interviews held at each equipment manufacturer. The consultant carried out the interviews during July and August 1997. Suppliers consulted are listed at Appendix 3.

Emergency Care Research Institute

4 We appointed Emergency Care Research Institute (ECRI) to provide advice and guidance on equipment management based on their experience both in the United Kingdom and in the United States. ECRI is a non-profit agency and a Collaborating Centre of the World Health Organisation. ECRI provides information and technical assistance on medical equipment and health technology assessment to the healthcare community throughout the world.

Audit visits

5 The purpose of the audit visits was to obtain information about the management processes and the other aspects of medical equipment management that could not be obtained from the questionnaire. Visits involved interviews with the medical and nursing director, the supplies manager, the manager of the medical engineering department (or equivalent), the risk manager (or equivalent), a consultant anaesthetist, a consultant gastroenterologist, a representative from the Intensive Care Unit, a representative from the Finance Department and resuscitation training officers. We also examined documentary information.

6 We selected five trusts which were seen as having good local practices, and which were also different in terms of characteristics such as size (as measured by the level of income), whether the trust was teaching or non-teaching, and which were located in different NHS regions. We then selected another five trusts that had similar features, in order to be able to compare approaches in other similar trusts.

Benchmarking

7 We invited 12 equipment maintenance managers to discuss their approaches to medical equipment management. We provided analyses of our census data to assist in the discussion concerning issues such as equipment purchasing, maintenance and training. The NHS Executive and Medical Devices Agency attended as observers.

Appendix 2

Statistical analysis of provision of medical equipment and maintenance costs at NHS trusts in England

This appendix provides details of the methodology adopted and results given in the main report in relation to explaining the value of medical equipment held by trusts in 1996-97, and the costs of maintaining it.

Explanatory factors

Both levels of provision and maintenance costs of medical equipment depend on a variety of influences. For example, an obvious factor is the size of the trust. Large trusts will have more equipment and have higher maintenance expenditure than small trusts. We held discussions with around 30 trusts during the course of our site visits and through the benchmarking club to understand what influences might be important. A number of factors were suggested to us as bearing on equipment holdings and maintenance costs. Most of the factors in the following list apply to both holdings and maintenance costs, though not all:

Type of trust

Some trusts undertake more specialist work than others, or carry out teaching that requires a different and possibly more complex mix of equipment. There may also be more equipment per bed in specialist units. The type of trust is also some indication of case mix. To allow for such influences on equipment holdings and maintenance costs, we assigned trusts to three categories: acute, acute teaching and other. This assignment was based on information about trusts supplied to us by the Department of Health. 'Other' trusts comprise combined acute and community and mental health trusts.

Size of trust

Size of trust affects the amount of equipment needed to carry out the trust's activity and the resulting maintenance costs. We measured trust size on the basis of information on trust income and bed numbers, and used data taken, as recommended to us by the NHS Executive, from Binley's Directory²⁷.

Case Mix

More sophisticated allowance for variations in case mix is possible using a set of variables developed for the NHS Executive²⁸. An index of case mix can be constructed using information on either length of stay (LOS) or cost, or a combination of the two as weights. The first step in constructing the index is to calculate average LOS or cost across the NHS, for different Health Resource Groupings, HRGs, which measure procedures of a related type. The expected LOS or cost for an individual trust is then calculated using its HRG mix and the average LOS or cost for that HRG across the NHS. The case mix index measures this result against the LOS or cost for the average HRG mix across the NHS. We used two variants of the case mix index – one based entirely on length of stay data, and the other on a combination of cost and length of stay data. This second index makes use of cost information where this is available, but otherwise uses length of stay information.

The case mix index is however an incomplete measure of the variability of treatment types for a number of reasons:

- it applies only to inpatient costs;
- the age and gender splits within HRGs vary across trusts;
- severity aspects of case mix are not adequately measured simply by length of stay or cost.

Allowance for these factors can be made using data on outpatient and Accident and Emergency attenders, patient age and gender, emergency case load, and whether or not cases have been transferred in or out of a hospital. Another

27 Binley's Directory of NHS Management, Beechwood House Publishing, Essex

28 Technical Notes to accompany hospital benchmarking analysis, Economics & Operation Research Division, Department of Health internal paper, 1998

influence on equipment costs is likely to be the amount of research carried out, measured by expenditure as a percentage of total trust revenue. Data for each trust came from the Department of Health. They cover the case mix index; the proportion of patients under 15; the proportion of patients over 60; the proportion of female patients; the proportion of spells that involve an emergency; the proportion of spells that involve a transfer in from another hospital, or a transfer to another hospital (as measures of severity); total first outpatient attendances as a proportion of inpatient spells; total first Accident and Emergency attendances; and the percentage of total trust revenue spent on research. While the data are for 1995-96, the variables considered are unlikely to have altered greatly in relation to the amount of equipment held and its maintenance costs in 1996-97, as measured from our survey of trusts.

Activity

The income or number of beds at a trust may not completely reflect all the variations in activity that can occur, depending for instance on the type of work carried out and the extent to which day surgery is carried out. Day surgery may require less equipment with less associated maintenance. These effects can be allowed for using data on numbers and types of finished consultant episodes. We used NHS data on numbers of day and ordinary case admissions²⁹.

Volume of equipment managed

Trusts told us that they thought both equipment replacement value and the number of items could have a bearing on maintenance costs. We used data from our survey for these variables in our statistical analysis.

Standardisation of equipment

It was suggested to us that standardising equipment on a restricted number of makes and models would reduce provision levels and maintenance costs. We investigated these effects using data from our survey on the number of makes and models of key items where standardisation is possible. Such equipment includes infusion pumps, endoscopes and defibrillators.

Age of equipment

Maintenance costs are likely to be affected by the age of equipment. Our survey collected data on the proportion of equipment in various age ranges held by each trust. We calculated a weighted average age of equipment at each trust.

29 Ordinary and Day Case Admissions, Department of Health, 1997

Large items

Trusts explained to us that their maintenance costs could be affected by some large items of equipment that are expensive to maintain. Examples quoted to us were Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) scanners. To allow for this potential effect, we included MRI maintenance costs and the number of CT scanners as explanatory variables in our analysis. These data were taken from a survey of Scanners in the NHS, carried out along side our main work on medical equipment.

Maintenance regime

A further influence on maintenance costs mentioned to us during our site visits is the way in which maintenance is organised, and in particular the split between the in-house, contracted out, or insurance based approaches. Opinion was however mixed on the impact, as some trusts told us that in-house maintenance could be cheaper than contracting out, while others felt the opposite for similar type of work. We were also told that the costs of maintenance could be affected by the way in which inventories of equipment are maintained. Our survey collected separate information on internal and contracted out maintenance costs, as well as whether insurance based maintenance was used, so it was possible to assess whether the maintenance regime was a significant influence on costs. A further factor is whether trusts provide maintenance services to other trusts. Trusts buying in services thought this saved them money.

We also collected data in our survey on the number of inventories held and whether they were computerised. In addition, we made use of survey information on trusts' policy towards planned preventative maintenance, and whether the schedules were based on the manufacturers' recommendations or not. Trusts believed that their own schedules were likely to be cost saving, based on their own experience of maintaining equipment in a fit and safe condition.

We were told that the use of central equipment stores, which are not staffed, and equipment libraries, which are, enables economy of holdings of equipment. We used information from our survey on whether trusts used these types of facility.

Value of equipment

As well as being one of the variables we sought to explain, the value of equipment in trusts is also an explanatory factor for maintenance costs. We excluded leased equipment from value, as leasing costs generally cover maintenance.

Capital/Labour substitution

One additional possibility is that trusts with high levels of medical equipment have fewer staff as a result, holding other factors constant. This would come about, for example, through automation of processes such as those in laboratories. To test this hypothesis we used data on total staff costs in each trust, expecting a negative correlation if capital/labour substitution occurs and a positive relationship if medical equipment and staff are complements, for example, if medical equipment requires new staff to operate and maintain it. Economies of scale are indicated if maintenance costs reduce as staff costs rise, holding other factors constant.

Statistical methods

We first calculated bivariate product moment correlation coefficients to assess whether variables were statistically associated. For categorical variables we tested the significance of the difference of means of the dependent variable between trusts divided into the various categories. We also used regression analysis to investigate whether there were statistically significant relationships between groups of the variables above, and the value of equipment held and maintenance costs in individual trusts. Data on these two dependent variables – value of equipment held by a trust, and maintenance costs - were taken from our survey. Categorical variables were entered into the regressions as dummy variables. Ordinary least squares regression was used and significance of explanatory variables measured by the usual tests of coefficient standard errors at 95% confidence level. Regressions including all the relevant variables were carried out, as well as stepwise regression.

Provision of equipment

We looked for any association between provision of medical equipment and the characteristics of trusts. The results are shown in the table 1 below. R is a measure of association used for numerical data, the closer r is to 1, the greater the association.

The significant factors (95% confidence interval two tail test) are predominantly indicators of size, though they, together with some of the borderline significant variables, may also be relevant explanations of provision levels in their own right. Acute teaching hospitals tend to be larger hospitals; the number of makes and models reflects the amount of equipment; and equipment libraries tend to be at larger trusts. Larger trusts tend to have several inventories. The best indicator of

the size of the trusts is income, rather than bed numbers. The significant case mix factor is Accident and Emergency attenders, and the amount of research carried out at a trust is also correlated with equipment holdings.

However, such correlations should not be regarded as necessarily meaningful because other factors, particularly trust size, are not allowed for. To do this we used regression analysis.

Table 1

Associations between value of equipment held and a range of explanatory variables

Characteristics of Trust	Variable used	Association with the replacement value of medical equipment (square root)	r =
Type	Divided trusts into Acute Teaching, Acute and 'Other'	Significant relative to acute trusts	
		Teaching	+
		Other	-
Size	Income (square root)	Significant	0.85
	Number of Beds	Significant	0.66
Case mix	2 Case mix indices	Not significant	
	Proportion of patients under 15	Not significant	
	Proportion of patients over 60	Not significant	
	Proportion of female patients	Not significant	
	Emergency spells	Not significant	
	Transfer in to hospital	Not significant	
	Transfer out from hospital	Not significant	
	Proportion of outpatients	Not significant	
	A&E attenders	Significant	0.44
Research spend		Significant	0.31
Activity	% of day cases	Not significant	*
	Total number of day and ordinary cases		0.70
Standardisation of equipment	Number of Makes	Significant	0.34
	Number of Models	Significant	0.56
	Policy	Not significant	
Equipment	Use of Store	Not significant	
	Use of Equipment Library	Significant	+
Information held	Number of Inventories	Significant	+
	Use of computerised lists	Not significant	
Capital/Labour substitution	Total staff costs		0.79

Note: All data for 1996-97 except for case mix and related variables, which are for 1995-96. Where + or - is shown, the significance test relates to a difference of two means. The sign of the correlation is shown instead. The number of observations was between 170 and 220, depending on response to particular questions in our sample of 227 NHS trusts in England.

* Variable significant at 90%. Otherwise, where significant, significance level is 95% on two tail tests.

Variables explain three quarters of the variation in total equipment replacement value across acute trusts in England.

By using regression analysis we were able to examine the range of factors that could collectively explain replacement value of equipment at trusts. The income of trusts was highly significant, and the regression plot is shown in Figure 1. The number of beds at a trust was also highly significant, but a poorer explanatory variable than trust income when used in place of income. Trust income explained just over 70 per cent of the variation in equipment value, based on the regression model adjusted R^2 at 0.72, (adjusted R^2 is a measure of the explanatory power of the regression).

Stepwise regression showed that, in addition to trust income, statistically significant variables are research spending, the day and ordinary casework, and the proportion of spells that involve a transfer in from another hospital. All these variables were associated positively with equipment replacement cost, reflecting the influence mainly of case mix. The explanatory power of the regression adjusted for degrees of freedom is 0.74, (N=197) and the results are shown in Table 2. A square root transformation was used given the wide range of trust income, and the regression passed tests for normality and homoskedasticity of residuals.

Significant coefficients for replacement value of equipment (square root) held

Table 2

	Coefficients	T
Total income (£ million) (square root)	0.0255	6.6
Total Day case + ordinary case work	0.00002	5.8
Research spend as % of trust income	0.028	5.3
Transfers into hospital	5.5	3.8

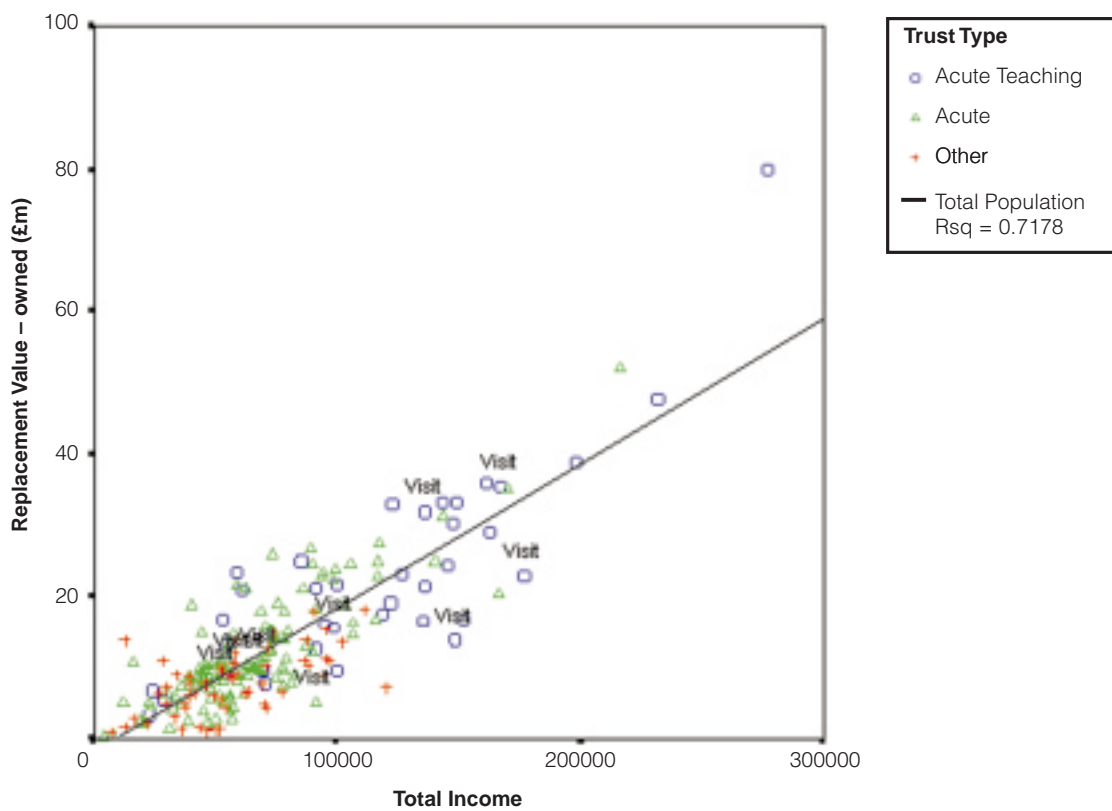
The total replacement value of equipment is £2.8 billion. Individual trusts will have additional explanations for the replacement value of equipment they hold that are not captured by our analysis, even though this is comprehensive in terms of the factors it has considered. However, if those trusts with medical equipment inventories higher than the model predicts could reduce their holding to that expected on the basis of their characteristics and the regression model, a one off reduction of up to about £400 million, or some 14 per cent of overall inventory value, would be achieved. We stress that this figure is indicative of the scope for investigating where savings might be made, and is not an estimate of possible

savings that can be achieved. The same figure applies for trusts with lower than predicted equipment. This may reflect either under-investment or efficiencies in the use of medical equipment.

Figure 1

Relationship between value of equipment held by trusts and trust income

Note: Visit denotes a trust we visited for detailed discussions.



Maintaining medical equipment

The total cost of maintenance at 220 trusts was £124 million in 1996-97 and this cost varied significantly between trusts, ranging from under £50,000 to over £1.5million. We looked at the range of factors including the size, type, equipment and administration of each trust that could explain varying maintenance costs at trusts. Correlation analysis results are set out in the following Table 3.

Table 3

Associations between maintenance costs and a range of explanatory variables

Characteristics of Trust	Variable used	Association with the replacement value of medical equipment (square root)	r =
Type	Divided trusts into Acute Teaching, Acute and 'Other'	Significant relative to acute trusts	
		Teaching	+
		Other	-
Size	Income	Significant	0.81
	Number of Beds	Significant	0.60
Case mix	Case mix index	Not significant	
	Proportion of patients under 15	Not significant	
	Proportion of patients over 60	Not significant	
	Proportion of female patients	Significant	-0.14
	Emergency spells	Not significant	
	Transfer in to hospital	Not significant	
	Transfer from hospital	Not significant	
	Proportion of outpatients	Significant	0.14
	A&E attenders	Significant	0.44
	Research spend		Significant
Activity	day cases	Not significant	
	Total day and ordinary cases		0.62
Standardisation of equipment	Number of Makes	Significant	0.34
	Number of Models	Significant	0.55
	Policy	Not significant	
Equipment supply	Use of Store	Not significant	
	Use of Library	Significant	+
Maintenance regime	Internal % of total costs	Not significant	
	PPM policy	Not significant	
	Use of Insurance	Not significant	
	Provide external service	Significant	+
Information held	Use of Inventory	Significant	
	Use of computerised lists	Not significant	+
Value of equipment	Replacement value of equipment (owned)	Significant	0.84
	Equipment value	Significant	0.56
	Equipment items	Significant	0.66
	Number of CTs	Significant	0.52
Economies of scale	Staff costs		0.79

Note: All data for 1996-97. Where + or - is shown, the significance test relates to a difference of two means. The sign of the correlation is shown instead. The number of observations was between 170 and 210, depending on response to particular questions in our sample of 227 NHS trusts in England. Where significant, significance level is 95% on two tail tests.

The size of a trust explains much of the cost of maintenance. Indicators of size include income, the number of beds, the type of hospital, and the replacement value of equipment and items of equipment. All these indicators show a significant association with the cost of maintenance. The best single measures are income and value of equipment, which accounted for around 75 per cent of the cost of maintenance across trusts.

Variables explain almost 80 per cent of the variation of maintenance costs across trusts

Stepwise regression results are reported in Table 4. These explain the cost of maintaining medical equipment predominantly by income, but also by the replacement value of equipment; the share of maintenance carried out in-house; providing services outside; the average age of medical equipment; and by staff costs. Holding other factors constant, a small reduction in costs occurs with increases in the proportion of medical equipment maintenance conducted internally. All else constant, costs increase, as expected, where a trust provides maintenance services to other trusts. The more recent the mix of medical equipment held, the greater the maintenance costs are allowing for the other factors. This may reflect greater adherence to manufacturers' maintenance schedules for more modern equipment, or it may be a reflection of the technology embodied in new equipment. Case mix variables do not appear as statistically significant in the best fit regression. The sign of the coefficient on staff costs suggests a possible economies of scale effect.

Significant regression coefficients for cost of maintaining medical equipment (square root)

Table 4

	Coefficients	T
Total income (£ million) (square root)	93	5.3
Total replacement value owned (£million) (square root)	117	8.1
Internal % of maintenance costs	-2.0	-4.9
Provide services to other trusts	79	-3.5
Cost of staff (square root)	-2.0	-3.2
Average age of equipment	-18	-2.7
Number of Makes (square root)	27	2.9

Notes: N= 195. The t statistic is the ratio of regression coefficient and its standard error. The adjusted R² for the fitted model is 0.77.

Overall, the best fitting regression accounted for 77 per cent of variation in maintenance costs. A square root transformation was used, and as with the regression for equipment provision, it passed relevant tests of the residuals. Although individual trusts may have good reasons for higher or lower maintenance costs than predicted by the regression model, if the trusts with higher costs could reduce their costs to those predicted by the model, a saving of £18 million, or 13 per cent of total maintenance costs would be achieved. As with holdings of equipment, we stress that this is not an estimate of actual savings possible, but an indication of the scope for further investigation of maintenance costs by trusts. Where trusts had costs lower than predicted this may reflect specific factors such as the adoption of best practice that reduce costs. Alternatively, it may mean that insufficient maintenance is carried out.

Appendix 3

Medical equipment suppliers and manufacturers consulted by the NAO

Introduction

As part of the study we interviewed twelve suppliers, who together cover a substantial part of the market for medical equipment, to gather their views of working with the NHS. The interviews were carried out by a consultant employed by the NAO and took place between July and December 1997.

At least two major suppliers were interviewed for each of five items of medical equipment in common use. Supplier information and views were sought mainly on the way purchases of the five items of medical equipment are made by the NHS.

Suppliers and manufacturers visited

The twelve suppliers and manufacturers interviewed covered five items of medical equipment in common use:

- **Anaesthetic machines:** Datex Engstrom Ltd, Ohmeda Ltd (now Datex-Ohmeda Ltd), Draeger Medical, and Siemens Plc.
- **Defibrillators:** Hewlett Packard Healthcare Group, Physio Control Ltd.
- **Endoscopes:** Endoscopy UK Ltd, Endoscopy Services Ltd, Keymed (Olympus) Ltd, Pentax Ltd.
- **Infusion systems:** Baxter Healthcare Ltd, Graseby Medical Ltd.
- **Neo-natal incubators:** Draeger Medical, Hewlett Packard Healthcare Group.

Glossary of terms

Adverse incident	An event that produces, or has potential to produce, unwanted effects involving the safety of patients, users or other persons.
Anaesthetic machine	A unit that provides anaesthetic gases, and can also include integral ventilation and monitoring of a patient during a surgical procedure.
Computed Tomography	A non-invasive radiographic technique for imaging body parts involving reconstruction of a tomographic plane of the body (a slice) from a large number of collected x-ray absorption measurements taken during a scan around the body's periphery.
DB9801	The Medical Devices Agency's Device Bulletin issued in January 1998 comprising a guide for people responsible for purchasing, deploying, maintaining and repairing medical devices, including equipment, and training in their use in the hospital and in the community.
Defibrillator	A device which provides an electric shock to the heart encouraging the subsequent resumption of co-ordinated heart contractions.
EBME Department	Electronic, Bio-medical and Mechanical Engineering Department with responsibilities including maintenance of medical devices.
Endoscope	Instrument that allows visual inspection of parts of the interior of the body.
Equipment library	An area where equipment is stored, which is staffed, where there are controls over issue and receipt of items, and where activities such as cleaning, recharging and some maintenance are carried out.
HEI98	The Medical Devices Agency Health Equipment Information publication, first published in 1982, and now superseded by DB9801. HEI98 governed the management of medical equipment and devices.
Infusion system	Equipment used to provide a powered infusion of blood or other fluid into a patient.
Infusion pump	An electronically powered pump used to provide a powered infusion of fluids or drugs in solution to a patient by the intravenous, subcutaneous or epidural route over a prescribed period.

Life cycle costing	Investment appraisal based on taking account of both initial capital costs and subsequent costs, including consumables, upgrades, maintenance, and training costs. The appraisal would also take account of different lives of equipment.
Magnetic Resonance Imaging	The use of strong magnetic fields and radio frequency radiation to translate hydrogen nuclei distribution in body tissue into computer generated images of anatomic structures.
MDA, Medical Devices Agency	A Next Steps Executive Agency that aims “to protect the public health and safeguard the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant directives of the European Union”.
MDA evaluation report	In-depth single or comparative reports published by the MDA on the technical and user aspects of medical devices.
Medical equipment	A sub-set of medical devices, we have defined medical equipment as all devices that are connected to the patient as part of their treatment and care in hospital, and devices used for diagnostic or laboratory purposes.
Medical devices	All instruments, apparatus, appliances, materials or other articles, used for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease or injury or handicap.
Nebulizer	A device for generating an aerosol which can be used to enable drugs to be inhaled through a mask or tube.
Neo-natal care incubator	Equipment used to provide a controlled environment for newly born babies.
Planned preventative maintenance (PPM)	PPM is a process by which planned checks, adjustments and replacements are made to equipment before breakdown occurs.
Replacement value	Current replacement value for equipment of the same or similar specification.
Serious Incident	An equipment related incident that led to or could have led to death, life threatening illness or injury or a similar deterioration in health.
Standardisation of equipment	Reducing the number of different makes and models of equipment held by a trust.

Types of trust

Acute teaching hospitals provide undergraduate medical training as well as emergency and routine elective services.

Acute (non teaching) hospitals provide emergency and elective services which usually include accident and emergency, medical and surgical services.

“Other” hospitals include trusts that provide acute services as well as other services such as community, mental health and learning disabilities.