

PERFORMANCE AUDIT

# Equipped to care

Managing medical equipment in the NHS in Scotland



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## Equipped to care: Managing medical equipment in the NHS in Scotland

A report to the Scottish Parliament by the Auditor General for Scotland

### Auditor General for Scotland

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He is responsible for investigating whether public spending bodies achieve the best possible value for money and adhere to the highest standards of financial management.

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The following bodies fall within the remit of the Auditor General

- departments of the Scottish Executive eg the Department of Health
- executive agencies eg the Prison Service, Historic Scotland
- NHS boards and trusts
- further education colleges
- water authorities
- NDPBs and others eg Scottish Enterprise.

### Audit Scotland

Audit Scotland is a statutory body set up in April 2000 under the Public Finance and Accountability (Scotland) Act 2000. It provides services to the Accounts Commission and the Auditor General for Scotland. Together they ensure that the Scottish Executive and public sector bodies in Scotland are held to account for the proper, efficient and effective use of public funds.

### Acknowledgements

This study of medical equipment was initiated as part of the Accounts Commission's 1998-99 programme and is now the responsibility of Audit Scotland on behalf of the Auditor General for Scotland.

Audit Scotland is grateful to the trusts and islands health boards that completed data collection questionnaires and to those that participated in local reviews.

We are also grateful to the members of the advisory panel (Appendix 1) and to other individuals who provided comments and advice throughout the development of this study and on the draft of this report.

Rhona Jack and Fred Talbot developed the study, under the general direction of Caroline Gardner, Deputy Auditor General.

# Executive summary

## Introduction

Medical equipment is essential to patient care. The right equipment must be available in the right place at the right time, together with staff trained to use it. Failing to ensure that medical equipment is available and used properly is increasingly likely to result in poorer patient care and extra costs through litigation. In some cases it could be a life or death issue. This means that trusts need to have adequate systems in place to manage their medical equipment. These issues are becoming increasingly important with the establishment of a formal duty of clinical governance in trusts.

Medical equipment is wide-ranging and complex. It takes many forms: some items are used for diagnostic purposes, whilst others are used in the treatment of patients. Some items of equipment are high in cost but low in volume, such as magnetic resonance imaging (MRI) scanners; while others, such as intravenous (IV) systems, are low cost but high volume. Different issues will apply to each. In purchasing high cost items, trusts need to prepare business cases, apply life cycle costing and adhere to EC procurement regulations. For high volume items, trusts need to consider issues such as standardisation, inventories and asset control, and ensuring access, for example, by means of a pool or library system.

This report considers the strategic management of medical equipment in NHS trusts in Scotland, its funding and acquisition, its use and how it is maintained. It contains information on NHS expenditure, activity and management processes, together with guidance on good practice.

National returns do not provide reliable comparative financial information: total expenditure comprises both capital and revenue monies – many low cost / high volume items are purchased from revenue but not separately identified in the national data. Therefore we directly surveyed trusts for this information. The aim of this report is to provide a baseline against which subsequent improvements can be assessed. The data for the study were collected during 1999, when data for the financial year 1997/98 were available. We used a survey to collect data on both capital and revenue expenditure, which informed local reviews of trusts undertaken by auditors. Each trust received its own local report and action plan. This was prior to trust reconfiguration. In April 1999 the number of NHS trusts was reduced from 47 to 28. This provided opportunities for the new trusts to improve their management of medical equipment by rationalisation and collaboration, and by identifying and sharing good practice. A follow-up study will take place during 2001/2002 – based on 2000/2001 data – and will investigate whether improvements have been achieved in practice.

## Strategic management

The strategic importance of medical equipment, the need for clear leadership and the implications for clinical governance, highlight the need for overall responsibility to be taken at trust board level. But this is not always apparent in practice.

- In six trusts (22%) – including both former acute and community trusts – overall responsibility for the management of medical equipment was unclear, and in some trusts there was no obvious board involvement.
- Only 11 trusts (40%) had a formal overall policy for medical equipment, and 18 trusts had no formal policy covering standardisation, a key aspect of medical equipment management. Variations in the makes, models and suppliers for three common items of equipment suggest that there are opportunities to extend standardisation to improve safety, reduce costs of servicing, and achieve discounts for bulk purchases.
- Management information regarding medical equipment is not often considered at board level, and equipment registers designed for other purposes are seldom adequate to support planning. This means that trust boards are not able to establish clear priorities for medical equipment based on sound information.

Needs assessments (supported by business cases where appropriate) are generally satisfactory for high cost items. Formal needs assessment is less common for low cost/high volume items, with decisions in the main delegated to budget holders.

The procurement of high cost items is generally based on local variations of standard national specifications, although auditors indicated that documentation was lacking in four trusts. Only 13 trusts had begun to develop standard specifications for low cost/high volume items. Trusts take a multi-disciplinary approach to procurement decisions, and generally take account of a range of appropriate factors when awarding contracts. However, improvements could be made by:

- agreeing a more rational basis for determining what should be provided nationally, regionally and locally so that purchases are aggregated where it is sensible to do so. We were unable to obtain information from trusts relating to the uptake of national contracts although Scottish Healthcare Supplies does get uptake figures from suppliers. A 1997 report commissioned by Trust Chief Executives on supplies (including medical equipment), set out a commitment to take advantage of the combined purchasing power of the NHS in Scotland. In spite of this, a substantial proportion of medical equipment continues to be purchased at a local level with no central coordination.
- ensuring that all trusts have clear bidding procedures and prioritised lists of medical equipment so that items can be purchased as soon as funds become available
- allocating funds as early as possible.

## Funding and acquisition

Consideration of the funding of medical equipment needs to take account of both its asset value and the annual expenditure associated with it. Trusts must set priorities for expenditure on medical equipment and be aware, as part of their risk management processes, of any shortcomings in their ability to meet medical equipment needs, since this is likely to affect clinical governance. When funds are limited, it is particularly important for trusts to consider a range of options for funding medical equipment.

We estimate that the total net book value (NBV) of medical equipment was £170 million at 31 March 1998, while total expenditure on new and replacement equipment was £25 million (including both capital and revenue expenditure). Of this £25 million, approximately £17.5 million funded replacements, whilst the remaining £7.5 million was for new developments. On the basis of a one-year snapshot there were marked variations in expenditure as a percentage of operating income between trusts. This was up to seven-fold for acute and community trusts, and more for mixed trusts and island boards.

Our survey findings also suggest that, across Scotland, expenditure on new and replacement medical equipment is failing to match depreciation and that trusts are not replacing items of medical equipment when they come to the end of their useful lives. This is reflected in the failure at 28 trusts<sup>7</sup> to provide sufficient funds for new and replacement equipment to match depreciation in 1997/98. The total shortfall reported for these trusts was £13.1 million. This is likely to be exacerbated by a generally upward trend in replacement costs for many items of equipment.

In 1997/98, for the whole of Scotland, trusts reported £33 million depreciation against combined capital and revenue purchases of £25 million, leaving an overall shortfall of approximately £8 million. This is again based on a one-year snapshot, but it appears to be borne out by the four-year trend in national expenditure figures on all equipment. This suggests that trusts will face increasing problems due to systematic under-investment.

Figures on out-of-date equipment need to be treated with caution since the useful life of an item of equipment may well outstrip the period over which it is 'written down' for financial purposes. Where equipment is working well, can be maintained, and has not been superseded by a significantly improved model, there is no need to replace it. Even so, trusts need to beware that significant use of ageing equipment places increasing reliance on the manufacturers and, if they pull out of supporting the equipment, the equipment will need to be replaced in a short period of time.

The Scottish Executive has already recognised the need to act on funding issues and has:

- increased funding by £16 million for specific types of medical equipment – £5 million for MRI scanners and £11 million for cancer imaging equipment – the procurement of which is to be coordinated nationally to maximise the combined purchasing power of the health service
- changed the accounting rules in order to ensure that monies allocated for capital are not used to reduce trust deficits.

Our follow-up study of medical equipment will take a sample of types of equipment and collect information on the age and condition of these. This will include a consideration of the proportion of equipment, which is past its 'write

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<sup>7</sup> Audit Scotland questionnaire

down' date and by how many years. We shall also do further work on reviewing trusts' arrangements for the replacement of existing equipment.

Most medical equipment (91%) is purchased directly by trusts, with a further 7% donated or on loan and 2% leased. Auditors found that trusts' finance departments are ensuring compliance with EC legislation and Standing Financial Instructions (SFI), and trusts are consistent in applying financial and quality standards regardless of whether the equipment is owned or acquired by other means. However, the pattern of expenditure across the financial year is very uneven with over half in the final quarter, and just over 20% in March alone.

There may be some legitimate reasons for this pattern of expenditure. For example:

- the length of the formal procurement process to meet SFI and legal requirements – even using the accelerated EC procurement procedure, the process will take at least 8-9 months
- late allocations of funds which may have become available for reasons outwith the trust's control.

However, the timing of purchasing can be an issue if it has not been carefully planned. Concerns have been raised by both the Medical Devices Agency (MDA) and the National Audit Office (NAO) about the widespread use of late purchasing in the financial year because it is not conducive to effective purchasing:

*“trusts should avoid the hurried or unstructured purchase of medical equipment at the end of a financial year since this may preclude rational selection”<sup>2</sup>*

### Using medical equipment

Ensuring that medical equipment is available in the right place at the right time, together with properly trained staff, is essential for good patient care. However, at the time of our review most trusts lacked adequate information systems for monitoring the use of medical equipment, and tracking the location of individual items. Without adequate tracking systems and management information, the extent of writing off equipment due to loss, damage or theft is unknown. NBV as a percentage of trust operating income is a measure that can be used to indicate trusts' levels of provision. Using this there appears to be marked variations between trusts in the levels of medical equipment available.

There are risks associated with inadequate training for staff in the use of medical equipment, and in failing to have in place clear protocols for identifying which staff can specify the need for a particular piece of equipment. Figures from the MDA indicate that patients are three to ten times more likely to be at risk from user error than from faulty equipment<sup>3</sup>. It is a serious issue, therefore, that there were no formal documented training policies at more than 40% of trusts. Similarly, many trusts do not appear to have formal policies covering who can use the equipment, and who has the authority to decide on which item of equipment should be used.

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<sup>2</sup> Medical Devices Agency, HE198, 1991.  
<sup>3</sup> Devices & Desires, HSJ 7/5/98.

## Maintaining medical equipment

Effective maintenance is essential to minimise the risks of malfunctions and breakdowns. Maintenance and training are the two factors that the MDA cites as having the greatest impact on device safety<sup>4</sup>. We estimate that expenditure on the maintenance of medical equipment was in the region of £20 million in 1997/98, but again there are marked variations between trusts in maintenance expenditure as a percentage of the value of their equipment. Some of this variation will be explained by factors such as the range of equipment that is held and its age, but it is worthy of further investigation as part of the follow-up study.

Auditors raised a number of issues about the quality of maintenance.

- Some smaller trusts did not have clearly delegated responsibility for medical equipment maintenance.
- Only 30% of in-house maintenance departments were reported as being accredited under a recognised quality standard.
- The number of suppliers used by trusts varied widely, and was not explained by trust category or by the amounts spent on maintenance. Trusts should do more benchmarking to identify whether the number of suppliers could be rationalised to improve effectiveness and value for money.
- Whilst most trusts (90%) operate a system of planned preventative maintenance, six trusts reported that they do not.

In spite of these concerns, clinicians generally reported that they were satisfied with response times in the event of equipment failure and that interruptions to service were rare.

## Conclusion

There is room for improvement in the management of medical equipment. A common theme throughout the study was inadequate management information and reporting systems. In particular, given its strategic importance and clinical governance considerations, it is disappointing that at many trusts board members do not have access to robust information which would help them set priorities and manage the risks associated with medical equipment. For example, they need to ensure that they are aware of and understand the implications of any shortfall between depreciation and the combined capital and revenue purchases, since this is likely to affect clinical governance. Board members should ensure that responsibility for medical equipment is delegated to someone on the trust board. In turn they should ensure that good practice guidelines (outlined in Appendix 2, centrefold) are implemented and monitored.

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<sup>4</sup> Devices & Desires, HSJ 7/5/98.

# Introduction

## Why study medical equipment?

Medical equipment is essential to patient care. Ensuring that the right piece of equipment is available in the right place at the right time, together with staff trained to use it, is vital. Failing to ensure that medical equipment is available and used properly is increasingly likely to result in poorer patient care and extra costs through litigation. This means that trusts need to have adequate systems in place to manage their medical equipment.

The increasing sophistication of medical equipment can provide benefits to patients through:

- new, less invasive techniques
- better clinical outcomes
- shorter hospital stays.

There are also benefits to the NHS, including the ability to treat more patients, and lower diagnosis and treatment costs. However, medical equipment can also bring risks to patients and staff if it is not available when needed, and used properly. The level of risk is low compared with the number of medical procedures undertaken<sup>5</sup>, but trusts need to manage these risks as part of their duty of clinical governance<sup>6</sup>.

It is also important to achieve value for money in the use of medical equipment, since the resources involved are substantial. We estimate that, at 31 March 1998, the total value of medical equipment owned by NHS trusts in Scotland was more than £170 million. In 1997/98 trusts spent some £25 million on new and replacement equipment, and a further £20 million on maintenance. Charitable donations also contribute funds, particularly for medical equipment related to high profile conditions and services such as coronary care, cancer and children's services.

Medical equipment is wide-ranging and complex. Some items of equipment are high in cost but low in volume, such as magnetic resonance imaging (MRI) scanners; while others, such as intravenous (IV) systems, are low cost but high volume. Different issues will apply to each. The main issues in the purchase of high cost items such as MRI scanners are likely to be the need to prepare business cases, apply life cycle costing, and adhere to EC procurement regulations. For high volume items, trusts need to consider issues such as standardisation, inventories and asset control, and ensuring access, for example, by means of a pool or library system.

High cost items are likely to be funded from capital. Low cost items are often funded from revenue. Consequently, the financial information is not directly available from national returns and can only be obtained by directly surveying trusts. Our baseline for this study was the financial year 1997/98 and we collected data on both capital and revenue expenditure. It is our intention to undertake a further survey as part of our follow-up during 2001/02 and this will be based on 2000/01 data.

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<sup>5</sup> National Audit Office, *The management of medical equipment in NHS acute trusts in England*, 1999.  
<sup>6</sup> The Scottish Office Department of Health, *Designed to Care*, 1997.



There have been several initiatives to improve the management of medical equipment in Scotland, but improvements have not always been achieved in practice. A report commissioned by trust chief executives on supplies (including medical equipment), published in March 1997, set out the intention to take advantage of the combined purchasing power of the NHS in Scotland. In spite of this, a substantial proportion of medical equipment is still purchased at local level with no national coordination. The reduction in the number of trusts from 1 April 1999, provided opportunities for trusts to improve their management of medical equipment, by rationalisation and collaboration, and by identifying and sharing good practice.

This report considers the strategic management of medical equipment in NHS trusts in Scotland, its funding and acquisition, its use and how it is maintained. It contains information on NHS expenditure, activity and management processes, together with guidance on good practice.

### Approach

We consulted widely with stakeholders, including clinicians who use equipment, technical experts and supplies specialists, at both local and national levels. Consultation was achieved principally through site visits and through our advisory panel (Appendix 1).

A study guide was developed containing good practice guidelines, particularly those from the Medical Devices Agency (MDA). These guidelines are reproduced in Appendix 2, centrefold, for use by both audited bodies and appointed auditors in assessing local practice.

All trusts and island boards were asked to submit responses to a data collection questionnaire covering financial issues and basic management arrangements. A response rate of 92% was achieved, with 43 trusts and three boards submitting returns. Based on this information and on local knowledge, appointed auditors agreed with trusts whether to undertake further work. As a result the study was undertaken to overview stage at 27 trusts, and in seven cases a more detailed study, leading to a full report, was carried out.

This report examines the performance of trusts in managing medical equipment against good practice guidelines. There are three main sources for our findings:

- Audit Scotland<sup>7</sup> questionnaire (46 responses: although not all questions were answered completely)
- auditors' overview reports (27)
- auditors' full reports (7).

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<sup>7</sup> Staff of the Accounts Commission managed the study. These staff transferred to Audit Scotland in April 2000. References in this report are therefore to Audit Scotland.

# Strategic management

Ensuring that trusts have the right medical equipment in the right place at the right time requires sound strategic management. Trusts need good leadership, robust policies and the management information to ensure that medical equipment policies are being implemented. Their purchasing decisions should be based on formal needs assessments.

## Leadership, policymaking and management information

The strategic importance of medical equipment and the need for leadership, suggest that there should be clear responsibility for this issue on the trust board, together with sound policies (Exhibit 1) and robust management information systems. This is particularly important given the duty of clinical governance for trusts.

### Exhibit 1: Coverage of policy for medical equipment

In accordance with good practice, a formal documented policy should cover the whole system of medical equipment, including:

- consideration of impact on buildings, including mechanical and electrical services
- needs assessment and specification, incorporating standardisation issues to ensure that safety is enhanced and costs are minimised
- funding and acquisition, including aggregation issues so that the benefits of large scale contracting are achieved
- utilisation
- maintenance.

The arrangements for delegating responsibility for medical equipment are likely to vary among trusts. In some trusts, responsibility may lie with an individual such as the medical director. However, given the importance and complexity of medical equipment issues, it is likely that many trusts will have delegated responsibility to a multi-disciplinary group, or will have such a group working in an advisory capacity. The most appropriate arrangements will depend on factors such as trust size and type. There is no single solution.

The price of goods is only one factor to be considered for medical equipment: skilled purchasing has to take account of the clinical problems involved and what will result in the optimum patient care. Trusts should be able to demonstrate that their arrangements take account of the needs and preferences of users, and support consistent and well controlled policy-making and implementation.

Robust and timely information is required to support strategic and operational management of medical equipment. Without this information:

- patient care may be put at risk if medical equipment cannot be located promptly
- trusts may be unable to make rational long term plans for their future equipment needs
- they are less likely to be able to make efficient use of medical equipment, and plan maintenance effectively.

### Findings

We found some examples of good practice where trusts had in place appropriate arrangements for medical equipment. However, in six trusts (22 %) overall responsibility was unclear. In addition we found that at some trusts there were several officers involved but with no obvious board involvement. It would appear therefore, that some trust boards still treat medical equipment purely as an operational supplies issue.

Formal policy-making is the exception rather than the rule: only 11 out of the 27 trusts had an overall policy for medical equipment. Even for key aspects of medical equipment management, formal policies are lacking. For example, 18 trusts indicated that they had no formal policy on standardisation. It is unlikely therefore that they are maximising the benefits expected from standardisation that include:

- improved safety by reducing the risk of user error
- reduced costs of servicing, spares and training
- discounts by aggregating orders at local, regional or national levels.

Monitoring information about medical equipment seldom reaches board level. We did find an example of good practice whereby a Medical Equipment and Devices Committee monitored and reported on key issues. However, most boards seem to be unaware of their trust's performance in relation to medical equipment, suggesting that they cannot be confident that their management arrangements are supporting value for money and meeting governance requirements.

In addition to equipment inventories, information on equipment may be held in a variety of registers (eg. Finance, Directorate or Maintenance registers), each with their own specific purpose and which do not easily lend themselves to other uses. For planning purposes relevant data should be held on a single register. Whilst we do not underestimate the effort of maintaining a single register for this purpose, it is a key element of management information required to support decision-making.

### Needs assessment

It is essential that clinicians have access to the medical equipment they need to deliver high quality patient care. Medical equipment needs assessments must take a range of factors into account, including:

- the potential number and frequency of patients benefiting from the use of a particular piece of equipment
- the availability and efficacy of other devices or procedures which could achieve the same or similar results
- the consequences of the non-availability of the necessary equipment.

The frequency with which needs assessments are carried out will vary with the type of equipment under review. For those high cost items over the EU Procurement Directive threshold, there will also be a requirement to produce a

formal business case including life cycle costing. There is no single 'right' solution, but the process should ensure that the views of representatives of all those involved are taken into account. This may include:

- patients, where appropriate
- clinicians
- technical advice, for example from medical physics staff
- the health board (especially for high cost items to ensure that levels of provision are appropriate on an area-wide basis).

A robust system of needs assessment is a key part of the management of medical equipment. It can contribute to improved value for money in two key ways.

1. Trust management should seek adequate data to inform decision-making, thus ensuring that any proposal for investment is in line with trust priorities and that a net benefit can be demonstrated.
2. When considering how to respond to the needs assessment, trusts are in a position to review, and strengthen where necessary, key aspects of medical equipment policy. For example, they might choose to tighten up on their standardisation policy or they might choose to pursue a more vigorous procurement policy by aggregating purchases at local, regional or national levels in order to reduce costs.

### *Findings*

In general auditors were satisfied with needs assessment at their trusts in relation to high cost items. They confirmed that trusts do generally adopt a multi-disciplinary approach and that business cases demonstrating expected net benefits are generally produced in line with requirements. There were, however, some exceptions (Exhibit 2).

#### **Exhibit 2: Examples of poor practice in managing medical equipment**

Out of seven full audit reports there were:

- two instances of a CT scanner being purchased without a business case being prepared
- two instances of a failure to undertake full life cycle costings for high cost items
- one instance where funds were made available to purchase equipment without an allowance for maintenance and servicing being made
- two instances where gifts or 'free on loan' items were accepted without due consideration of the full financial implications of eg, consumables and training
- one instance where clinicians did not want to be involved in needs assessment since they perceived it would only add to their burdens.

Formal needs assessments were less common for low cost, high volume items with decisions being left to delegated budget holders.

## Planning to procure

Planning to procure comprises two elements:

- the specification process
- the purchasing decision.

### *The specification process*

The specification is an important aspect of the acquisition of medical equipment, and it requires multi-disciplinary input to ensure that user needs are met. A specification aims to set out clearly the description of the customer requirements, and it should be the document against which tenders can be compared. In order to compare like with like, the specification should be unambiguous about which facilities or features are mandatory and which are merely desirable. A balance needs to be struck between taking account of user preferences, and writing the specification in a way that may limit reasonable competition.

The timing and frequency with which specifications are required will depend on the nature of the equipment under review, particularly the value of the equipment and the pace of technological change. For high cost items, the specification is likely to be reviewed at the start of each procurement; for low cost items, bought on a regular basis, reviews are likely to be much less frequent. Trusts should ensure not only that the process for drawing up specifications is robust by involving an appropriate mix of users, but also that specifications exist and are sufficiently up-to-date.

### *Findings*

Auditors reported that a multi-disciplinary approach is the norm. Medical physics departments play a major role in producing specifications. There may also be substantial assistance and involvement, depending on the type of equipment, from users, supplies departments and other technical staff.

For high cost equipment, trusts generally used local variations on standard national specifications, where these are available, or sought assistance from Scottish Healthcare Supplies (SHS). Interview findings confirmed that local needs had been taken into account by involving user, technical and procurement representatives, although in four trusts there was little documented evidence of this taking place.

For low cost equipment purchased on a regular basis, only 13 of the 27 overview reports indicated that trusts had developed standard specifications. Some of those who had them qualified their response indicating that full coverage had not yet been achieved. Clearly, this has implications for procurement since it limits the likelihood of standardisation and the potential for aggregation to maximise purchasing power.

### *The purchasing decision*

The purchasing decision involves determining whether, what and from whom to purchase. Because of the importance, sensitivity and complexity of this it is likely that a multi-disciplinary approach will be required.

There are significant benefits to be gained by sharing knowledge and aggregating purchases both of high cost and high volume items of equipment. Trust policies should maximise the cost and quality gains by making full use of national, regional and local contracts and purchasing arrangements. NHS MEL(1992)4 emphasised the potential for maximising value for money and for ensuring reliable sources of supply. The recent re-configuration of trusts,

together with the shift to a more collaborative approach, should have removed some of the barriers that previously prevented trusts from making the most of aggregating purchases. A recent example of national coordination of a 'one off' bulk purchase was for the purchase of radiotherapy equipment resulting in an estimated 20% (£1million) saving for the health service.

Aggregation is possible where users can be persuaded to standardise on makes and models of equipment. Standardisation needs to be handled sensitively since purchasing decisions need to take account of a legitimate element of clinician choice. Standardisation itself also carries risks, for example:

- a potential over-dependency on one supplier in the event of a recall of equipment
- the possibility of tying the organisation into a particular product or range of products.

Nevertheless, where it can be achieved, there are substantial potential benefits. Consequently, we sought to identify the extent to which trusts had standardised on three common groups of equipment: IV systems, defibrillators, and endoscopes (Exhibits 3 to 5).

The choice of supplier will depend on the particular piece of equipment under review. In some cases (particularly for high cost items) the health service may be limited to dealing with a single supplier. More usually, some element of competition is possible, and the decision about which supplier to use should be driven by the suppliers' proposals in response to the specification. Issues to be considered by trusts when awarding contracts include:

- price
- quality
- opportunities for standardisation and aggregation
- user feedback
- service history
- maintenance and training support.

In addition for high cost items trusts need to consider:

- technical capabilities
- back up requirements
- cost of consumables.

It is unlikely that trusts will be able to meet all the identified needs for medical equipment, which means that priorities will have to be established. Trusts should identify the case for:

- increasing existing stock because patient activity has increased
- replacing equipment with either an existing or a new model
- introducing a new item of equipment to extend the range of clinical facilities available.

This case should also include the estimated total costs involved and priority ratings. Since the availability of funding is a constraining factor, those responsible for procuring equipment need to know as soon as possible what monies they can access.

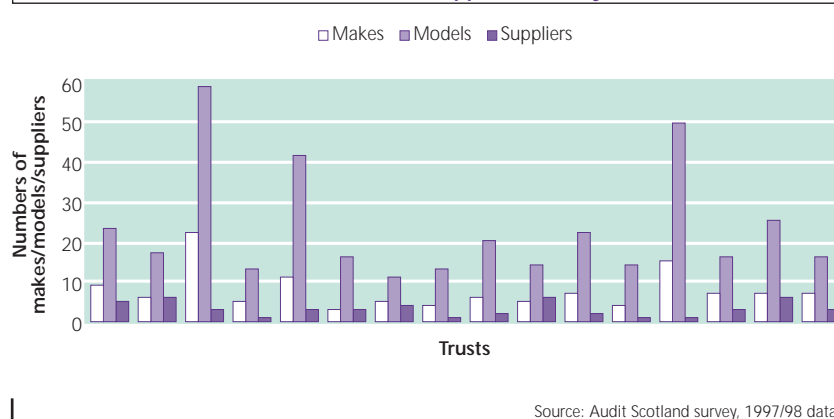
### Findings

From the survey, site visits and auditors' reports the main findings were that:

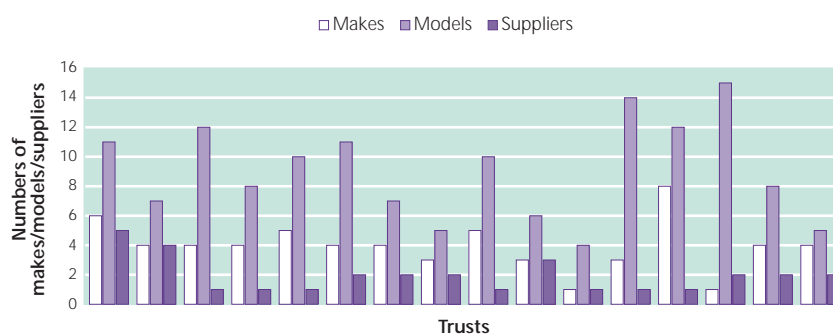
- all trusts covered by our review did take a multi-disciplinary approach. Auditors reported that directorate staff and business managers, who ensure the input of clinical, financial and technical staff as required, coordinate this. Where trusts do not have skills in-house for procuring particular items of equipment, they seek assistance from, for example, SHS either by using their contracting services or by obtaining advice on an ad hoc basis.
- despite the acknowledged advantages to be achieved from aggregation, this is not being actively pursued. Neither trusts nor SHS have formal agreed criteria for determining how different items of equipment should be purchased. The optimal means of procuring some items might be through national coordination of a one off bulk purchase; some might be better suited to national call off contracts; others might best be procured at regional or local level.

There are significant variations between trusts in the choice of suppliers, makes and models for common groups of purchased items as demonstrated in Exhibits 3 to 5. Many trusts were unable to provide the basic information we required since we received just 16 responses to this part of our questionnaire. Exhibits 3 to 5 show the ranges of makes, models and suppliers reported for IV Systems, defibrillators and endoscopes at 13 acute and three non-acute trusts. We found that endoscopes were procured locally in 1997/98 although there may have been scope to achieve savings if the combined purchasing power of the health service had been used. For the other two pieces of equipment, we cannot readily tell, from trust records, the expenditure in 1997/98 on contracts arranged by SHS. However, SHS do obtain "take up" figures from suppliers.

Exhibit 3: Number of makes, models and suppliers of IV Systems

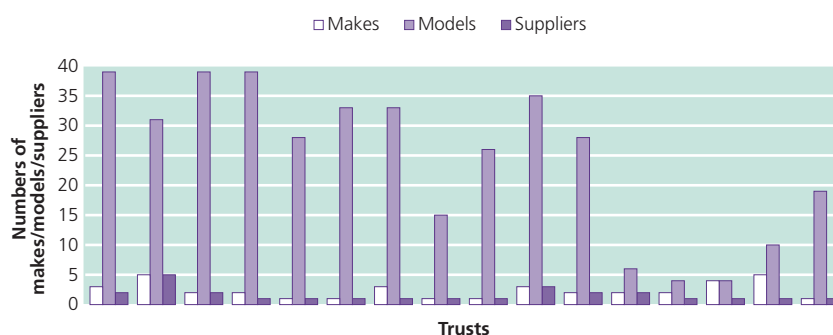


**Exhibit 4: Number of makes, models and suppliers of defibrillators**



Source: Audit Scotland survey, 1997/98 data

**Exhibit 5: Number of makes, models and suppliers of endoscopes**



Source: Audit Scotland survey, 1997/98 data

All trusts were able to demonstrate that they took a range of appropriate factors into account when determining which supplier should be awarded the contract. Bids for equipment funding always outstrip monies available so all trusts are required to prioritise. For high cost equipment this is generally done by a formal multi-disciplinary group; for low cost equipment this is generally delegated to budget holders.

In the main, trust boards are not involved in prioritising medical equipment expenditure which, given its clinical importance, is a cause of concern. Auditors reported little evidence of actual board level discussions either in relation to priority setting or to monitoring the implementation of funding policy. Consequently, we noted few good examples of boards taking funding decisions based on robust management information, including formal risk analyses, although there were some notable exceptions (Exhibit 6).



#### Exhibit 6: Good practice from board involvement

- One trust board considers reports from a joint medical equipment committee on a regular basis.
- A medical director at one trust had drawn members' attention to the fact that insufficient funds were available to match depreciation on equipment.

### Recommendations

*Using the good practice outlined in Appendix 2 (centrefold), trust boards need to ensure that:*

- *they are satisfied that their strategic management of medical equipment is effective*
- *they have information to monitor trust performance in the management of medical equipment*
- *medical equipment allocations and expenditure patterns reflect trust priorities.*

*In addition, trusts should ensure that:*

- *roles and responsibilities are clear*
- *policies are comprehensive and formal*
- *information is developed to support the monitoring of policy implementation*
- *source data from equipment inventories are robust and accessible*
- *clinicians are involved appropriately at each stage of the procurement process*
- *bidding procedures and priorities are clear*
- *purchasing decisions:*
  - *are safe, for example by standardising on equipment*
  - *are evidence based and supported by business cases, where appropriate, and always take full account of cost implications*
  - *take account of the potential to maximise purchasing power by standardising on equipment and by aggregating contracts where possible*
- *the combined purchasing power of the NHS in Scotland is used when appropriate.*

# Funding and acquisition of medical equipment

## Funding

Consideration of the funding of medical equipment needs to take account of both its asset value and the annual expenditure associated with it. Trusts must set priorities for expenditure on equipment and be aware, as part of their risk management processes, of any shortcomings in their ability to meet medical equipment needs, since this is likely to affect clinical governance. When funds are limited, it is particularly important for trusts to consider other options for funding medical equipment.

## Findings

On the basis of our survey, we estimate that at 31 March 1998, the total net book value of medical equipment held by trusts in Scotland was in excess of £170 million. Individual holdings ranged from as little as £100,000 for a small trust to more than £12 million for the largest trusts. Trusts also indicated that they procured approximately £25 million of medical equipment (through capital and revenue expenditure<sup>8</sup>) and spent over £20 million on maintenance. Of the £25 million, approximately £17.5 million funded replacements, whilst the remaining £7.5 million was for new developments.

Sources of funding for medical equipment, at March 1998 by value were:

- 91% owned
- 7% gifted, on loan or held under a similar agreement
- 2% leased.

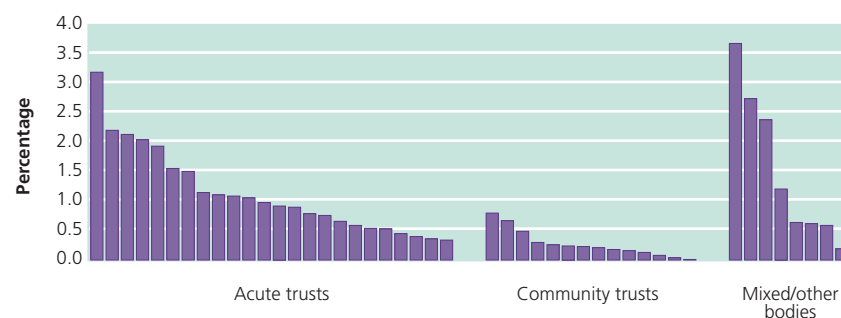
Thus, despite resources being limited, there is little evidence to suggest that trusts are pursuing alternative approaches to funding medical equipment.

Our findings highlight two main issues:

- variations in expenditure between trusts
- depreciation levels.

A marked variation in standardised expenditure, shown as a percentage of trusts' operating income, among trusts, is shown in Exhibit 7.

**Exhibit 7: Medical equipment expenditure as a percentage of operating income**



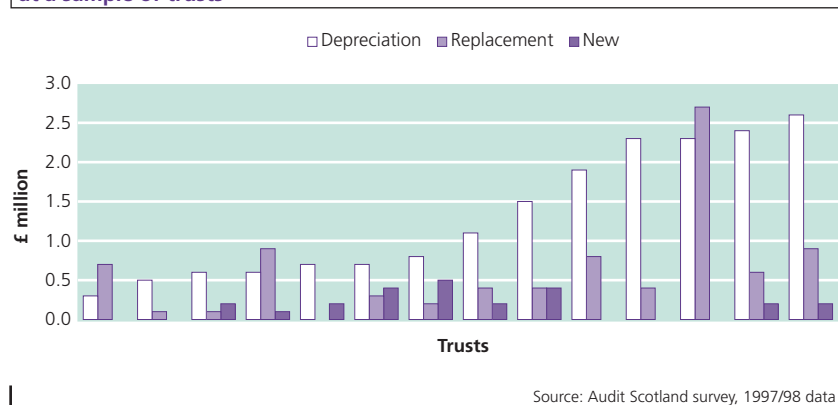
Source: Audit Scotland survey, 1997/98 data

<sup>8</sup> This £25 million represents total expenditure, comprising both capital and revenue monies since many low cost/high volume items are purchased from revenue.

These figures relate to only one financial year and so too much should not be made of them. However, if they reflect established expenditure trends, then it is likely that some trusts will face increasing problems due to systematic, significant under-investment.

Our survey findings also suggest that, across Scotland, expenditure on new and replacement medical equipment is failing to match depreciation, and that trusts are not replacing items of medical equipment when they come to the end of their useful lives. This is reflected in the failure at 28 trusts<sup>9</sup> to provide sufficient funds for new and replacement equipment to match depreciation in 1997/98. The total shortfall reported for these trusts was £13.1 million. This is likely to be exacerbated by a generally upward trend in replacement costs for many items of equipment. In 1997/98, for the whole of Scotland, trusts reported £33 million depreciation against combined capital and revenue purchases of £25 million, leaving an overall shortfall of approximately £8 million. The pattern varies as shown for a sample of trusts in Exhibit 8.

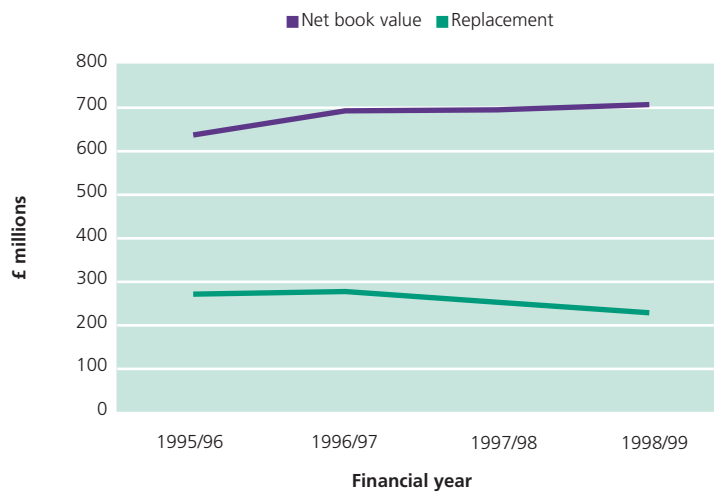
**Exhibit 8: Depreciation and expenditure on replacement and new equipment at a sample of trusts**



Again, the figures represent a snapshot so the extent of the problem depends on whether this reflects a real trend. In order to establish this, we reviewed trust annual accounts over a four year period from 1995/96 to 1998/99. At this level, we were only able to look at total equipment (including medical equipment) figures. We examined the changes in the estimated replacement value of all equipment and how these compared with the net book value (NBV) over a period of four years. Increases in the NBV did not keep pace with increases in the estimated replacement cost. Indeed, the gap between these two values is increasing overall in Scotland (Exhibit 9). From this we conclude that trusts' expenditure levels appear to be failing to permit them to maintain and extend their stock of equipment.

<sup>9</sup> Audit Scotland questionnaire.

**Exhibit 9: Depreciation of all equipment over a four-year period, 1995-1999**



Source: National Audit Office summarised accounts of the NHS in Scotland, 1995/96 - 1998/99

Concern about trusts' ability to replace medical equipment continues. Members of the Scottish Parliament have expressed concern about the practice of trusts using monies allocated to capital to fund other expenditure. Neither are concerns restricted to the NHS in Scotland. In England, a recent study<sup>10</sup> concluded that there had been an estimated 20 years of under-funding of equipment so that:

- more than half the anaesthetic machines in use are more than five years old and should be replaced
- almost a fifth of the equipment used in cancer treatment is obsolete.

Figures on out-of-date equipment need to be treated with caution since the useful life of an item of equipment may well outstrip the period over which it is 'written down' for financial purposes. Where equipment is working well, can be maintained and is still fit for purpose, there is no need to replace it. Even so, trusts need to beware that significant use of ageing equipment places increasing reliance on the manufacturers and, if they pull out of supporting the equipment, the equipment will need to be replaced in a short period of time.

The Scottish Executive has already taken two steps to address these funding issues.

- In March 2000, they issued an instruction that capital to revenue transfers are no longer permitted in order to enable trusts to meet their financial targets.
- In July 2000 the Health and Community Care Minister announced a £30 million boost to capital expenditure of which £16 million was earmarked for specific items of medical equipment covering MRI scanners, (£5 million) and cancer imaging equipment, (£11 million). This procurement is to be co-ordinated nationally.

<sup>10</sup> 'Out of Order', HSJ 17/8/00.

## Appendix 2: Good practice checklist for self-assessment

These 'pull-out' good practice guidelines derive from work carried out by the Medical Devices Agency and are reproduced as part of Audit Scotland's *'Equipped to care – Managing medical equipment in the NHS in Scotland'* (2001).

Trusts and appointed auditors are expected to use these materials to assess local practice.

Issue	Good practice
<p><b>Policy and planning</b></p> <p>1. Responsibility for medical equipment policy</p>	<ul style="list-style-type: none"> <li>✓ it should be clear who has been delegated <b>overall</b> responsibility for medical equipment policy development/implementation within the trust. Where responsibility is shared, it is particularly important that the boundaries of roles and responsibilities are clearly defined</li> <li>✓ clarity regarding the person(s) with responsibility for device management should cover the whole system pertaining to medical equipment embracing: <ul style="list-style-type: none"> <li>– needs assessment</li> <li>– specification</li> <li>– decisions to procure – financing/purchasing</li> <li>– utilisation (including training and safety issues)</li> <li>– maintenance (including training and safety issues)</li> </ul> </li> <li>✓ policies should address the whole medical equipment system</li> <li>✓ the systems for taking account of user views should be set out clearly and followed in practice</li> <li>✓ the systems in place to monitor the implementation of policy should be set out clearly and followed in practice.</li> </ul>
<p>2. The needs assessment process</p>	<ul style="list-style-type: none"> <li>✓ there is multi-disciplinary and, where appropriate, end user input into the process</li> <li>✓ for single items over the EU Supplies Directive threshold (or less if national guidance /local Standing Financial Instructions require), a full business case is required including the results of a formal needs assessment</li> <li>✓ for high volume/low cost items, a rolling programme of needs assessment reviews is undertaken to confirm that needs are still being met</li> <li>✓ the frequency of reviews for particular items is dependent on the nature of the market, eg the pace of technological change underway.</li> </ul>

Issue	Good practice
3. The specification process	<ul style="list-style-type: none"> <li>✓ there is a clear policy on when a formal specification should be (re)produced</li> <li>✓ all those with a legitimate interest have been represented in the specification process</li> <li>✓ the specification is sufficiently generic not to limit competition unnecessarily</li> <li>✓ the mandatory requirements and criteria against which tenders will be assessed are clear</li> <li>✓ where they exist, UK, European and international standards should be used.</li> </ul>
4. The purchasing decision process	<ul style="list-style-type: none"> <li>✓ all those with a legitimate interest will have been represented in the decision making process</li> <li>✓ the funding available for medical equipment should be made clear as soon as possible to those with responsibility for disbursing it</li> <li>✓ budget holders should have a clear system for prioritising planned expenditure</li> <li>✓ the system should take account of the possibility of additional monies becoming available during the course of the financial year, and be capable of ensuring late allocations address stated priorities</li> <li>✓ there are clear criteria for determining specific purchases and choice of supplier</li> <li>✓ net benefits are evident before the decision to procure high cost items is made</li> <li>✓ the estimated net benefit of significant groups of items is reviewed in a rolling programme over time.</li> </ul>

Issue	Good practice
<p><b>Procuring and financing</b> 1. Managing the purchasing process</p>	<ul style="list-style-type: none"> <li>✓ the elements of the procurement system are clearly understood and followed through in practice</li> <li>✓ instructions are clear to staff in terms of what arrangements apply in different procurement circumstances eg,               <ul style="list-style-type: none"> <li>– high cost / low volume versus low cost / high volume situations</li> <li>– authority to order versus indent in different situations</li> </ul> </li> <li>✓ arrangements are responsive to user needs eg, in terms of product selection and availability</li> <li>✓ arrangements ensure compliance with legal requirements eg EC procurement legislation</li> <li>✓ arrangements ensure compliance with the trust's own Standing Financial Instructions/ Procedures.</li> </ul>
<p>2. Financing medical equipment</p>	<ul style="list-style-type: none"> <li>✓ there is board level discussion re: the relative merits of medical equipment needs versus other trust expenditure priorities in light of available funds</li> <li>✓ trust policies exist covering planned procurement/maintenance for medical equipment, and their implementation is monitored with significant variances highlighted at board level</li> <li>✓ when contracts with suppliers are being negotiated, alternative financing arrangements should be explored and evaluated</li> <li>✓ any leasing arrangements are carried out in accordance with generally accepted accounting principles</li> <li>✓ formal risk analyses are undertaken and results made available at board level.</li> </ul>



Issue	Good practice
3. Non-ownership issues	<ul style="list-style-type: none"><li data-bbox="976 357 1962 448">✓ clear arrangements are in place for ensuring that the appropriate finance representative is involved at an early stage in any acquisition of equipment that might have significant financial implications eg. in terms of either purchase or running costs</li><li data-bbox="976 475 1962 512">✓ indemnity forms are used for borrowed equipment.</li></ul>

Issue	Good practice
<p><b>Using medical equipment</b> 1. Accessing equipment</p>	<ul style="list-style-type: none"> <li>✓ documentation and/or advice is readily accessible to clinicians on: <ul style="list-style-type: none"> <li>– what types of device are available</li> <li>– the location of devices which are currently in service</li> <li>– how devices can be accessed</li> </ul> </li>   <li>✓ procedures for the delivery and continuing use of devices (regardless of their source) are in place and implemented</li>   <li>✓ procedures for the delivery and commissioning of new devices (regardless of their source) are in place and implemented</li>   <li>✓ users are aware if they are first to use a new device</li>   <li>✓ procedures for starting to use a new device are available/in use and cover the checklist suggested by the Medical Devices Agency</li>   <li>✓ the system for deploying devices is reviewed formally at appropriate intervals, to consider the benefits of a pooling versus an “ownership” approach for the various types of devices</li>   <li>✓ the system in place is monitored to ensure benefits are maximised and weaknesses minimised</li>   <li>✓ manufacturers’ recommendations are followed so that a planned programme of maintenance is undertaken</li>   <li>✓ users are aware of how to ensure their supply is not disrupted eg, routine versus emergency indenting/ordering</li>   <li>✓ utilisation records are available, monitored and managed.</li> </ul>

Issue	Good practice
2. Knowing how to use medical equipment	<ul style="list-style-type: none"> <li>✓ users and technical staff are made aware of the capabilities and limitations of the device</li> <li>✓ manufacturers instructions for commissioning/maintaining equipment are available and followed by technical staff and users</li> <li>✓ formal training programmes (covering use and safety issues for both replacement and new equipment) are in place and being implemented</li> <li>✓ training is recorded and results are documented (eg, via certificates)</li> <li>✓ training implications considered when devices are borrowed</li> <li>✓ standardisation policies are in place and implemented to ensure that training issues are minimised</li> <li>✓ instances of returned items for repair/maintenance which prove not to be faulty are followed up as potential staff training issues.</li> </ul>
3. Which device?	<ul style="list-style-type: none"> <li>✓ procedures and policies have been introduced and are monitored to ensure that the prescription of different types of equipment is undertaken by suitably qualified and experienced staff</li> <li>✓ policies are reviewed regularly to ensure that they continue to be based on reliable information and are not too rigid</li> <li>✓ staff are clear about their delegated responsibilities</li> <li>✓ prescribers have access to administrative and technical support.</li> </ul>

Issue	Good practice
4. When things go wrong...	<ul style="list-style-type: none"> <li>✓ a policy of planned preventative maintenance is in place and implemented to minimise the risk of breakdown</li> <li>✓ stock levels/maintenance policies take account of the risks of the impact of breakdowns and the withdrawal of the device from service</li> <li>✓ policies on dealing with faulty equipment/inappropriate use are documented and their implementation is monitored</li> <li>✓ staff are trained to recognise and to correct malfunctions (and, when necessary, know the procedures for withdrawing the device from service)</li> <li>✓ inventories are documented to permit the efficient and effective withdrawal of devices from use eg, due to a supplier recall</li> <li>✓ devices are decommissioned if any of the following criteria apply: <ul style="list-style-type: none"> <li>– worn out beyond economic repair</li> <li>– damaged beyond economic repair</li> <li>– unreliable (per service history)</li> <li>– clinically or technically obsolete</li> <li>– spare parts no longer available</li> <li>– availability of more cost effective or clinically effective devices.</li> </ul> </li> </ul>

Issue	Good practice
5. Using in-house/modified/refurbished/cannibalised equipment	<ul style="list-style-type: none"> <li>✓ devices follow the same rules for acceptance/use of equipment regardless of source</li> <li>✓ in-house/modified/fully refurbished devices comply with Medical Devices Regulations and are controlled by senior technical staff</li> <li>✓ refurbishments are carried out by authorised personnel in line with manufacturer's instructions</li> <li>✓ cannibalisation is avoided wherever possible but is always subject to approval by senior technical staff.</li> </ul>
6. Using equipment that is not owned	<ul style="list-style-type: none"> <li>✓ the same rules apply for delivery, acceptance testing and training as for owned equipment</li> <li>✓ staff are aware of the dangers of use of certain items eg. mobile phones in terms of their potential effect on sensitive medical devices. (Management should take reasonable steps, both to make the public aware of such dangers and to ensure that staff are informed of what action should be taken to stop their use in specified areas.)</li> </ul>

Issue	Good practice
<p><b>Maintaining medical equipment</b></p> <p>1. Who is responsible for maintenance?</p>	<ul style="list-style-type: none"> <li>✓ there is clear division of responsibilities between those involved</li> <li>✓ there is good communication and free access to information by all</li> <li>✓ a routine maintenance policy is in place and implemented</li> <li>✓ planned preventative maintenance is well organised</li> <li>✓ training to meet maintenance requirements is identified and provided to all those involved.</li> </ul>
<p>2. Who undertakes maintenance?</p>	<ul style="list-style-type: none"> <li>✓ there is compliance with Medical Devices Agency guidance on providing an effective maintenance service</li> <li>✓ formal consideration is given to the advantages and disadvantages of in-house versus external service provision.</li> </ul>
<p>3. Routine/planned preventative maintenance</p>	<ul style="list-style-type: none"> <li>✓ users have appropriate training on routine maintenance</li> <li>✓ documented instructions on routine maintenance and device management are available and in use</li> <li>✓ documented procedures for dealing with cleaning and decontamination are available and in use</li> <li>✓ procedures are in place to ensure that planned preventative maintenance complies with manufacturers' instructions.</li> </ul>

Issue	Good practice
4. When things go wrong ...	<ul style="list-style-type: none"> <li>✓ a clearly defined fault reporting system is in place</li> <li>✓ clear procedures for dealing with serious incidents are available and in use</li> <li>✓ maintenance cover decisions take account of the relative cost effectiveness of available options</li> <li>✓ repairs are carried out only by suitably qualified staff</li> <li>✓ temporary repairs are discouraged/only carried out in extenuating circumstances – the preferred option is that the device is withdrawn from service.</li> </ul>
5. Decommissioning	<ul style="list-style-type: none"> <li>✓ there is a clear decommissioning policy to ensure that devices which meet the following criteria are taken out of service: <ul style="list-style-type: none"> <li>– worn out beyond economic repair</li> <li>– damaged beyond economic repair</li> <li>– unreliable (per service history)</li> <li>– clinically or technically obsolete</li> <li>– spare parts no longer available</li> <li>– more cost effective or clinically effective devices have become available.</li> </ul> </li> </ul>





Our follow-up study of medical equipment will take a sample of types of equipment and collect information on the age and condition of these. This will include a consideration of the proportion of equipment that is past its 'write down' date and by how many years. We shall also review trusts' contingency planning arrangements for the replacement of existing equipment.

### Acquiring medical equipment

Most medical equipment (91%) is purchased directly by trusts with a further 2% being leased. Procurement arrangements vary between trusts depending on, for example, whether there is access to a local stores organisation. They also vary within trusts, depending on the nature of the procurement being undertaken and the availability of centralised contracts offering favourable terms for particular items. The arrangements need to be sufficiently flexible to take account of the different circumstances, while ensuring that adequate control is maintained so that all procurements comply with EC legislation and Standing Financial Instructions (SFIs).

In addition, the timing of expenditure can be an issue when it has not been adequately planned. The MDA states that

*“trusts should avoid the hurried or unstructured purchase of medical equipment at the end of a financial year since this may preclude rational selection”.*<sup>11</sup>

The findings of a NAO report support this view. They indicated that suppliers were concerned about the trend in NHS year end spending, and concluded that such trends were not conducive to effective purchasing<sup>12</sup>.

For medical equipment, which is donated or on loan, the issues for trusts are different. They should, for example, identify and evaluate fully the implications before any decision on acceptance or use is made. The implications include:

- any additional costs arising from commissioning the equipment and associated staff training
- clear lines of responsibility for the revenue consequences (for example, materials costs, maintenance and repairs) of accepting and using the equipment
- the financial consequences of any risk of litigation arising from the use of the equipment.

### Findings

Auditors reported that compliance with EC legislation and SFIs is well coordinated by finance departments. Even in cases where formal documentation was lacking, auditors indicated that there appeared to be a good level of staff understanding about procurement processes and requirements.

Trusts were consistent in applying financial and quality standards regardless of whether medical equipment was owned or acquired by means other than purchase or lease.

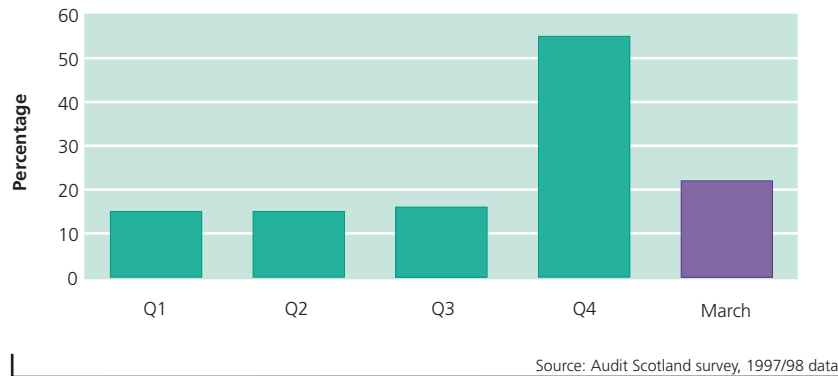
The pattern of expenditure in Scotland throughout 1997/98 was very uneven (Exhibit 10).

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<sup>11</sup> Medical Devices Agency, HEI 198, 1991.

<sup>12</sup> National Audit Office, 'The management of medical equipment in NHS acute trusts in England', 1999.

**Exhibit 10: Percentage expenditure on medical equipment by financial quarter and final month**



Nearly half the trusts reported that more than 50% of their expenditure was incurred in the final quarter. On an all Scotland basis, we estimate that over 20% of expenditure was incurred in March alone. The fact that not all trusts supplied information is unlikely to significantly affect the above representation. Possible reasons for the pattern are:

- the length of the formal procurement process to meet SFI and legal requirements. For example, even using the accelerated EC procurement procedure, the process will take at least eight to nine months
- long delivery plus installation and commissioning times
- late allocations of funds which may have become available for reasons outwith the trust's control
- significant other pressures on staff time
- the need for year end cash management
- poor planning and management.

Some trusts were unable to provide basic management information on the quarterly breakdown.

## Recommendations

*Trust board members and managers should ensure that:*

- *all potential sources of funding are considered*
- *the level of investment in medical equipment adequately supports clinical governance. In particular, due attention needs to be paid to monitoring the levels of equipment depreciation and having in place a system for prioritising replacements.*
- *purchases are made on the basis of rational selection and prioritisation, and year-end 'spending up' for cash management purposes is avoided as much as possible.*

## Using medical equipment

Medical equipment needs to be in the right place at the right time, together with staff trained to use it. Therefore, we aimed to identify:

- the level of equipment provision across trusts
- how users know what is available and how they obtain access to the equipment
- how staff know how to use equipment
- how staff decide on which device to use
- what happens when things go wrong
- whether staff are using equipment which has been made in-house, modified, refurbished or otherwise 'cannibalised'
- how equipment not owned by the trust is managed.

### Level of medical equipment provision

Trusts need to have sufficient medical equipment to support clinicians in the efficient and effective delivery of patient care. Excessive provision is wasteful, while under-provision threatens the effective treatment of patients. The activity and case mix of a trust will have an influence on the type of medical equipment held; for example a teaching hospital is likely to have more sophisticated and complex equipment than a general hospital; an acute hospital will have different needs to a primary care trust. The physical layout of a trust can also have a significant effect on equipment requirements – where sites are split, additional equipment may be required.

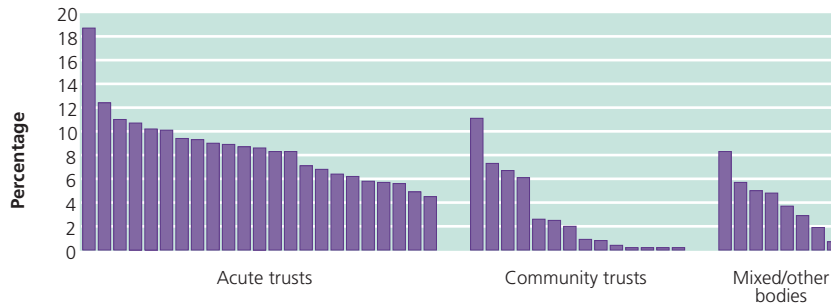
Trust managers need to show that they are managing equipment effectively. This includes:

- ensuring that there is no inefficient or excessive stocks of equipment but bearing in mind peaks and troughs in their required use
- producing management reports to identify potentially high or low usage
- benchmarking between and/or within trusts to assist in ascertaining cost effectiveness of holdings and identifying and sharing good practice
- monitoring access, storage, damage, breakdowns, maintenance and training.

Trusts should also have special arrangements in place to cover the introduction of new equipment. Special measures are required as records need updating, staff may need training, and planned preventative maintenance arrangements need to be put in place.

Exhibit 11 is based on Audit Scotland's survey returns and NHS annual accounts relating to 1997/98. NBV as a percentage of trust operating income is a measure that can be used to indicate trusts' levels of medical equipment provision. Any benchmarking should look at trends rather than simply a one-year snapshot. Nevertheless, this exhibit demonstrates that there are marked variations between trusts.

**Exhibit 11: Medical equipment net book value as a percentage of operating income**



Source: Audit Scotland survey and Annual Accounts, 1997/98 data

At this stage management information is not adequate to allow us to interpret these findings so considerable work needs to be done in this area. Two key issues that should be considered by those responsible for managing medical equipment are:

- how to improve the quality of management information in order to achieve a better understanding of what medical equipment is available, and to what extent it adequately meets need
- whether the use of medical equipment libraries or equipment pools would allow for a more intensive and effective use of equipment.

Twenty five trusts have undertaken a recent review of their medical equipment stock, but auditors found few examples of this type of information being reported at trust board level during 1997/98. Given the absence of formal reporting at some trusts, boards may be unaware of the issues. Consequently, it is likely that the underlying reasons and risks of current medical equipment provision are not being assessed adequately, and that insufficient action is being taken.

In terms of new items of medical equipment, our survey findings indicated that, while arrangements may vary, 39 trusts had documented procedures for accepting and testing of new equipment. Most trusts had satisfactory arrangements in place for on-site commissioning of equipment. These arrangements varied, with the work involving a combination of suppliers, estates departments, medical physics staff or individual departments. In particular, medical physics staff were often involved in monitoring the quality of products against their specifications. However, the extent to which these activities were covered by formal procedures is limited.

### Accessing equipment

Access can be affected by a number of factors including:

- staff knowledge of the range of devices available
- staff knowledge of how to access the equipment for use or loan
- organisational issues and culture
- the supply of equipment in view of:
  - patient activity
  - repair/servicing programmes
  - poor response times from stores/ suppliers
  - losses.

The systems for accessing medical equipment vary between trusts and are influenced by factors such as trust size and the nature of the equipment. This means that there can be no prescriptive solution as to how staff should get access to the necessary equipment. Nevertheless, trusts should be able to demonstrate that the processes in place for accessing the various types of equipment adequately support clinicians in their delivery of care. An Audit Commission report<sup>13</sup> indicated that access was rarely considered but had a major influence on supplies (including medical equipment) expenditure. Consequently, trusts should be able to demonstrate that they do not carry unnecessarily high levels of equipment and that, for high cost items, utilisation rates meet those expected when the business case was approved.

While some staff use specialist equipment, many items of medical equipment are common between wards or departments. One way to ensure a more efficient use of equipment is through a medical equipment library (Exhibit 12). At a basic level, this could be an area where medical equipment is stored to enable staff from different departments to share in its use. Libraries featuring dedicated library staff would have the potential benefits of improving:

- the control over the issue and receipt of items
- monitoring of usage levels and identification of shortages or over provision
- facilities for cleaning, checking and maintenance work.

#### Exhibit 12: The benefits of medical equipment libraries

A National Audit Office report<sup>14</sup>, showed that 22% of acute trusts in England had a medical equipment library. Reported benefits included:

- helping with standardisation
- improving access
- safe storage and less breakages
- ensuring that equipment is complete with necessary accessories
- identification of training needs.

A case study of one hospital with a medical equipment library of 460 items reported the main benefits as:

- savings in nursing time spent looking for equipment
- regular checks on the condition and function of medical equipment
- more efficient use of medical equipment.

Larger high cost items of equipment are mainly service specific and therefore tend to be located and used in one place. Only minor problems were identified in cases where equipment was shared without recording transfers between wards and departments. However, poor tracking of equipment runs the risk of delayed access to vital equipment. In addition, there appears to be little evidence of monitoring actual, versus expected usage, as set out in the associated business case.

In the case of high volume/low cost items of medical equipment, clinicians were clear about how to access these. However, some trusts had no management systems to track or monitor usage. Where this is the case there is a risk of access problems along with a greater potential for losses but, without adequate management information, we cannot assess the extent of these. Where there are no access problems reported it might be that there is an element of 'local' over

<sup>13</sup> Audit Commission, 'Goods for your health - improving supplies management in NHS trusts', 1996.

<sup>14</sup> National Audit Office, 'The management of medical equipment in NHS acute trusts in England', 1999.

provision (ie, no proper tracking of equipment but no shortage or access problems reported).

We received 36 responses to our survey question asking if there had been a recent review of strategies for deploying and controlling medical equipment. Eleven trusts reported that reviews had led to the setting up of pooling or library arrangements. However, when asked for details of types of equipment included in pool or library arrangements, only six trusts specified more than a few items.

### Knowing how to use equipment

The availability of a particular piece of medical equipment is not sufficient in itself to support the delivery of patient care. It is also crucial that the equipment used is:

- suitable for its intended purpose
- properly understood by the professional user
- commissioned and maintained in a safe and reliable way, and in good condition.

The MDA views training, along with maintenance, as having the greatest impact on equipment safety. Figures from a 1998 survey by the Agency<sup>15</sup> indicated that a patient may be three to ten times more at risk from user error than from faulty equipment. Patient safety is paramount and this is recognised in legislation. The Health and Safety at Work Act 1974 requires that employees must be properly trained in the use of any equipment that they are required to operate. Trusts are at risk of negligence claims where incidents occur and staff are found not to be completely familiar with the equipment they are using. It is important therefore that an appropriate group such as a Medical Devices Committee oversees training issues.

We found a significant number of trusts (over 40%), which did not have documented policies on medical equipment training, although most auditors were able to confirm, via interviews with users and staff, that training requirements were satisfactorily dealt with through:

- fairly intensive induction courses with emphasis on items likely to be used
- identification of equipment only to be used by staff holding appropriate training certificates
- training provided by suppliers
- well maintained technical manuals.

However, there were two main exceptions to the above.

- One report expressed concern over the failure of some junior doctors to attend training courses, and the trust was advised to make training mandatory for all staff required to use medical equipment.
- With regard to manuals, there were mixed reports ranging from guidelines being held in all ward nurse stations, to 'not generally' or 'only for certain devices'.

### Deciding on which device to use

Trusts need to ensure that there is clarity about who may authorise the use of the various types of device for patients. The MDA has highlighted that the lack of clarity in defining the responsibilities of the various participants involved, and meeting their training needs, can lead to inadequate patient care and even harm. Given the complexity of issues to be taken into account when authorising and using equipment, clinicians should have access to administrative and

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<sup>15</sup> Devices & Desires, HSJ 7/5/98.

technical support systems. This will help them not only to ensure patient safety, but also to reduce the risk of litigation by avoiding hazards. The auditor's role in the study was not to question the clinical judgement of a prescribing decision, but to ensure that arrangements were in place to support clinicians.

Examples of good practice identified included good communications between clinicians and (mainly) bio-engineering or medical physics departments, and in many cases users confirmed this. We also noted that those responsible for authorising the use of different types of equipment were generally well supported by senior colleagues, clinical specialists and technical staff as appropriate. However, there was little evidence that this was an area which was subject to regular monitoring and review. This may have clinical governance implications.

### When things go wrong

Adopting the good practices highlighted in this report would assist trusts in ensuring patient safety. Even so, problems will arise from time to time due to:

- wear and tear on equipment
- human error
- new information becoming available on equipment quality and safety.

Trusts need to ensure that staff remain alert to the possibility of problems occurring and that they know how to anticipate and respond appropriately. This includes the formal reporting of adverse incidents to SHS who are in close touch with the MDA. The SHS collect the same basic safety information as the MDA but ensure that the political, legal and policy issues are covered for Scotland. In its latest annual report the MDA reported a 12% increase in the reported adverse incidents. The importance of reporting all incidents was cited in a *Health Management*<sup>16</sup> article:

*"The NHS has no reliable way of identifying serious lapses of standards of care, analysing them systematically, learning from them and introducing change which sticks so as to prevent similar events from recurring. Systematic reporting of near misses, an important early warning of serious problems, is almost non-existent across the NHS."*

New financial risk sharing arrangements for clinical risk negligence and certain non-clinical risk categories were introduced from 1 April 2000. The new scheme, Clinical Negligence and Other Risks Indemnity Scheme (CNORIS), is mandatory with contributions based on performance assessment against risk management standards. The application of CNORIS frameworks for risk assessment in relation to medical equipment will be an important element of our follow up study.

Most trusts have the necessary policies and procedures in place to minimise the risks of equipment breakdown or withdrawal from service. Our survey indicated that almost 90% of trusts have arrangements for planned preventative maintenance and more than 85% have managers with specific responsibility for maintenance issues. Most trusts reported that they had undertaken a recent formal review of the maintenance provision for equipment held.

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<sup>16</sup> 'The error of our ways', p14, Health Management Journal, August 2000.

Satisfactory contingency procedures were in place to cover urgent repairs, by way of loans, breakdown 'hotlines' to estates departments, controllers of pooled equipment or to suppliers. While these procedures may have dealt adequately with the immediate and vital problem of restoring service there were examples of trusts not recording fault and breakdown rates. Such information is important to managers in identifying 'suspect' equipment or possible staff training requirements. There were also only a few examples of trusts monitoring 'returned but no fault' rates – that is, where a piece of equipment that has been reported as faulty is checked and no fault found. These can indicate that staff training or re-training is required.

All trusts, with one exception, reported that they had documented policies on the reporting of adverse incidents [in line with the requirements set out in NHS MEL (1995)74]. We are advised by SHS that all trusts reported on adverse incidents. In 1997/98, 168 incidents were reported, and 245 reported last year. SHS's view is that there still exists an element of under reporting, and that one of the causes is fear of being "blamed" for user error. It is essential that all faults are recorded to ensure that staff training needs are identified and addressed. Trusts should communicate to staff the importance of safeguarding patient safety and hence the need to identify all adverse incidents.

### Using equipment made in-house, modified, refurbished or otherwise cannibalised

Medical equipment may be acquired by means other than from a manufacturer. For example:

- in-house, where medical physics personnel design and construct equipment
- where equipment is modified or used for a purpose not intended by the manufacturer, and which might result in limited manufacturer liability and legal action if an adverse event occurs
- 'cannibalising', where parts from one piece of equipment are used to replace broken parts in other bits of equipment.

In addition, staff may use equipment that has been:

- refurbished through routine cleaning and maintenance
- fully refurbished resulting in the equipment being reissued 'as good as new'.

Whatever the source, the concern at all times is to ensure patient safety. The MDA report<sup>17</sup> warns that great care should be exercised when modifying and refurbishing medical equipment. 'Cannibalisation' of devices is not recommended because:

- using parts of unknown quality and suitability could be negligent
- manufacturers will not accept liability
- traceability is impossible in the event of a manufacturer's recall.

Trusts do ensure that procedures include clear advice on the high levels of care and good technical judgement required. Senior managers and users alike were clearly aware of the risks and disadvantages of using equipment which had been modified. There were no reports of 'cannibalised' equipment in use.

### Using equipment that is not owned

Trust procedures and good practice apply equally to the use of medical equipment which is not owned by trusts. It is quite common for staff to be using equipment that was a gift or on trial from manufacturers. For equipment on loan from suppliers, it is essential that the trust obtain completed indemnity

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<sup>17</sup> Medical Devices Agency, 'Medical device and equipment management for hospital and community based organisations', 1998.



documentation unless covered by the SHS Indemnity Agreement. Work undertaken in acute trusts in England, by the NAO, had resulted in the identification of potential problems where procedures did not apply to equipment not owned by trusts. In Scotland, audit findings were satisfactory. Controls and good practice are applied generally, whether equipment being used by trusts is owned or not.

It is also important that trusts do not overlook the possibility that some items of electronic equipment could have serious adverse effects on sensitive medical equipment. A typical example of this is mobile phones being used by staff, patients or visitors, which can cause medical equipment malfunction. It is vital therefore that everybody is made aware of the dangers and that steps are taken to ensure compliance with instructions about the use of this kind of equipment. It is not clear what steps trusts are taking to ensure that risks to the trusts' sensitive medical equipment from personal equipment, such as mobile phones, are minimised.

## Recommendations

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*Trusts should:*

- *ensure that they have up to date information on the level of medical equipment available*
  - *monitor the use of medical equipment, paying particular attention to the way in which equipment for use is identified*
  - *introduce formal training policies for the use of medical equipment where these are not already in place*
  - *regularly review procedures to ensure that not only are the causes of medical equipment faults and misuse identified, but also that action is taken to minimise any recurrence. Staff should be encouraged to report all incidents.*
  - *maintain a watching brief to ensure that modified equipment is not being used at the risk of patient safety*
  - *ensure that staff, patients and visitors understand the potential dangers of using personal electronic equipment near sensitive medical equipment, and that systems are in place to ensure safe use.*
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# Maintaining medical equipment

Effective maintenance is essential for equipment to function as intended and to minimise risks to patients. Maintenance is one of the two factors (the other being training), that the MDA cites as having the greatest impact on equipment safety.

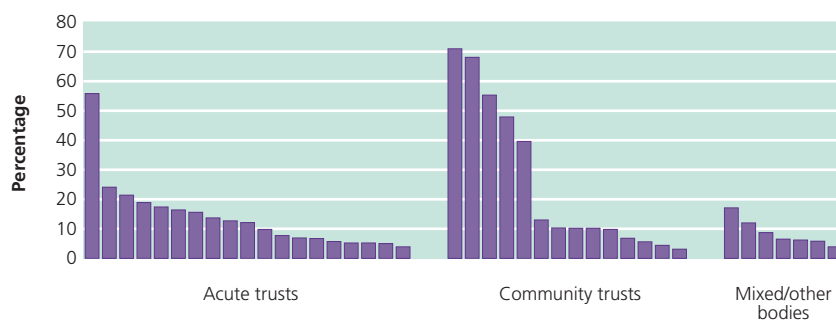
Consequently, we sought to identify:

- the level and range of expenditure on maintenance
- who is responsible for maintenance
- who undertakes maintenance
- the level of routine or planned preventative maintenance
- the procedures in place to address issues when things go wrong
- the arrangements for decommissioning.

## The level and range of expenditure on maintenance

In 1997/98 trusts spent over £20 million on maintaining medical equipment. This represents approximately 12% of the net book value of medical equipment in the NHS in Scotland. However, this varies considerably for a sample of trusts (Exhibit 13).

**Exhibit 13: Medical equipment maintenance expenditure as a percentage of net book value**



Source: Audit Scotland survey, 1997/98 data

Our review highlighted marked variations among trusts. As information in respect of the apparent outliers was subject to inspection and verification by local audit, we have no cause to exclude these from the exhibits. However, even without the very high percentages, the clear indication is that further investigation is desirable.

### Who is responsible for maintenance?

Keeping medical equipment working reliably and safely depends on multi-disciplinary collaboration involving:

- senior management
- technical staff
- clinical staff.

It is for management to decide on the most appropriate strategy for maintenance. They need to find the optimal balance between planned preventative maintenance and a repair on breakdown policy. In determining maintenance responsibilities and policy, trusts should also consider extending the procedures to include provision for replacing equipment. Good quality management information on maintenance will ensure that managers responsible for replacing equipment remain informed in relation to, for example:

- unacceptable levels of wear and tear
- damage
- unreliability
- obsolescence.

In larger trusts, maintenance issues are generally well co-ordinated through a medical equipment committee, individual directors, or managers with delegated responsibilities. In some smaller trusts, delegated responsibilities were not defined clearly and this must be addressed.

### Who undertakes maintenance?

In-house organisations, manufacturers or third party organisations may undertake maintenance and repair work. Given the range of medical equipment throughout a trust, it is likely that a combination of all three would be used. There are various pre-requisites which apply and which trusts should satisfy equally as part of their selection process for choice of maintenance organisation. The training of technical staff is certainly a key element of safe and effective maintenance work. Any servicing organisation or department must have properly trained staff, access to spare parts approved by manufacturers and adequate quality control. There is a widely held view that a fully qualified and experienced medical equipment maintenance engineer has the skills to deal with simple devices without undergoing a manufacturer's training course. In such circumstances, formal risk assessment should be undertaken before any decision is made.

The arrangements for maintaining medical equipment vary between trusts. Generally an individual trust uses both external contractors and in-house maintenance departments. It was not clear whether this was a position which has simply evolved over time or as a result of careful consideration of the relative advantages and disadvantages. Maintenance departments may vary in name but their functions are similar with regard to managing the maintenance of medical equipment.

There was a variety of responses to a question covering procedures for monitoring quality of maintenance provided. Estates and medical physics were the main departments involved. While incomplete returns may have affected our findings, we did note that only just over 30% of trusts reported being accredited under a recognised quality standard, most commonly quoted was ISO 9002. This is similar to the NAO survey results for acute trusts in England which indicated that 28% of in-house suppliers are accredited.<sup>18</sup>

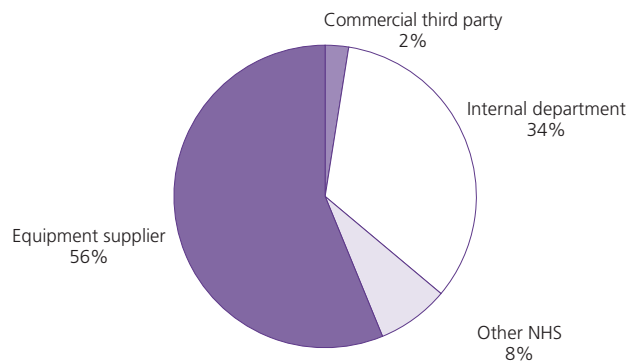
<sup>18</sup> National Audit Office, 'The management of medical equipment in NHS acute trusts in England', 1999.

Trusts also make 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
- third party who did not supply the equipment but offers a specialist maintenance service.

Exhibit 14 shows an analysis of maintenance expenditure by type of service provider during 1997/98.

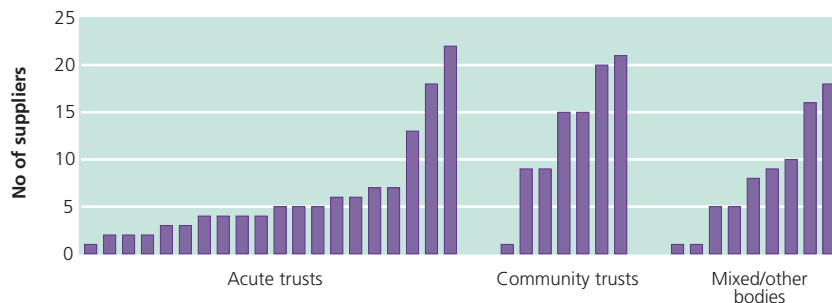
**Exhibit 14: Maintenance expenditure by type of supplier**



Source: Audit Scotland survey, 1997/98 data

Exhibit 15 shows the number of maintenance service providers per £50,000 expenditure on medical equipment maintenance. This exhibit is based on details reported to Audit Scotland by 34 trusts/island boards, and they identify wide variations even taking account of different trust types and sizes.

**Exhibit 15: Number of suppliers per £50,000 of medical equipment maintenance expenditure**



Source: Audit Scotland survey, 1997/98 data

There may be scope for rationalising the number of maintenance suppliers and improving value for money, particularly if trusts adopt more standardisation as discussed previously in this report (page 11). However, the same comments about standardisation bringing its own risks, also apply (page 12).

### Routine or planned preventative maintenance

Routine maintenance is carried out by users and involves simple equipment care, regular cleaning, preparation for use and device checking. Engineers or suitably trained technicians, in line with the manufacturer's instructions or with their express approval for any variations from those instructions, carry out planned preventative maintenance. Manufacturers' guidance on the frequency and details of checks and operations to be undertaken should be followed. The MDA guidance, is that, planned preventative maintenance maximises equipment availability and safety.

90% of trusts have planned preventative maintenance procedures, based on schedules determined by themselves, or by suppliers or a combination of both. The intention is that checks, adjustments, servicing and replacements are undertaken on a planned basis before breakdowns occur. However, six trusts said that they had no form of planned preventative maintenance, and 26 trusts reported that there were types of equipment for which they only had breakdown cover.

### When things go wrong

Faults may be discovered during a user's routine check or a device may break down. In either case, it is vital that the arrangements for reporting and dealing with the problem are in place, properly understood and followed. This may involve providing cover and either repairing or decommissioning the equipment. An efficient servicing organisation will aim for rapid recovery from breakdowns. The simplest method will often be to substitute a similar device, though this requires trusts to hold items in stock or at least have quick access to replacements (see the advantages of a pool or library system discussed on page 23). Wherever possible temporary repairs should be avoided. If temporary action is required to keep a piece of equipment running, then the equipment should be withdrawn from service and repaired before being used again. A failure to have effective procedures in place could put staff and patients at risk and might lead to litigation.

Auditors reported that trusts have adequate procedures for recording and reporting faults and breakdowns. Faults are generally reported by telephone, and staff were consistent in their views that procedures were clear. We also collected evidence of clinicians being satisfied with response times and that interruptions to service were rare.

### Decommissioning

Equipment which has become unreliable or unsafe must be taken out of service. When the stage is reached at which replacement is considered, informed purchasing decisions would involve making an estimate of the likely length of life of each group of devices. Since these estimates are held as inventory data, a possible procedure for considering decommissioning would be to inspect a piece of equipment when the estimated life had elapsed, with further checks at regular intervals to ensure continued reliability.

Responses to our 1997/98 questionnaire indicated that 25 trusts had undertaken a recent needs assessment and review of their stock of medical equipment. Most of these trusts had good information on the amount of equipment that was beyond its normal expected life but still in use. However, we noted little in the way of formal assessments or reports to board level.

We noted at three of the seven trusts which underwent full reviews, officers at operational level were aware of 'written down' equipment in use and not due to be replaced, but this information was not reported at board level. Another example of concern, was a report where the head of an endoscopy unit had been unable to renew a maintenance contract because the service company would not cover some items due to their age and condition.

## Recommendations

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*Trusts should:*

- *consider benchmarking maintenance expenditure against other trusts in pursuit of good practice and best value*
  - *ensure that there is clarity about delegated responsibilities for maintenance*
  - *consider obtaining external accreditation to a recognised quality standard for internal maintenance departments*
  - *review their number of maintenance service providers and consider whether there could be advantages in pursuing a more aggressive standardisation policy*
  - *adopt planned preventative maintenance, wherever appropriate, as the main means of maximising medical equipment availability and safety*
  - *ensure that their boards have access to information so that they are properly aware of the trust's position with regard to medical equipment, and the extent of risk associated with that position.*
-

## Glossary

Adverse incidents [NHS MEL (1995) 74 refers]	Chief Executives have a responsibility to ensure the reporting of information on hazardous/potentially hazardous medical equipment. An adverse incident is an event which adversely affects, or has the potential to affect, the health or safety of patients, users or other persons. Incidents may arise due to shortcomings in the equipment itself, user practice, service, maintenance, modifications or adjustments, management procedures, instructions for use or environmental conditions.
Clinician	Anyone providing direct clinical input.
Clinical Negligence and other Risks Indemnity Scheme (CNORIS)	Financial risk sharing arrangements for clinical risk negligence and certain non-clinical risk categories, introduced in April 2000. The scheme is mandatory with contributions based on performance assessment against risk management standards.
CT Scanner	Computerised tomography - gives a computerised reconstruction of a 'slice' of a patient using x-rays as its method of detection.
Device management procedure	Document including policies for purchase, responsibilities for maintenance and training, and actions needed in cases of breakdown or adverse incident.
Defibrillator	Restores heart to normal rhythm from a life threatening rhythm.
Infusion devices	Devices which control the timely delivery of large or small amounts of drugs to patient.
End user	Patient or client who uses device themselves.
Endoscopes	Optical fibre scope, flexible or rigid, which looks inside the body with an eyepiece at one end; may be used in conjunction with a camera system.
Medical Devices Agency (MDA)	MDA's role is to provide advice on purchasing, investigate adverse incidents, disseminate safety information and to act as the UK competent authority (the regulator for the medical devices industry). <b>See Scottish Healthcare Supplies</b>
MRI Scanner	Magnetic Resonance Imaging - magnetises the body and subsequently creates a computerised image (dependent on density) of the body.

Net Book Value (NBV)	The cost or valuation of fixed assets after adjustments for accumulated depreciation, additions, disposals, revaluations and indexation.
Operating Income	All NHS sources of exchequer income.
Planned preventative maintenance	Servicing operations undertaken at fixed intervals by technical staff.
Professional user	Qualified person using device for benefit of patient.
Routine maintenance	Inspection/device-care operations carried out by professional users.
Scottish Healthcare Supplies (SHS)	SHS works closely with the MDA on behalf of the Scottish Executive. This results in the issue of Scottish safety information that reflects the Scottish position; the basic safety information is the same as for the UK but SHS ensure that the political, legal, and policy issues are addressed appropriately.
Standing Financial Instructions (SFIs)	Guidance and instructions devised by a health body for the administration and stewardship of its financial affairs.



# Appendix 1: Advisory panel members

The project team was assisted in the development of this review by an advisory panel of professionals from the health service. The panel advised on the scope of the review, and commented on the audit guide and on the draft of this report.

Members of the panel were:

Mr D Bryson	Management Accountant/Laboratory Business Manager, Dumfries and Galloway Acute and Maternity Hospitals NHS Trust
Mr J M Moorehouse	Assistant Director, Scottish Healthcare Supplies
Mr M Nieman	Department of Bio-Medical Physics, Grampian University Hospitals NHS Trust
Dr C P Swainson	Medical Director, Lothian University Hospitals NHS Trust

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