

ANAESTHETIC-RELATED EQUIPMENT

Purchase, maintenance and replacement

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1. SUMMARY

- 1.1 Each directorate should nominate one consultant with responsibility for equipment management and liaising with the manager of technical servicing (3.1).
- 1.2 Anaesthetic equipment used in some locations may have shared use. An inventory should be kept and management responsibilities should be clearly defined for all equipment for which the anaesthetic department is responsible (3.2).
- 1.3 A separate capital asset register which includes equipment paid for by charities is required for depreciation and replacement purposes (3.4).
- 1.4 The nominated consultant must be aware of current legislation in the UK and Ireland. There are also relevant European Directives being developed (4.1).
- 1.5 A planned preventative maintenance programme is essential. Quality issues must be monitored (5.2, 5.4).
- 1.6 There should be a department policy for equipment breakdown (5.1).
- 1.7 A planned replacement programme which defines equipment life and disposal procedures should be agreed (6.1).
- 1.8 Purchase of new equipment involves wide consultation and technical advice is essential to ensure practicality and cost-effectiveness (7.3).
- 1.9 Use of private capital must be carefully considered (7.2).
- 1.10 An acceptance procedure and training programme should be part of a safety protocol (7.6).

2. INTRODUCTION

The Association of Anaesthetists of Great Britain and Ireland is committed to improving patient safety. Studies of mortality associated with anaesthesia are not new [1,2,3] but the introduction of medical audit has shifted the focus of attention towards precipitating factors which lead to injury and death. The Association has been in the forefront of such studies [4,5,6,7]. The vast majority of critical incidents occurring during anaesthesia have been shown to be due to human error but up to twenty per cent may be caused by equipment failure [8,9,10]. Several documents have already been published by the Association with the intention of reducing the number of human errors and the incidence of undetected equipment failure. These include *Recommended Standards for Monitoring during Anaesthesia*, *A Checklist for Anaesthetic Machines* and *Anaesthesia in Ireland - the Provision of a Safe Service*. Department of Health (DH) hazard warning notices are reproduced in *Anaesthesia*. The reader is also referred to other studies of safety in relation to cost [11] and to the contribution of monitoring to the prevention of anaesthetic mishaps [12].

This document gives guidance on maintenance, replacement and purchase of equipment. The anaesthetist has a pivotal role to play but recent increases in the technological sophistication and complexity of equipment means that he/she cannot expect to have a complete understanding of the field. Health Equipment Information (HEI) 98, entitled *Management of Medical Equipment* [13], is written from a technical viewpoint. It should be used as an adjunct to the information in this booklet.

3. THE ROLE OF THE ANAESTHETIST

The anaesthetist should play a part in the following activities relating to equipment:-

- Listing and review
- Justification of need
- Selection
- Acceptance
- Training
- Servicing and maintenance
- Replacement and disposal

3.1 *The nominated consultant*

It is recommended that each directorate nominate one consultant with responsibility for equipment. The nominated consultant will develop specific expertise with respect to equipment and be responsible for a coordinated approach to its management, replacement and purchase. The nominated consultant may wish to enlist the support of certain colleagues or operating department assistants/practitioners to assist with his duties as well as consulting regularly with all members of the anaesthetic directorate.

3.2 *The manager of technical servicing*

HEI 98 recommends that each hospital authority should appoint a Manager of Technical Servicing (MTS) who is given responsibility for managing equipment. Most hospitals have such a person in post although their title and the department to which they belong may vary e.g. department of

electronic and biomedical engineering, department of medical physics, estates department. Throughout this document, the terms MTS and Department of Technical Services (DTS) are used. It will be necessary for the nominated consultant to identify the titles used in their hospital or unit.

The nominated consultant anaesthetist should liaise closely with the MTS.

3.3 *Inventory of Equipment*

The nominated consultant must have access to an inventory of equipment for which the anaesthetic directorate is wholly or partly responsible. This is particularly important for directorates where equipment is located in more than one site and may be relocated between sites. HEI 98 states that it is the responsibility of the DTS to maintain an inventory. The inventory may be held on a computerised data-base to facilitate the generation of data needed to organise an equipment management programme. In addition to items for which the DTS has ongoing responsibility, the inventory should also include relatively inexpensive items such as laryngoscopes and non-clinical items such as computers and printers. Although these items do not necessarily need regular maintenance, they must be listed in order that they can be included in the replacement programme.

3.4 *“Shared” equipment*

Many types of equipment used by anaesthetists are also used by other specialities in a variety of locations. Throughout a hospital or unit, there may be safety and possible cost advantages in standardisation and bulk purchase of certain types of equipment. This may be facilitated if the nominated consultant liaises closely with the departments using similar equipment e.g. intensive care, accident and emergency,

radiology, cardiology and respiratory medicine. It is important that each department compiles an inventory of equipment for which it has managerial and financial responsibility. In compiling the inventory, the nominated consultant should clarify areas of uncertainty over ownership of equipment. Examples include patient controlled analgesia pumps used in ward areas and blood warmers in theatre. It may be appropriate for some high value assets to be shared. The financial implications of asset sharing must be clarified and each directorate must contribute to depreciation, servicing, maintenance and replacement costs. Responsibility for organising and monitoring servicing and maintenance schedules, and for planning replacement must be defined.

3.5 *Capital asset register*

The Capital Asset Register (CAR) which is maintained by all hospital authorities is different from the inventory. The CAR includes not only medical equipment but also other fixed assets which are and require replacement e.g. air conditioning plant. Currently, items with a value of £1000 (£5000 in April 1994) or more are listed [14,15]. Capital charges are levied on a percentage of the replacement costs with the intention of accumulating a reserve against replacement. Charitably acquired equipment must also be recorded and depreciated for replacement purposes. It should be included in the equipment replacement programme and hence future departmental budgets. Irrespective of clinical appropriateness, the asset value of a given item is always depreciated in a straight line over a fixed number of years.

Many hospitals use a numerical and/or bar coded system for identifying items on the CAR. Extension of this identification system to all anaesthetic equipment may be helpful with compiling and updating the inventory. The data set for each

item should include hospital location, building location, asset number, name of item, the management unit to which the item belongs, a code for expected life over which depreciation occurs and expected replacement cost. The last item is usually an estimate and may be grossly inaccurate.

4. THE ROLE OF THE MANUFACTURER

4.1 *The Consumer Protection Act and Liability for Defective Products Act*

The Consumer Protection Act 1988 (CPA) [16] in Britain and the Liability for Defective Products Act 1991 (LDPA) [17] in Ireland, embody the current legislation which describes the manufacturer's responsibility with regard to equipment. They are limited in detail but are the framework within which the British and the Irish parliaments will enact the European Medical Device Directive (MDD) [18] as a Regulation under the CPA and the LDPA. The MDD must be enacted by January 1st, 1995 and implemented by 1998.

4.2 *General responsibilities*

The CPA/LDPA places absolute responsibility for the safety of products on the manufacturer. In the event of a defect causing injury, the manufacturer can be sued by any injured party i.e. the patient or the purchaser. Negligence need not be proved and it is not possible for the seller to escape liability by exclusion clauses in the contract of sale. The manufacturer's responsibility, as described in the CPA/LDPA, ends ten years after delivery of the equipment. After ten years, the purchaser, but not the patient, could still sue the manufacturer under the Sale of Goods Act in Britain or the Sale of Goods and Supply of Services Act in Ireland but it would probably be difficult to convince the court that the equipment was still "as supplied". Because the 10-year rule is not retroactive, only equipment supplied from 1988 onwards is covered by the CPA/LDPA.

4.3 *Spares and servicing*

The implications of the CPA/LDPA for manufacturers have not yet been assessed fully so that, at present, there is no general policy in industry concerning the supply of spares or continued servicing beyond the ten year period. It is however, agreed that spares must continue to be available for ten years after delivery of the last example of a particular model. There does not appear to be any legislation preventing continued use or servicing of old equipment provided that it is recognised that responsibility for the equipment has shifted to the hospital authority and that the need for insurance has been assessed and acted upon. In the United States, where legislation similar to the CPA is more firmly established, some manufacturers take a cautious view with regard to old machines which have been upgraded because this may be considered to restart the ten year clock of responsibility. Extensive rebuilds are being offered to those who wish to continue to use their old equipment.

4.4 *Changes after the introduction of the Medical Device Directive*

The MDD is a typical example of many documents emanating from the European Community and needs careful reading. Manufacturers will have to be registered with a “competent authority” which in Britain is the DH and, in respect of good manufacturing practice, be approved by a “notified body” such as the British Standards Institution Test House or The National Standards Authority of Ireland. The requirements for approval in Britain are described in the DH *Guide to Good Manufacturing Practice* but European standards EN 46000 series and EN 50103 which are currently under development, will supersede these between 1995 and 1998. For some years, manufacturers have been subject to similar regulations issued by the DH. The MDD will not, therefore, cause major changes.

Manufacturers will have strict responsibility for ensuring that equipment is properly serviced. This responsibility can only be discharged by servicing through the manufacturer's own organisation or by a continuing relationship with

another service organisation such as the DTS.

Purchases made before January 1995 are subject to the provisions of the CPA/LDPA. During the period between 1995 and 1998, any newly designed product will have to comply with the new regulations and carry the 'CE' mark. Products already on the market can be given the 'CE' mark if the manufacturer is satisfied that they comply with the essential requirements and has followed one of the approval procedures described in the MDD. After January 1998, all equipment supplied must comply with the essential requirements stated in the MDD and must carry a 'CE' mark to show that this is so. Any products which do not comply must be withdrawn from the market although those which have already been delivered can continue to be used.

4.5 *Clinical significance of the Medical Device Directive*

Many European standards are currently under development and British and Irish interests are being represented. Standards such as that for the anaesthetic work station and the lung ventilator include requirements for the use of monitors to measure the performance of the equipment. Patient monitors are specifically excluded but some machine monitors such as the minute volume monitor and capnometer will impinge on the clinical monitoring field.

Eventually European standards will be harmonised and published in the official *Journal of the European Communities* obtainable from HMSO. The new standards are currently being reconsidered following circulation for public comment. It will be prudent for anaesthetists as well as manufacturers to follow their developments closely.

5. MAINTENANCE

5.1 *Equipment breakdown*

The nominated consultant should ensure that a complete set of back-up equipment is available. If it is not, removal of faulty equipment from service may result in the cancellation of operating lists with consequent distress to patients and possible implications for the fulfilment of contracts. The nominated consultant should agree a departmental policy covering the unusual event that two identical items break down at the same time, and should support colleagues who invoke this policy. The policy should be written so that the patient's best interests are protected whatever the prevailing circumstances.

5.2 *Planned preventative maintenance programme*

Anaesthetic equipment which is not serviced regularly is liable to break down with potentially life-threatening consequences. A planned preventative maintenance programme is essential. A record of all breakdowns should be kept. These can be linked to the departmental inventory to produce a record of maintenance. Regular review of each class of item should reveal the incidence of breakdowns which could indicate a need for further user training, modification of equipment or its urgent replacement.

5.3 *Who should carry out maintenance?*

Contract maintenance is offered by most manufacturers. Ideally the cost of maintenance contracts should be inclusive of emergency call outs and travel time for engineers, as well as fixed interval servicing and parts. Cheaper alternatives usually exclude the cost of emergency call outs and travel time

and may be appropriate for hospitals with sufficient back-up equipment.

Many hospitals are opting for “in-house” maintenance by the DTS. This often has logistic and cost advantages. The support to be provided by manufacturers must be defined when equipment is purchased and should include the provision of service manuals, on-going technical training and spare parts. If upgrading or modification of equipment is required at a later date, there are likely to be additional costs even if the work is to be done in-house. An annual maintenance budget of at least 10% of the equipment’s purchase cost is necessary.

Third party servicing is another option which may be of particularly value for the maintenance of equipment which requires specialist knowledge and testing e.g. vaporisers.

Whichever of these options are chosen, it is essential that they are fully integrated into the planned maintenance programme.

5.4 *Quality assurance and training*

The equipment management system used by the manufacturer, their agents or an in-house technical group can be certified to British or European standards such as BS 5750/ ISO 9000/ EN 29000. These standards for quality management systems aid effective control through the definition and documentation of activities, the keeping of records to prove that these activities are being effectively executed and the audit of records by both internal and external personnel.

In practice, for the DTS, this will usually involve the preparation of quality manuals which document operating policies and procedures. These will cover not only existing activities such as purchasing, repair and pre-planned maintenance but also other activities such as document

control, corrective action and quality records. Some of these activities may be new to the DTS and require reorganisation of the department or additional training for staff in new skills such as internal audit.

If in-house maintenance is chosen, enough time and money must be allocated for training of technicians to a high level so that they are able to provide a high-quality, safe service. Regular, monthly training sessions on all new and existing equipment should be the norm.

6. REPLACEMENT AND DISPOSAL

6.1 *Planned equipment replacement programme*

Equipment must be condemned and replaced before it becomes unreliable and endangers the patient. Rising maintenance costs and clinical or technical obsolescence are further indications for replacement. It is sensible to instigate a planned equipment replacement programme which is phased over a number of years to spread the costs. This should be planned in conjunction with the MTS and finance department. The choice of new equipment can then be made at leisure incorporating plans for standardisation and rationalisation to meet existing and future needs. Equipment under consideration should be assessed by literature studies including health department evaluation reports, enquiries of and visits to other users, trade exhibitors at congresses and sometimes factories. A shortlist of one or two items can then be made. These may be borrowed from the manufacturers for a trial period for clinical and technical evaluation. It is important to remember that NHS contract terms impose full responsibility on the manufacturers for equipment on loan. Formal, properly documented loan arrangements must be made which should be approved by the nominated consultant and MTS and include in-house checks and training for clinical and technical staff.

6.2 *Timing of equipment replacement*

Nationally recognised guidelines on the timing of equipment replacement do not exist. The problems introduced by the CAR may mean that the only option accepted by finance officers is the replacement of equipment at the end of its registered life. In certain cases replacement of unsafe or obsolete equipment may be theoretically premature and incur

financial penalties and in others, functional equipment may be considered for replacement. It is recommended therefore, that equipment be replaced at a time deemed to be appropriate by clinicians in consultation with finance officers.

Anaesthetic equipment falls into two broad categories. These are electronic and mechanical. Electronic equipment is commonly believed to have a functional life of approximately eight years and mechanical equipment a life of twelve years. In the past, many items of anaesthetic equipment were mechanical. Today, it is rare to find items which do not contain any electronic components. This is placing an increasing burden on equipment replacement budgets.

A planned replacement programme requires an estimate to be made of the expected functional life of each piece of equipment. In practice, the actual life of a piece of equipment depends on the quality of its original design, how often and how carefully it is used and maintained and the continuing availability of spare parts. These factors may increase significantly the functional life of equipment. Conversely, technological development may render the equipment clinically obsolete in a far shorter period. For planning purposes therefore, the following schedule is recommended as guide to life expectancy:-

- up to 8 years: all equipment with electronic components
- up to 12 years: all other equipment

6.3 *Disposal*

Unreliable, damaged or worn out equipment should be removed from service and destroyed. Obsolete but functional equipment has potential resale value but carries with it liabilities under the CPA/LDPA. There are companies who can manage such

transactions. The DH have issued guidelines on the resale of medical equipment in HN(89)22 [19]. Alternatively, equipment can be donated to a charity. The donor has a moral responsibility to ensure that the recipients are given all relevant information about the equipment.

However it is disposed of, the equipment concerned must be removed from the capital asset register. If the equipment is still incurring a capital charge, the anaesthetic department may be liable for payment of the remaining value to the hospital finance department. There is another problem with the CAR in that placement of time-expired equipment on the register carries no charge and hence no money is budgeted for replacement. It is vital that this fact is appreciated by anaesthetists, the MTS and finance officers. It must make economic sense to use equipment for as long as it is clinically appropriate and reliable. Alternative budgetary provision must, therefore, be made for time-expired items and it is also important to make an allowance for technological developments which render replacement items relatively more expensive than the item in current use. The departmental inventory is a more useful and complete basis for budgeting and planning an equipment replacement programme. The importance of adequate budgetary allocations for equipment replacement must be impressed on finance officers and the unit board.

7. PURCHASE AND ACCEPTANCE

7.1 *Choice of equipment*

A number of general principles should govern the choice of equipment for a department. The equipment must be:-

- able to meet national and European quality and safety standards
- suitable for its intended purpose
- likely to be suitable for anticipated clinical developments
- understood and accepted by its users after appropriate training
- able to be maintained in a safe and serviceable condition
- chosen to meet the above requirements in the most cost-effective manner

7.2 *Ownership of the equipment budget*

Traditionally, items of low cost equipment have been purchased from departmental budgets and those of high cost from a district, regional or health board budget. Recent NHS reforms have altered the position such that provider units have become responsible for the purchase of all items. Within the provider unit, there are various mechanisms which can be used to manage the purchase of equipment. It is important that the nominated consultant and MTS are involved in the choice and implementation of mechanism. The options available are:-

- (i) the equipment budget may be held by the anaesthetic department or directorate. At first sight this would seem to be the ideal option because it gives the

directorate control over the purchase and maintenance of its own equipment. There may, however, be a problem with the purchase of certain expensive items especially if they are bought in bulk. Multifunction monitors are an example. National controls on NHS budgets mean that it is rarely possible to carry over more than 20% of a budget into the next financial year. If a directorate agrees to manage its own equipment budget, it must be of sufficient size and flexibility to accommodate expensive purchases and all the revenue consequences of such purchases.

- (ii) A service level agreement may exist between the anaesthetic directorate and the DTS. The DTS should have a larger budget than an individual directorate. The funding of large purchases should be less of a problem but the anaesthetic directorate may have to compete with other specialities for funding at the appropriate time. The DTS will also be subject to limitations on the amount of money which can be carried forward. This may mean that less deserving purchases take precedence because they fall within the limits of the budget.
- (iii) Directorates may be given responsibility for low cost items whilst those of higher cost are purchased using a topsliced unit or hospital budget. This arrangement is analogous to that existing before the NHS reforms. The DH is encouraging the use of private finance in the NHS. Initial guidelines in the NHS Trust Finance Manual have been amplified by various official statements [20]. Most recently, FDL(93)03 [21] and FDL(93)33 [22] have urged finance directors to be innovative and receptive to new ideas. Furthermore, the freedom of directly managed units to use private finance without specific Treasury approval has been clarified. The advantage of the provider unit

retaining responsibility for the purchase of some equipment is its ability to utilise alternative methods of finance. Despite the DH's enthusiasm for the use of private finance by public bodies, anaesthetists would do well to remember the fiasco when local government authorities used similar freedoms without proper understanding and control. This method of funding had, and continues to have, the disadvantage that the anaesthetic directorate must compete with other directorates such as intensive care and radiology who also have an ongoing requirement for costly equipment. The ability of an individual directorate to plan a replacement programme is limited by its inability to predict with certainty the availability of funding. The planned programme should be flexible to allow for proportional reductions or expansions which will cope with the size of allocations.

The nominated consultant should understand the advantages and limitations of any budgetary arrangements before these are agreed. Negotiation of appropriate budgets is facilitated by the existence of a planned replacement programme particularly if this is updated regularly using the inventory. The purchase of expensive items can be anticipated and the cost spread over two years. Consideration should be given to inclusion of an allowance for equipment replacement costs in purchaser-provider contract agreements.

7.3 Justification of need

Before an item of equipment is purchased (or accepted from charitable bodies), it is essential that the need for it is justified and its suitability is assessed. The use of a

pro forma can assist in this process and should contain the following information:-

- the equipment it is intended to replace (if appropriate)
- the purpose for which the equipment is intended

- the functions of the equipment which meet the intended purpose
- additional functions which do not meet the stated purpose
- the advantages of the equipment with additional functions
- a description of the model chosen and reasons for the choice.

This information should be produced by anaesthetists who will be using the equipment. The MTS will also require information from the manufacturers, most of which can be obtained from a completed Medical Liability Questionnaire (MLQ) form. At present, a separate form is completed for each potential purchaser. It is unfortunate that this system has not been streamlined so that a standardised information pack, which can be used by all purchasers, is available for each piece of equipment.

7.4 Methods of paying

There are several methods of paying for equipment. It can be paid for at the time of purchase or the equipment may be supplied free in return for an agreement to purchase a certain number of consumables over a stated period. An alternative is for the purchase price to be reduced in return for a commitment to purchase consumables. Leasing and lease purchase are methods of buying equipment which are particularly appropriate for items of equipment costing more than £20,000 because payments are spread over a number of years. Many quotes offer optional servicing, call out and replacement within the price. Leasing and lease purchase involve the inclusion of a leasing company, who are the legal

owners of the equipment, between the manufacturer and the purchaser. Liability arrangements must be agreed between the three parties because hospitals do not generally carry insurance for loss or damage to equipment.

The advantage of leasing is that a lease can be terminated at any time in favour of a new lease on an updated piece of equipment. In contrast to lease purchase where the user becomes the eventual owner of a potentially obsolete piece of equipment, leasing gives the purchaser flexibility to upgrade equipment at will although there may well be financial penalties to early termination of a contract. Normally, it is possible to fund leasing contracts from revenue allocations.

When deciding which method of payment to choose, the whole life cost of the equipment must be assessed. The whole life cost includes the basic cost of the equipment, an allowance for capital charges plus the cost of disposables, maintenance costs including the training of technical staff and the cost of replacement parts over the expected life of the equipment. An item of equipment with an apparently advantageous purchase price may prove far costlier in total over the functional life of the equipment than an item which at first sight appears expensive because the lower purchase price may be nullified by the high cost of disposables or maintenance. Single-patient-user and semi-disposable items, such as some oximeter probes, can add considerably to whole-life costs and caution should be exercised when equipment with dedicated disposables is chosen. Infusion pumps are particularly liable to this type of problem because an increase in the cost of dedicated giving sets may be impossible to overcome by choosing sets from a more competitive manufacturer.

7.5 *Sources of funds*

NHS funding has already been discussed (7.2). Charitable foundations often contribute to the purchase of anaesthetic equipment. When purchases are made by charitable foundations, the revenue consequences must be provided for and the usual acceptance procedure followed.

In many hospitals, financial constraints have resulted in failure to develop or implement a planned programme of equipment replacement. Suitable anaesthetic equipment and comprehensive monitoring devices must be provided in all areas where anaesthesia is administered e.g. operating theatre, CT scanning room, angiography suite, day surgery unit, intensive care unit, A&E department. During the commissioning of a capital development project there will be an opportunity to consider reorganisation of the anaesthetic service and hence the relocation of some existing items of anaesthetic equipment so that the new equipment is located in the most appropriate area.

7.6 Acceptance procedures

HEI 98 requires that a formal acceptance procedure be adopted for each item of equipment. This is the responsibility of the MTS who will arrange for safety and performance checks prior to the introduction of equipment into clinical areas and its inclusion in the inventory and CAR. An investment in training time following the introduction of new equipment is essential for both users and in-house technical staff. In-house training is part of the acceptance procedure and the nominated consultant should define a suitable programme for all clinical staff including consultants and monitor its implementation. Such training is invaluable because it reduces the flood of calls about breakdowns of new equipment which usually can be attributed to incorrect usage.

Training arranged by the MTS for technical staff allows them to gain knowledge of the equipment from the day of its introduction.

It is essential that all new staff, both clinical and technical, are familiar with existing equipment. A training record should be kept. This is especially important for complex items of equipment such as integrated anaesthetic work stations or ICU multi-parameter monitors. Additionally, the incidence of breakdowns can be minimised if the nominated consultant in conjunction with the MTS engenders a sense of ownership amongst users.

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* Obtainable from The Department of Health, Medical Devices Directorate, 14 Russell Square, London WC1B 5EP.

** Obtainable from the Consumer Safety Unit, Department of Trade and Industry, 10-18 Victoria Street, London SW1H 0NN.

*** Obtainable from Government Publications Sales Office, Sun Alliance House Molesworth Street, Dublin 2.

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