Guidance for clinicians leading an LMERG equipment replacement programme

NHS Lothian

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Contents

1.0 Purpose

This document aims to give guidance to NHS Lothian (NHSL) clinicians who are leading an equipment replacement programme for the Lothian Medical Equipment Review Group (LMERG). Each equipment replacement programme will have a clinical lead from a relevant clinical service that utilises the equipment. The Clinical Lead will work alongside the Scientific or Technical Lead and members of the Procurement Team.

2.0 Scope

NHS Lothian equipment replacement programmes vary in scope. This can range from replacing one item that is used by only one department in NHSL to a pan Lothian replacement programme such as infusion pumps or monitors where there may be several niche specifications to consider as part of the whole procurement process. The principles of the clinical lead role are the same for both scenarios but a larger more complex procurement programme will require an experienced clinical lead and will require secondary clinical leads to manage the whole procurement process with optimal clinical engagement from all affected clinical services. A Technical User Group should be established for the larger more complex procurement programmes.

3.0 Definitions

The Lothian Medical Equipment Review Group (LMERG) is a capital group responsible for replacing all medical equipment purchased using NHS Lothian capital formula allocations. This involves all equipment costing £5,000 or more inclusive of VAT. Some equipment which is capital in nature, which has an expected useful economic life in excess of one year and an individual value of less than £5,000, is grouped together and funded from the LMERG allocation. The total value can exceed £1,000,000 for items such as infusion pumps. Also, the value of a single item such as a CT scanner can exceed £1,000,000.

Service and maintenance contracts and consumables must all be paid from the service revenue budget. LMERG is only responsible for replacing medical equipment.

The funding sources and associated processes are different for the purchase of new medical equipment or for equipment purchased from charitable sources including gifts and endowments. Press Control then Click on the link for further information about capital processes. What is Capital and How Do I Apply for Funding? (scot.nhs.uk)

4.0 Roles and responsibilities

4.1 Medical Director for University Hospital Services

The Medical Director for University Hospital Services has strategic clinical responsibility for LMERG replacement programmes. They will advise LMERG on who the appropriate Associate Medical Directors would be for any specific replacement programmes. The Medical Director provides Strategic Clinical Approval sign off on the Capital Medical Equipment Form. Capital Medical Equipment Form

4.2 Associate Medical Director and Clinical Director

The Associate Medical Director for a service has local clinical responsibility for equipment replacement programmes affecting their service. They will appoint an appropriate Clinical Lead for the equipment replacement programme although this role may be delegated to a Clinical Director or to an appropriate member of the clinical team. Equipment heavy departments may have staff specifically job planned for equipment management and procurement. The Associate Medical Director or Clinical Director provides Local Clinical Approval sign off on the Capital Medical Equipment Form.

4.3 Services Manager

The Services Manager is responsible for revenue approval associated with the equipment purchase. Revenue costs include maintenance or service contract costs and consumable costs.

4.4 Health and Social Care Partnerships

For NHS Lothian services out with Acute Services such as the Health and Social Care Partnerships (HSCPs) the organisational structures are different and engagement with replacement processes for medical equipment requires further development. The Clinical Director for the relevant service will have responsibility for Local Clinical Approval sign off. The Services Manager or Responsible Budget Holder will be responsible for signing off the revenue costs. The Head of Service such as for a Health and Social Care Partnership HSCP is an appropriate signatory for the Strategic Clinical Approval. Advice can be sought from the Medical Equipment Asset Manager who is the final signatory on the Capital Equipment Form.

4.5 Procurements involving Multiple Services

In some circumstances there may be more than one service involved in an equipment procurement process. It should be agreed which Associate Medical Director and Service

Manager will sign off the Local Clinical Approval and which Service Manager will approve the revenue spend. It is good practice if there is accompanying email correspondence demonstrating that all affected services have agreed to the procurement. The revenue costs are shared across the respective services. For pan Lothian procurements involving many or all NHSL services the Chair of the Medical Devices Committee can provide the Local Clinical Approval. An example would be infusion pump replacement across NHSL. Such programmes can be highlighted in advance.

4.6 LMERG Programme Scientific or Technical Lead

The LMERG equipment replacement programmes each have a Scientific or Technical Lead. This role is fulfilled by the Chief Radiographer (or nominated Sector Manager) for the imaging programme and by the Clinical Simulation Programme Manager (or nominated Simulation Technician) for the simulation programme. Refer to the link LMERG Rolling Programmes (scot.nhs.uk) for the table of the 24 replacement programmes.

The Scientific or Technical Lead is responsible for identifying when equipment under their remit is due for replacement taking into account the age of the equipment, the failure rate and whether it can still be maintained if it fails. In general, they will be responsible for managing 10 year replacement plans for the equipment under their remit including identifying very high and high risk priority requests to LMERG.

The Scientific or Technical lead is responsible for ensuring the equipment purchased is fit for purpose and can be serviced within NHSL or via a service contract. The Scientific or Technical Lead is responsible for ensuring the equipment meets all current legal and regulatory requirements.

Some equipment purchases may require specific environmental conditions and the Scientific and Technical Lead is responsible for ensuring these are specified prior to purchase and that there is dialogue with the Local Estates Manager to check if the current systems are adequate or if they require attention before finalising a program of works for the project. See section 6 of the Capital Medical Equipment Form. Examples include room ventilation and local power supply capacity.

The Scientific or Technical Lead will provide Scientific or Technical Approval for the procurement. Click on the link Capital Medical Equipment Form

4.7 Digital and IT

Digital and IT (formerly eHealth) are responsible for approval of IT Security and Data Protection requirements associated with the equipment and for approving and providing costs for any network infrastructure requirements. This is an increasing requirement for replacement medical equipment and the Scientific or Technical Lead will usually have direct liaison with Digital and IT but the Clinical Lead for the replacement programme is also responsible for describing the clinical networking requirements. This is an important requirement for radiology procurements.

4.8 Procurement Commodity Managers

Procurement Commodity Managers are responsible for ensuring the correct procurement process is followed.

NHS National Services Scotland has a national procurement service, National Procurement (NP), which tenders for equipment contract. These are usually set up as frameworks where several companies supplying the same type of equipment have contracts with NP.

NHSL can purchase from these contracts.

If the equipment to be purchased is not on an existing procurement contract then the following rules apply.

Supply of goods or services up to £10,000	1 quote required
Supply of goods or services from £10,000 to £25,000	2 quotes required
Supply of goods or services from £25,000 to £50,000	3 quotes required
Supply of goods or services from £50,000 to £100,000	Competitive Tender
Supply of goods or services over £100,000	Public Procurement required

The money spent is based on the whole life costs of the equipment which take into account: the equipment purchase cost, consumable pricing and volume, service and maintenance costs aggregated over the lifetime of the equipment.

The requirement for a competitive tender or a public procurement must be discussed with procurement.

Any waiver of a competitive tender approval must be discussed with procurement prior to competition. This would be an unusual event.

Procurement Commodity Managers are available to the LMERG replacement programmes for advice.

4.9 Infection Prevention and Control

The Infection Prevention and Control Team have a responsibility to advise on any specific equipment cleaning requirements and ensure that NHSL policies for cleaning of equipment are available for reference for equipment specifications.

For decontamination of reusable non-invasive care equipment the Infection Prevention and Control Nurse (IPCN) will advise.

A flow chart for decontamination of re-usable non-invasive equipment is available using this link 2018-07-nipcm-appendix-7.pdf (scot.nhs.uk) to the National Infection Prevention and Control Manual (NIPCM).

It may be appropriate to involve either an Infection Control Nurse or Doctor/Consultant Microbiologist in the evaluation for aspects of clinical infection risk, microbiological sampling etc. in specific scenarios.

4.10 The Lead for Decontamination and HSDU

4.10.1 Decontamination of re-usable surgical instruments and endoscopes

SHTM 01-01 Parts A – F describe a framework for ensuring the safe reprocessing of these devices. The Lead for Decontamination has a key role of oversight here in conjunction with other roles and responsibilities described in the memorandum as has the Authorising Engineer (Decontamination) in supporting NHS Lothian to ensure the reprocessing equipment meets regulatory requirements via audit and equipment certification.

4.10.2 Re-usable surgical instruments

The Lead for Decontamination is responsible for disinfection and sterilisation processes in the Hospital Sterilisation and Disinfection Unit (HSDU) for Dental and Theatres.

It should be noted that surgical instruments are not purchased via LMERG. Other funding routes are used.

4.10.3 Disinfection or sterilisation of re-usable medical equipment

Some medical equipment has reusable equipment parts that require disinfection or sterilisation. An example is the expiratory block in some ventilators needs sterilised by HSDU. The technical and regulatory approval for this equipment comes from the Lead for Decontamination under liaison with Medical Physics.

4.10.4 Decontamination of re-usable flexible and rigid endoscopes

Decontamination processes for all re-usable endoscopes must be approved by the Lead for Decontamination. The technical and regulatory approval for the equipment comes from the Lead for Decontamination under liaison with Medical Physics.

4.10.5 Manufacturer's Instructions for Use for re-usable medical devices

The manufacturer's Instructions for Use should be studied to ensure that NHS Lothian has the capability to reprocess the device using its existing capability and liaison with the Lead for Decontamination must be undertaken prior to purchase.

4.10.6 Capital Medical Equipment Form

There are questions on the Capital Medical Equipment Form relating to Infection Control and HSDU consultation, which must be accurately answered.

4.11 Manual Handling Service

The Manual Handling Service can be contacted as a source of information and advice to support usability from a staff, team and patient perspective.

4.12 Medical Equipment Asset Manager

The Medical Equipment Asset Manager has overall responsibility for the LMERG programme and 10 year plans including delegated responsibility, from the Director of Capital Planning and Projects, for management of the annual capital allocation, identification of programme budgets and approval of all capital expenditure. They have final approval of all LMERG orders placed. This individual is an excellent source of advice for all LMERG equipment replacement programmes and processes.

4.13 Clinical Lead of an LMERG Equipment Replacement Programme

A Clinical Lead for an LMERG equipment replacement programme may be from a medical, nursing, clinical physiology or allied health care professional background. Sometimes a services manager may lead the procurement process by chairing and coordinating a group of clinicians who provide the knowledge and skills to deliver the procurement process.

The appointed Clinical Lead of an LMERG equipment replacement programme works as part of this team and is accountable to the relevant Associate Medical Director for the clinical service they work in or to the Medical Director for University Hospital Services if the replacement programme covers several services or is pan Lothian. The role of the Clinical Lead for an LMERG replacement programme will be described in more detail in section 5.

The Clinical Lead for an LMERG equipment replacement programme will lead a team of relevant clinical users and will do so to provide the best clinical outcome for the user group ensuring that the equipment purchased meets the specification for all clinical users, including niche groups, has been fairly and thoroughly evaluated and is inclusive of all views and clinical requirements. Consideration of the scientific and technical perspective should be taken as well as networking requirements and cleaning requirements. An evaluation of training for both clinical and technical staff should be done. Procurement advice must be taken and followed in order to ensure compliance with all current legislation.

If there are any disputes between clinicians or lack of engagement with clinicians the Clinical Lead for the replacement programme is responsible for resolving these. If these cannot be resolved within the group the Clinical Lead should escalate the issues raised to the relevant Associate Medical Director or to the Medical Director for University Hospitals or to the relevant Clinical Director in non acute settings such as the HSCPs. The Clinical Lead is responsible for ensuring there is an effective and appropriate education and installation plan. They are also responsible for gathering any post installation clinical problems and working to resolve them.

If a replacement programme needs to halt because of difficulties that cannot be resolved within that financial year then the Medical Equipment Asset Manager must be informed immediately so that monies can be allocated to other LMERG equipment replacement programmes.

5.0 Main content and evidence base

5.1 The Immediate Team

The Clinical Lead for the equipment replacement programme will work closely with the Scientific or Technical Lead for the equipment replacement programme. There will be close liaison with the Commodity Managers from NHSL Procurement and contact with Procurement is usually made by the Scientific or Technical Lead.

5.2 Skills

The skills that are helpful for a Clinical Lead for an LMERG equipment replacement programme are good planning and organisation, an eye for both strategy and detail, the ability to work flexibly and with a team. Line manager support to shift workload at key points of the process is also helpful. If working in a group some of these key skills may come from different members of the group. The Clinical Lead should be a user of the equipment concerned and have a good level of knowledge of that equipment. If the group is led by a manager or a clinician experienced in procurement processes from another specialty then the role is as Chair of a group of knowledgeable clinicians who are users of the equipment being replaced and can inform the replacement process.

5.3 Experience

Relevant clinical experience for a Clinical Lead for an LMERG equipment replacement programme can include attendance at National Procurement Commodity Advisory Panels (CAP) on behalf of NHSL for either consumable contracts or medical device contracts. This provides good training on the procurement process which includes the objective, the legal constraints and the confidentiality of the process. Attendance at a relevant Medical Device CAP gives the clinician a good overview of the range of products available on the market in a particular category of interest such as ventilators.

5.4 National Procurement

National Procurement (NP) is NHS National Services Scotland's national procurement service. National Procurement (NP) use Commodity Advisory Panels (CAP) to tender for a range of products in both consumable medical devices and medical equipment which are placed on a Framework contract. These contracts are generally awarded to a range of suppliers.

These products have gone through a full tendering process delivered by National Procurement therefore Health Boards can purchase these items directly from the National Procurement contract.

For medical equipment this is helpful if a Health Board only needs to buy one or two items. However, if multiple suppliers are on contract, the Clinical Lead and Scientific or Technical

Lead need to develop an assessment of need agreed with procurement to ensure NHSL can demonstrate we have purchased the most appropriate product from the framework.

Depending on the structure of the national contract and the volume of equipment to be purchased, NHSL may prefer to undertake a mini-competition to leverage pricing from the supply market for a bulk purchase opportunity. Procurement colleagues will be involved with this activity.

If NHSL wants to standardise on equipment where there is existing equipment that has already been bought from the NP Framework, an assessment of need must be completed.

Following the development of the assessment of need there may be an option to work with National Procurement colleagues to agree a preferential price for the bulk purchase. Again procurement colleagues will be involved with this activity.

A mini-competition is the most frequent procurement process for significant volumes of equipment. This is the process that will be described below.

If a particular equipment Framework does not exist in Scotland, NHSL can access Frameworks that have been established for use across the UK, the most common purchasing body that NHSL works with is NHS Supply Chain. The process followed is similar regardless of the purchasing body which hosts the framework contract.

5.5 The Objective

The objective of the Clinical Lead and the Scientific or Technical Lead is to determine what equipment is to be replaced and agree the process that will be followed with procurement colleagues. The first stage is to determine how many items are to be replaced and how many clinical areas are affected. The Clinical Lead is responsible for ensuring that all relevant clinical areas and all clinical user groups are represented. It is crucial that the correct user groups are represented. Critical Care doctors may have a keen interest in ventilators but the main day to day users are the nursing staff. Likewise, infusion pumps are predominantly used by nursing staff even though doctors and pharmacists may drive innovation in the form of drug libraries on the infusion pumps.

For Pan Lothian procurements there may need to be a Clinical Lead for the project and secondary Clinical Leads for specific areas or hospitals within NHSL.

5.6 The Specification

Next determine the strategy. Does the procurement process warrant standardisation of a product across NHSL or is the procurement for a niche area where the specification is clearly different such as for neonatal ventilators. If the strategy is not immediately clear it will be, once the specification has been written. This process will identify any niche areas which have clearly defined differences. In NHSL the specification process associated with infusion pumps identified niche areas. These were MRI conditional pumps and pumps with Total Intravenous Anaesthesia (TIVA) algorithms. These pump types were separated out and purchased based on the required specification for their use in NHSL. The neonatal and paediatric specifications were different from each other and different from the adult

specification and because of the different configuration requirements, these pumps needed to be clearly identified as neonatal or paediatric even if that meant purchasing a different pump. The adult pumps were unlabelled. The paediatric and neonatal niche specifications could be accommodated along with the adult specification by the same pump provider. It is possible to do a mini-competition for several different specifications at the one time making it clear that if necessary, different products from different suppliers may be successful. This is essentially how National Procurement tender for the NP Frameworks.

The specification is critical. Each user and each clinical area must define their essential requirements. This is where clinical user experience on CAP panels is valuable. If the group has no clinical user with this experience then the Scientific or Technical Lead is likely to have experience and can advise the group. They may have access to the last specification used by NHSL for that replacement programme as a start point. Mandatory items on the specification are items that if they are not present the group would not buy the equipment.

A good generic specification will narrow down the number of companies that are able to respond to the mini-tender and narrow the field of prospective products to a manageable number for evaluation. A list of desirable features is then useful to differentiate the products that are evaluated. The Scientific or Technical Lead will add the standards the manufacturer is expected to comply with to the specification and ensure that the product concerned is an appropriately licensed medical device. Information on cleaning of the medical device will be requested as part of the specification. Training of clinical and technical staff is also added as part of the specification. Sustainability considerations should be covered within the specification e.g. energy consumption, waste production etc.

5.7 Evaluation Sheet

A good evaluation sheet is critical. The mandatory features and functionalities on the specification should be listed with a Yes/No box. The desirable items should be listed for reference with information on how these will be scored. A product evaluation questionnaire should be written by the clinical team and needs to be understandable to the team evaluators and include items of particular importance to the user. Some examples of what would constitute a particular score are helpful with room for comment so that items or functions that are unexpected, good or bad, can be accommodated and scored. Some functions may have different importance for different users. Nursing staff may describe an oxygen boost button on a ventilator highly or even essential whereas medical staff may never use this. Examples of a clinical scoring sheet can be obtained from the Scientific or Technical Lead.

5.8 Weighting Table

All NP mini-tenders will have an allowable range for weighting each of the categories and this is described in the associated CAP on the NP Framework. These must be adhered to.

An example of a weighting table follows.

Criteria	Weighting	Specification Reference
Conformance with specification and functionality	Mandatory	Sections 1&2
Clinical Evaluation	40%	Section 3
Clinical/Technical Training and Support	10%	Section 4
Technical Evaluation	20%	Section 5
Total Cost of ownership over 10 year period	30%	Section 6
Total	100%	

5.9 The Mini-competition process

The Scientific or Technical Lead will take the full specification document including the evaluation scoring sheets to NHSL Procurement who liaise with NP and a mini-tender is set up or an alternative procurement route is followed. The process from this point onwards is confidential and no personal contact should be made with company representatives at this stage other than as part of the mini-competition process.

The companies on the NP Framework will be given time to respond and after the closing date the Commodity Manager will make the returns available to both the Clinical Lead and the Scientific or Technical Lead. A meeting will be held to check that all returns do meet the specification. Only returns that meet the specification will be evaluated thereafter. The evaluation must take the form that has been described in the specification document. If a large number of returns are expected from the framework then a two stage process can be used where all companies that meet the specification deliver a show and tell demonstration and the evaluator bench tests the equipment eliminating some. Ideally 2 to 4 products will be evaluated clinically.

5.10 Clinical Evaluation

The time period for clinical evaluation will have been set in the specification document. This may be two weeks or longer. Each company will be contacted and a time period booked for them. Each company starts by training enough staff to safely use the equipment and will provide supervised support during the evaluation period. It may be necessary to only use the equipment under evaluation during the daytime or early evening although many companies will provide 24 hour support.

For some devices such as defibrillators or CT scanners, an evaluation in a simulated environment may be more suitable. For large items such as CT scanners this may require travel to a distant site. Advice should be sought from the Procurement Team with respect to any travel and hospitality requirements.

The companies will need to deliver training as part of the clinical evaluation. This should be scored. If the clinical users are not impressed with the training delivered during the

evaluation period then training should be given a low score or even a zero. Trainers not turning up, not knowing the equipment or double tasking with their usual day job has been known and is not acceptable.

It is good practice to have named evaluators from each user group who see all of the products under evaluation. Other clinical users should still fill out evaluation forms and feedback any points to the named evaluators. If a product is found not to meet the specification on clinical evaluation it should be given a 0 score. Ideally products not meeting the specification should not reach clinical evaluation. The scoring system uses 0, 1, 3 and 5 to improve separation of products during the evaluation. Recording reasons that justify any score are helpful. A zero score should always be justified in writing on the form. The quality of the technical and clinical training should also be scored.

The Clinical Lead and Scientific/Technical Leads are both responsible for gathering in the scoring sheets and ensuring they are summated. The Clinical Lead and Scientific/Technical Lead should read the user manual of each product and agree there are no operational safety issues with the product. This may involve seeking advice from other experts such as the Decontamination Lead or the Estates Manager. This should be documented as part of the process. One example found on reading the manual was that the hot wire flow sensor on the ventilator was found to be a fire hazard when used with nebulised drugs. The clinicians intended to use nebulised drugs in babies in the weight range where the flow sensor is used. Other such unexpected findings have been found and are best identified prior to purchase. The Procurement Commodity Manager will calculate the lifetime costs of each product and score accordingly. All of the gathered scores are then inserted into the weighting table.

5.11 The Outcome

Following the evaluation process a meeting will be held between the Clinical Lead the Scientific or Technical Lead, Procurement and the Medical Equipment Asset Manager and the outcome agreed. Procurement will notify the companies and there will be a stand still period of 10 calendar days. The outcome remains confidential until the standstill period is over.

5.12 Ordering the Equipment

The quote will be generated by the successful company and will require input from both the Clinical and the Scientific/Technical Lead to ensure it is correct. The Capital Medical Equipment Form is then completed and signed as described in Section 4. A purchase order will be raised by the Procurement Commodity Manager and the equipment will be delivered to NHSL prior to the 31st March of the relevant financial year.

5.13 Commissioning the Equipment

Once the equipment has arrived, the Scientific or Technical Lead along with the company will check and accept the equipment order and ensure the equipment is asset tagged and

recorded on Medusa, the medical equipment database or other relevant NHSL database. This ensures the equipment is added to the 10 year plan for future replacement.

5.14 Training and Installation

The Clinical Lead will then have a role in planning the education and installation of the equipment into each clinical area. This involves direct liaison with the company and the Scientific or Technical Lead. Many large companies have good training strategies and you will have scored this as part of the evaluation process. The Scientific or Technical Lead will be the point of contact for the equipment installation but other members of the appropriate NHSL support service may be involved in the installation.

5.15 Feedback to the Unsuccessful Companies

The Clinical Lead and the Scientific or Technical Lead, are responsible for providing feedback to the unsuccessful companies along with the procurement team. This is important in driving improvements in products over time. There are many examples of companies making changes for the better to their products after unsuccessful competitive tendering then acting on the feedback.

5.16 Writing Guidelines and Procedures

The Clinical Lead may then be involved in writing or ensuring guidelines or procedures are written for future use, although this can be delegated.

5.17 Top Tips

Unless you are purchasing more of a product you are already using then all equipment should be evaluated clinically. Try before you buy.

Any product that is very new to the market may be subject to initial problems. If this innovative approach is consciously taken, then appropriate setting of the price by the company and enhanced support from the company with frequent no cost software updates is something to look for.

The most important tip for the Clinical Lead is to remember that an LMERG equipment replacement is a team effort with a wealth of NHSL expertise and support available to guide you through the processes. Some people enjoy the process and do it again, or at least think it important enough to do again!

5.18 Governance and Ethical Behaviour

Members serving on the user group must comply with all Lothian Health Board's Standing Orders as well as all professional codes of conduct, regarding receipt of hospitality, gifts and declaration of interests.

Prior to joining the user group each member will complete a Declaration of Interest Form, as detailed in appendix 3 of the Board's Business Conduct Procedure. These will be provided by the Procurement Commodity Manager for the programme and kept on file.

Some procurement projects for large items such as CT and MRI scanners may require the team to visit distant sites and require some form of hospitality. Always seek and follow advice from the Procurement Team on how this is to be managed and funded.

6.0 Associated materials

NHS Lothian Medical Devices Policy approved by the Policy Approval Group

Capital Medical Equipment Form Approved by LMERG

LMERG Rolling Programmes (scot.nhs.uk) Approved by LMERG

What is Capital and How Do I Apply for Funding? (scot.nhs.uk) Approved by NHSL Finance Online

2018-07-nipcm-appendix-7.pdf (scot.nhs.uk) Approved by Health Protection Scotland

Decontamination of medical devices in a Central Decontamination Unit (SHTM 01-01) | National Services Scotland (nhs.scot) Approved by Health Facilities Scotland

7.0 Stakeholder consultation

Lothian Medical Equipment Review Group (LMERG)

Medical Devices Committee (MDC)

Clinical Management Group Acute Services

8.0 Monitoring and review

These processes are likely to change and develop further so this guideline is a supporting guideline to the NHSL Medical Devices Policy. This means the guideline can be changed prior to the next policy review.