London Ambulance Service NHS Trust

Policy for the Management of Medical Devices

Document Control

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Author	Health & Safety/Medical Devices Manager
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Change History

Date	*Version	Author/Contributor	Amendment Details
19/04/21	1.7	Consultant Paramedic	Minor amendments relating to Alerts management system
29/12/20	1.6	Corporate Logistics Manager – Logistics	Reviewed Logistics references
01/12/20	1.5	Procurement Category Manager – Logistics and Medical	Reviewed Procurement references
17/11/20	1.4	Health & Safety/Medical Devices Manager	Reviewed and amended & Changed to new Corporate Format.
11/05/17	1.3	IG Manager	Document Profile and Control update
20/03/17	1.2	Deputy Medical Director following approval at ELT	Minor amendments relating to disposal of medical devices
02/02/17	1.1	Deputy Medical Director following PMAG Review	Minor corrections to terminology; Addition of vehicle packing and loading lists
31/01/17	0.13	IG Manager	Document Profile and Control update

30/01/17	0.12	Deputy Medical Director	Updated
26/01/17	0.11	IG Manager	Amendments and reformatting
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18/12/17	0.9	DDO Fleet and Logistics	Clarification on Asset Management
08/12/16	0.8	Head of Infection Prevention and Control	Addition of text and page 4, section 11.2, and addition of external references
08/12/16	0.7	Deputy Medical Director; DDO Fleet and Logistics	Minor changes following feedback from Finance
04/1/16	0.6	Deputy Medical Director	Minor changes
17/10/16	0.5	Health and Safety Advisor	Minor changes
26/09/16	0.4	Governance Manager Education and Development; Head of CARU	Minor changes
09/09/16	0.3	Head of Procurement	
23/08/16	0.2	Deputy Medical Director	
29/07/16	0.1	Logistics Manager; Head of Procurement	

***Version Control Note**: All documents in development are indicated by minor versions i.e. 0.1; 0.2 etc. The first version of a document to be approved for release is given major version 1.0. Upon review the first version of a revised document is given the designation 1.1, the second 1.2 etc. until the revised version is approved, whereupon it becomes version 2.0. The system continues in numerical order each time a document is reviewed and approved.

Contents

1. Introduction

Medical devices are used extensively in the London Ambulance Service NHS Trust (LAS) in the delivery of patient care.

The LAS is committed to providing safe and suitable medical devices in sufficient quantities to meet the needs of our patients and staff.

The LAS is responsible for ensuring that the management of all medical devices complies with appropriate legislation, regulation and guidance

This policy applies to devices that are purchased and those that are on lease or loan

2. Purpose/Scope

The purpose of this Medical Devices Management Policy is to provide a systematic approach to the;

- Selection, trial, acquisition and deployment
- Training and implementation
- Maintenance and repair
- Decommissioning and disposal
- Cleaning and Decontamination

Primary guidance from the Medicine and Healthcare Products Regulator Agency (MHRA) April 2015 – Managing Medical Devices states:

“Medical devices play a key role in healthcare; vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimising risks of adverse incidents. Unless medical devices are managed proactively, the same type of adverse incidents will happen repeatedly. Good medical device management will greatly assist in reducing their potential for harm.”

This policy applies to all London Ambulance Service Staff (including bank employees and contracted personnel) who use medical devices and / or are responsible for their management.

3. Objectives

To advance and support medical care across the whole organisation, through effective deployment of medical devices to the point of use, while ensuring that there are appropriate monitoring procedures in place.

To ensure that the management of medical devices is carried out in line with current legislation, guidance and manufacturer’s recommendations.

To establish the responsibilities of managers and staff in relation to the management of medical devices.

4. Duties

4.1 Board

The Trust Board has a collective responsibility for managing medical devices and for ensuring effective risk management systems are in place.

4.2 Chief Executive Officer

It is the Chief Executive Officer's responsibility to ensure implementation of the Medical Devices Management Policy.

4.3 Nominated Director/Board member

The Chief Executive Officer will nominate the Chief Medical Officer to have responsibility for medical devices management.

4.4 Director of Corporate Affairs

The Director of Corporate Affairs is responsible for ensuring;

- The effectiveness of the medical devices management system.
- The condition and performance of medical devices including: device failures and issues; utilisation, performance, maintenance; repair and calibration history.
- The execution of investment, replacement and disposal plans.
- Decontamination.
- The equipment life cycle (including: selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices.
- Risk management including adverse incident reporting and actions required on MHRA's Medical Device Alerts and manufacturers' field safety notices.
- Training and access to manufacturer's instructions
- Records, including device inventory, outsourcing, equipment deployment, tracking and utilisation & equipment financing.

4.5 Deputy Medical Director

The Deputy Medical Director will ensure this policy is kept up to date with relevant law, best practice and guidance. They will also provide guidance, leadership and support across the Trust in the application of this policy and will be a member of the Clinical Equipment Working Group (CEWG). They are also responsible for ensuring that any vehicle- related medical devices are managed in accordance with this Policy and associated procedures.

4.6 Health & Safety/Medical Devices Manager - Medical Devices Safety Officer

The H&S/Medical Devices Manager is responsible for monitoring, receiving, assessing and where appropriate, actioning, all medical device related safety notices and alerts received by the Trust through the Central Alerting System (CAS). The H&S/Medical Devices Manager will provide guidance on safe system of medical devices management. The MDSO will provide the link to the Risk Compliance and Assurance Group (RCAG), MHRA, and the National Reporting and Learning Centre.

4.7 Head of Clinical Education

The Trust's Training Leads are responsible for defining and delivering suitable user training on new and existing medical devices.

4.8 The Clinical Equipment Working Group (CEWG)

The Clinical Equipment Working Group (CEWG) is responsible for:

- Improving communication about medical devices within LAS.
- Ensuring involvement of clinicians, technical staff, stakeholders and users in relation to any proposed changes.
- Defining persons responsible for device management tasks, training and safe device operation.
- Defining and reviewing this policy.
- Work closely with the Learning Group (Serious Incident Assurance and Learning Group) to disseminate learning from adverse incidents related to medical devices.
- Reviewing incidents including governance issues relating to medical device management.
- Developing and approving risk assessments.
- Defining procedures for the management of medical devices.
- Defining and updating a sourcing/replacement strategy and approved products list for medical devices.
- Standardisation of Products.
- Reduction in whole life costs of Products.
- Improved Quality of Products.
- Regulatory Compliance.
- Improve patient and staff user experience, through efficiency of process.
- Ensure consistent streamlining of current processes and equipment, recalling of old products.
- Continual re validation of catalogue and clinical loading lists.
- Reducing clinical variation – tying in with the strategy of the organisation.

- Reduce the amount of products used, this will free up money for the better products that are needed.
- Sharing best practice nationally, to be seen as the forerunners in procurement.

The Terms of Reference and Membership of CEWG are detailed in the appendix C.

4.9 Patient Safety and Clinical Effectiveness Group

The Patient Safety and Clinical Effectiveness Group is responsible for considering proposed medical device developments and changes to current practice and assess whether they are in accordance with the Trust's clinical strategy. Any alterations will be escalated to QOG for a decision based on the recommendation of CEWG and PSCEG.

4.10 Quality Oversight Group (QOG)

The Quality Oversight Group (QOG) is responsible for reviewing the activities of the Clinical Equipment Working Group (CEWG) and for assuring all aspects of medical devices are in line with the Trust clinical, quality and safety policies and procedures.

4.11 Procurement Department

The Procurement Department will ensure only medical devices and consumables approved by this policy and related procedures, are ordered. The Procurement Department is also responsible for ensuring that all medical device procurement complies with relevant procurement legislation (Public Contract Regulations 2015 – PCR 2015) and Trust Standing Financial Instructions.

The Procurement Department are responsible for collating and maintaining a list of single use medical devices, their suppliers and alternative products.

4.12 Fleet and Logistics Department

The Fleet and Logistics Department are responsible for ensuring that medical devices, including consumables, are available to operational staff and stations as needed. The Department is also responsible for coordinating scheduled inspection, and maintenance, and unscheduled repair, and for overseeing asset management processes.

4.13 Clinical Education and Standards Department

The Clinical Education and Standards Department is responsible for ensuring that appropriate information and training is provided to end-users to enable all new and current medical devices to be used safely and effectively.

4.14 Infection Control and Decontamination Group (ICDG)

The Infection Control and Decontamination Group (ICDG) have responsibility for providing input and advice to CEWG, Clinical Education and Standards and Operational management relating to matters of infection prevention and control, with the aim of ensuring that medical devices conform to existing legislation and Trust guidance.

4.15 Resilience and Specialist Operations Managers

Managers within these departments are responsible for ensuring that their specialist medical devices are compliant with this policy. Where it is currently not practical to manage these medical devices within the Trust's Medical Devices database, local compliance records must be kept and made available.

4.16 Managers and Supervisors

Managers and Supervisors in all areas of the Trust are responsible for ensuring this policy is communicated to staff and for ensuring compliance with the policy. This policy is available to all staff via the Trust's intranet.

4.17 Staff/Volunteers

All operational staff have a professional responsibility to ensure that they are competent to use medical devices within their scope of practice in a safe and effective manner, and that they maintain familiarity and competency with seldom-used devices. Staff and volunteers are expected to ensure that they understand and comply with their responsibilities under this policy, and associated procedures.

4.18 Consultation and Communications with Stakeholders

The Trust is committed to involving personnel and key stakeholders in the development, review and monitoring of Procedural Documents. Consultation has been undertaken through the Clinical Equipment Working Group (CEWG).

5. Definitions

5.1 Medical Device

The MHRA defines a medical device to be a device that is used to:

- Diagnose, prevent, monitor, treat or alleviate a disease.
- Diagnose, prevent, monitor, treat, alleviate or compensate for an injury or handicap.
- Investigate, replace or modify the anatomy or of a physiological process
- Control conception.
- Improve function and independence of people with physical impairments.

Further definitions are provided in the Appendix A.

6. Development

6.1 Prioritisation of Work

The need for this policy was identified through new guidance, 'Managing Medical Devices', issued by the MHRA in April 2014 (re-issued April 2015).

6.2 Identification of Stakeholders

Stakeholder identification is coordinated by the Trust's Clinical Equipment Working Group (CEWG).

6.3 Responsibility for Document's Development

This policy will be reviewed yearly under the direction of the Clinical Equipment Working Group (CEWG).

Further development will be co-ordinated by the Deputy Medical Director, and the Clinical Equipment Working Group (CEWG).

This policy will be approved by the Clinical Equipment Working Group (CEWG), Quality Oversight Group (QOG), and the Senior Leadership Board. It will be disseminated by use of the Trust Intranet through the Communications Department.

7. Use of Medical Devices

All users must ensure that:

- They only use medical devices approved and supplied by LAS in the delivery of its clinical services.
- Medical devices must only be used for the purpose for which they were originally designed and intended for.
- Single use medical devices are not re-used.
- Medical devices which have been identified for decommissioning must not be used on patients.
- Medical devices are not modified without the manufacturers' and Trust's approval.
- They are competent to use the medical devices safely and appropriately.

8. Acquisition

8.1 Triggers

Acquisition of medical devices will be triggered by one of the following:

- Change in clinical practice.

- Replacement of an existing device.
- Additional existing devices required.
- Change in legislation or guidance.

8.2 Process/Approvals

The Clinical Equipment Working Group (CEWG) will be responsible for developing and implementing local procedures on the acquisition and selection of medical devices. The process should take into account:

- Safety, quality and performance.
- Trust objectives and the needs of patients/stakeholders.
- The whole life cost of the device including consumables.
- The needs of all interested parties including those involved in use, commissioning, decontamination, maintenance and decommissioning.
- The balance between accessibility of medical devices and controlling their use.

8.3 Procurement

All medical devices acquired must have been ordered through the Trust's Procurement Department. The Clinical Equipment Working Group (CEWG) is responsible for the development and implementation of procedures to ensure new medical devices are appropriate and supported by safe working practices. Any acquisition must be in accordance with the Trust's Standing Financial instructions (SFI's) and Public Contract Regulations 2015.

8.4 Selection, trial and acquisition of new medical devices

Once a clinical need for a new (or replacement) medical device has been identified, CEWG will coordinate a process of assessment, review, trial and selection of products that meet the requirements, as detailed in the appendices. This will include seeking, as needed, opinion from end-users, IPCC, Clinical Education, Health and Safety and other experts.

Procurement will be involved at all stages where consideration and selection of products takes place in order to ensure that SFI's and PCR 2015 are adhered to.

No equipment shall be introduced for trial or evaluation without approval of CEWG.

Equipment that is the subject of research or a clinical trial can only be introduced with the approval of the Clinical Audit and Research Unit (CARU) who have responsibility for oversight of clinical research and trials. All research will be carried out in accordance with the appropriate legislation and frameworks as outlined in the LAS's Research Strategy.

All new electronic medical devices must be tested and commissioned by the Logistics Department prior to operational use.

9. Loan/Trial Equipment

Only loan/trial equipment approved by the Clinical Equipment Working Group (CEWG), in conjunction with the Procurement department can be brought into the Trust; in addition, Finance will be advised of the cost if purchased new. All reusable loan/trial medical devices must be registered with medical devices database/asset management system, and checked by the Logistics Department before entering service. At the end of the trial the equipment must be returned to the supplier.

The Clinical Equipment Working Group (CEWG) will identify, approve and audit local operating procedures on loan/trial equipment.

Indemnity Cover needs to be provided by the supplier for any loan/trial medical device. In the first instance, the Department of Health's Master Indemnity Agreement process should be followed.

10. Installation/Commissioning/Configuration

Before medical devices enter service they must, where appropriate, undergo installation, commissioning and configuration. In addition, new devices must have a suitable clinical use risk assessment and Provision and Use of Work Equipment Regulations (PUWER) assessment. These assessments will be coordinated by the Clinical Equipment Working Group (CEWG). Any installation, commissioning or configuration must only be undertaken by competent staff approved by the Trust. Roll-out of new equipment will be planned and delivered in conjunction with Logistics and operational managers.

All re-usable medical devices must have a unique identifier attached (Trust Asset Number).

Where appropriate, a label to clearly show the date of the next maintenance/inspection/service due should be attached to the device.

If no maintenance is required in accordance with Manufacturers guidelines, a 'No Service Required' label will be placed on the device.

Only Trust approved single-use medical devices must be used.

11. Packing and Loading Lists

Packing lists for standard equipment bags will be developed and maintained through CEWG and Logistics working with VP contractors.

Vehicle loading lists for standard vehicles (Ambulances, Fast Response Units

etc.) will be developed and maintained through CEWG, Fleet Improvement Group and Fleet & Logistics Departments.

Deviation from these packing and loading lists will not be permitted.

Specialist Resources such as HART, EPRR, MRU and CRU will develop and maintain packing and loading lists on their own which meet their needs.

12. Asset Management

All new reusable medical devices must be registered onto the Trust's medical devices database/asset management system.

Where a medical device requires routine maintenance or checks, these will be scheduled by the medical devices database/asset management system. All maintenance work carried out on a Medical Device will be recorded accurately on the medical devices database/asset management system.

Medical devices database/asset management system will link the manufacturer's serial number to the asset; on commissioning, Finance will be provided with a list with details of the serial number, asset and location.

13. Records

Storage procedures will ensure that accurate and complete copies of records, in paper or electronic format, will be made available throughout the retention period of the records for future reference, including; for traceability, for review, inspections, internal audits and investigations. The retention period of records will be in accordance with the Department of Health guidance; Records Management: NHS Code of Practice 2006.

A record of decisions relating to procurement, introduction, use and eventual withdrawal of medical devices will be kept.

Medical equipment, which has a need for regular inspection, testing, calibration or maintenance will be individually identifiable either by serial number or an asset identification system and entered onto an medical devices database/asset management system held by Logistics.

Records on the supply of single use medical devices will be held by the Logistics Department.

All consumable medical equipment will be entered onto the Trust procurement medical consumable catalogue.

Equipment that does not show up as 'seen' by the medical devices database/asset management system for a defined period of time will be reported as missing and local management at the site where it was last seen

will be asked to investigate the loss.

Where appropriate, all staff that have undergone training for a medical device, will have a record of the training recorded on the Trusts training database.

14. Maintenance/Repair

The medical devices database/asset management system will ensure that equipment needing regular testing and maintenance is done so at a frequency that meets or exceeds that recommended by the manufacturers.

Maintenance and repairs to medical devices must only be undertaken by suitably competent persons. Records of any maintenance or repair must be kept in accordance with the Trust's Records Management Information Lifecycle Policy.

Any spare parts or accessories used must be either from the original equipment manufacturer or through the use of compatible parts as deemed in a defined process. The Clinical Equipment Working Group (CEWG) will identify, approve and audit local operating procedures for the maintenance and repair of medical devices.

Items not presented for routine servicing will be identified by Logistics and a recall notice disseminated to relevant end-user groups.

Trust medical devices are primarily maintained by equipment maintenance staff. When demand to maintain medical devices exceeds the resource available to do so within specified maintenance schedules, consideration is given to seeking support from third party service providers, such as; the manufacturer's or other healthcare organizations' under contract to provide such support.

Staff authorised to use medical devices should ensure that the device continues to function correctly. This entails regular inspection and care, as recommended in the manufacturer's user information and local procedures. Instructions for user maintenance of medical devices will include:

- Checking that it is working correctly before use.
- Regular cleaning.
- Specific daily/weekly checks.
- Noting when it has stopped working properly or when obvious damage has occurred. (In these circumstances discontinue use of the device).
- Reporting faults and damage to Logistics via the equipment exchange scheme and in Datix.

Operational staff and end-users have a responsibility to check any medical

device prior to use. The extent of this check will vary based on the nature of the device. For example:

- Single use only medical devices.
- Packaging needs to be clean and intact.
- The device must be in-date.

Mission-critical re-useable equipment (suction units, defibrillators etc.) should be checked as part of a Vehicle Daily Inspection.

All other equipment should be inspected for damage before use.

Local arrangements will dictate if some of these checks can be delegated to vehicle preparation ('make ready') teams.

Items found to be damaged or defective will be returned to logistics for repair, with an incident report generated as needed.

15. Decontamination

Medical devices must be decontaminated in accordance with the Trust IPC Policy and Procedure and associated manufacturers' instructions.

Re-usable medical devices must be decontaminated prior to inspection, repair and disposal.

Equipment left at hospital will be managed according to Trust Operational Policy OP/025 – Procedure for the Scheduled Maintenance and Exchange of Ambulance Equipment.

Equipment that has a requirement for regular decontamination will be tracked by the Logistics Department.

16. Decommission/Disposal

All re-usable medical devices will be formally decommissioned by Logistics prior to disposal. If the medical device stores patient identifiable data this must certified as securely erased before disposal. Medical devices should be decontaminated prior to disposal.

Disposal of medical devices will be in accordance with the Trust's Waste Management Policy and Standing Financial Instructions/Standing Orders.

The finance department will be provided with a list of equipment and serial numbers prior to final disposal.

Any medical device not deemed safe for current patient use must not be resold

or donated.

17. Replacement Planning

The Deputy Medical Director, in conjunction with the Procurement Department will provide information to the Clinical Equipment Working Group (CEWG) to illustrate expected replacement dates, quantities and cost on a seven-year forecast.

The Logistics Manager, in conjunction with the Procurement and Fleet Departments, will monitor and identify changes in medical device failure rates/reliability, availability of spare parts and maintenance repair costs to inform the Clinical Equipment Working Group (CEWG).

The Clinical Equipment Working Group (CEWG) will, in conjunction with the Risk Compliance and Assurance Group (RCAG) and Patient Safety and Clinical Effectiveness Group (PSCEG), be responsible for the development of criteria to be used to identify the planned replacement date of medical devices.

18. Loss/Damage of Devices

The Clinical Equipment Working Group (CEWG) will be responsible for developing a process on the reporting and monitoring loss or damage to medical devices.

19. Modifying/Change of use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications.

No modifications or change of use of devices can be implemented without the prior approval of the Clinical Equipment Working Group (CEWG), and the Risk Compliance and Assurance Group (RCAG).

20. Training and Education

20.1 Legal requirements relating to staff training

Health and Safety at Work Act 1974 requires the Trust to ensure employees are adequately trained.

20.2 User

User training will include training of staff and provision of instructions.

The Clinical Education and Standards Department will identify user training requirements for new medical devices during the selection processes.

The training of staff will be in accordance with the Trust's Learning and Development Policy. Any training for operational staff on the use of medical

devices is delivered as specified within the Trust Training Needs Analysis (TNA).

Training records must be held for individuals involved and should identify that they are appropriately trained to a level proportionate to the activities they are undertaking.

20.3 Technical

Individuals providing maintenance and repair services need to be adequately trained and appropriately qualified. This applies to all directly employed staff, contracted services or others.

Training records must be held for individuals involved and should identify that they are appropriately trained to a level proportionate to the activities they are undertaking.

21. Risk Management

21.1 Adverse Incidents

Adverse Incidents relating to medical devices will be handled in accordance with the Trust's Incident Reporting Procedure.

Reporting is essential to ensure that lessons are learnt and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices.

The Clinical Equipment Working Group (CEWG) will be responsible for developing a process of monitoring adverse incidents relating to medical devices.

An adverse incident involving a medical device should be reported to the Medical Health Care Regulatory Authority (MHRA) under Yellow Card Scheme if the incident has led to, or were it to occur again could lead to:

- Death, life-threatening illness or injury.
- Deterioration in health.
- The necessity for medical or surgical intervention.
- Unreliable test results leading to inappropriate diagnosis or therapy.

21.2 Patient Safety Notices/Recalls and Field Safety Notices

Patient safety alerts are a crucial part of NHS England's work to rapidly alert the healthcare system to risks and provide guidance on preventing potential incidents that may lead to harm or death. These incidents are identified using a reporting system to spot emerging patterns at a national level, so that

appropriate guidance can be developed and issued to protect patients from harm.

Patient safety alerts specific to medical devices are published as Medical Devices Alerts (MDA's), which are the prime means of communicating safety information to the Trust and other healthcare organisations on medical devices.

MDA's are issued via the Central Alerting System (CAS), a web-based cascading system for issuing alerts, important public health messages and other safety critical information and guidance.

A Field Safety Notices (FSN) is a communication sent by medical device manufacturers, or their representatives, in connection with a Field Safety Corrective Action (FSCA).

FSNs outline actions to be taken to reduce the risk of death or serious injuries associated with the use of medical devices, and are used by manufacturers to tell their customers about them.

The Medical Devices Manager (Medical Devices Safety Officer) is responsible for receiving, assessing and where appropriate, actioning, all medical device related safety notices and alerts received through the CAS system. All received FSNs and Patient safety Notices are recorded and the actions taken are monitored in our in-house alert management tracker to provide assurance.

The Medical Devices Manager (Medical Devices Safety Officer) will also monitor the weekly Field Safety Notice (FSN) bulletins for relevance and where appropriate, undertake the required actions as recommended by the manufacturer.

21.3 Risk Assessments

The Trust uses a range of risk assessments to identify and manage risks involving medical devices, including; risk register, risk assessments, general risk assessments and health & safety departmental risk assessments. The practical application of these risk assessments are detailed in the Trust Risk Management Policy and Procedures.

21.4 Risk Register

The Trust has a risk register which records risks involving medical devices and is recorded on the Trust Incident Reporting System (Datix).

The risk register is reviewed monthly and changes made to the risk register, as appropriate. The practical application of this process is detailed in the Trust Risk Management Policy and Procedures.

22. Dissemination and Implementation

22.1 Dissemination

This policy will be disseminated via the intranet and held within the Policy Library. The Communications Team will issue a notice to all staff on the updating of this policy via Trust intranet.

22.2 Implementation

After approval and dissemination of this policy, implementation will follow immediately. No specific training is required but where required support can be provided by the Training and Medical Devices/Clinical leads.

23. Process for Monitoring Compliance and Effectiveness

Compliance to this policy will be monitored through reports to the Clinical Equipment Working Group (CEWG) which meets in full every quarter. It receives reports on audits, reports from the Trust's incident reporting system and reports from key managers, staff and stakeholders. Further detail is provided in the Monitoring Table in Appendix B.

Where a lack of compliance is found, the identified group, committee or individual will identify required actions, allocate responsible leads, target completion dates and ensure an assurance report is represented showing how any gaps have been addressed.

24. Equality Impact Assessment

This policy has been reviewed in line with the Equality Act 2010 which places a duty on the Trust to have due regard to the need to:

- Eliminate discrimination, harassment and victimisation.
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it.
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The specific needs of protected characteristic groups have been considered throughout the development of this policy. Special attention should be made to ensure the policies are understood by staff, who are new to the NHS, those whose first language is not English, staff whose literacy skills may be weak, those with special educational needs or those who have little experience of working life.

25. References

Links to Related documents or references providing additional information		
Ref. No.	**Title**	**Version**
TP/027	Infection Prevention & Control Policy	2017
	Infection Prevention & Control Training Workbook	2017
OP/025	Procedure for the Scheduled Maintenance and Exchange of Ambulance Equipment	2019
TP117	Incident Reporting and Management Policy	2019
HS/023	Central Alerting System Procedure	2020
TP/057	Waste Management Policy	2017
TP/008	Policy & Procedure for Personally Issued Equipment	2019
HS/008	Provision and use of work equipment procedure	2019
TP/029	Records Management and Information Lifecycle Policy	2018
TP/035	Risk Management Procedure	2020
	CQC - Guidance for providers on meeting the regulations. March 2015	2015
	Medical Devices Regulations 2002 (as amended)	2002
	MHRA Document - Managing Medical Devices. April 2015	2015
	MHRA Medicines and Healthcare products Regulatory Agency (MHRA). Single-use medical devices- implications and consequences of re-use	2018
	Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC	2007
	NHS England Patient Safety Alert No NHS/PSA/D/2014/006 'Improving Medical Device Incident Reporting and Learning'.	2014
	Health and Social Care Act 2008: Code of Practice for the Prevention and Control of infections and related guidance	2015
	Health and Safety at Work etc. Act 1974	1974
	Management of Health and Safety at Work Regulations 1999.	1999
	IEC 62353 Edition 1: Medical Electrical Equipment & IEC 60601-1Medical Design Standards.	
	Department of Health. Records Management: NHS Code of Practice. 2006 MHRA. Devices in Practice.	2006
	BS EN 62366:2008 Medical devices. Application of usability engineering to medical devices.	2008
	BS EN ISO 13485:2012 Medical devices. Quality Management Systems. Requirements for regulatory purposes.	2012

26. Associated Documents

Appendix A – Definitions

Medical Device

Any reference to a medical device indicates a unit of equipment that is owned by the Trust, operated by a suitably trained clinician and used for the purpose of clinical care under the jurisdiction of the Trust. Such devices fall into two main categories; single patient use and reusable.

Single Patient Use

A medical device which is only used once for its designated purpose. They are almost exclusively contained in an air-tight package, have a designated 'shelf-life' and must be disposed of appropriately after first use. Such devices are controlled in consumable stock and are not identified as Trust capital assets. They are not regarded as 'serviceable' items.

Re-usable

A medical device which is used for its designated purpose on multiple occasions for the duration of its operational life. They are not regarded as consumables but may incorporate single-use items as ancillary devices for the purpose of application. Most devices are expensive and are registered as Trust capital assets. They are regarded as 'serviceable' items and therefore require a scheduled inspection, test or calibration.

Patient monitoring devices

These medical devices are almost exclusively re-usable but are often operated in conjunction with single-use ancillary devices. They are generally used in order to monitor the patient's condition of health. The clinician will often use the information indicated by the device to determine any further course of action. Such devices can be expensive, often contain electronic components and are serviceable devices, such as:

- Manual Defibrillator/ECG Monitors
- Automated External Defibrillator/Monitors
- Lucas 2 automatic CPR systems
- Blood Glucose Monitors
- Tympanic Thermometers
- Otoscope/Ophthalmoscope
- Manual Sphygmomanometers
- SPO2, and Capnography Equipment.

Resuscitation Devices

These medical devices are almost exclusively re-usable but are often operated in conjunction with single-use ancillary devices. They are generally powered by

gas, be it oxygen or ambient air. Most devices are used to assist the respiratory recovery of a patient. The devices are serviceable, can be expensive and contain electronic components, such as:

- Oxygen Flowmeters/Pipeline Systems
- Suction Units
- Pneumatic Resuscitators
- Ventilators
- Bag/Valve/Mask Resuscitators
- Lifting and Handling Equipment
- Entonox demand valves.

These medical devices are re-usable and are utilised for the safe movement, immobilising and handling of patients. Stretchers may contain electronic components and hydraulic systems for operating the device. The devices are generally serviceable and can be expensive, such as:

- Stretchers
- Carry Chairs
- Wheelchairs
- Scoops
- Spinal Boards
- Straps.

Appendix B – Implementation Plan & Monitoring Compliance

IMPLEMENTATION PLAN				
Intended Audience	All Staff			
Dissemination	Available to all staff on the Pulse			
Communications	New Procedure to be announced in the RIB and link provided to the document			
Training	Included in training for new staff			
MONITORING COMPLIANCE				
Aspect to be monitored	**Frequency of monitoring and tool used**	**Individual/ team responsible for carrying out monitoring AND Committee/ group where results are reported**	**Committee/ group responsible for monitoring outcomes/ recommendations**	**How learning will take place**
Accuracy of the inventory	Annually Audit of service areas	Logistics Clinical Equipment Working Group	Reports to QOG and QAC	Tracking / tracing of missing items; feedback to operational managers on loss rates and possible causes
Repair and Maintenance of Medical Devices	Quarterly Performance meetings and reports from service contractors. 10% of service records will be audited	Logistics Clinical Equipment Working Group	Reports to QOG	Changes / improvement to systems fed back to operations and to Vehicle Preparation contractors
Review of training needs versus training delivered	Annual Review of Training Needs Analysis	Training Clinical Equipment Working Group	Input to Clinical Education & Professional Standards / Curriculum Development groups	Ensure that staff are adequately trained / maintain familiarity with full range of equipment. Update

Appendix C – Terms of Reference - Clinical Equipment Working Group (CEWG)

Terms of Reference

Date: 04/05/2021
Clinical Equipment Working Group (CEWG)

1. Authority

1.1 The constitution and terms of reference for the Clinical Equipment Working Group will be set out below and subject to amendment when directed and agreed by the Quality Oversight Group (QOG).

1.2 The group is authorised by the Quality Oversight Group to investigate any activity within its terms of reference. It is authorised to seek any information it requires from any employee and all employees are directed to co-operate with any request made by the group.

1.3 The group is authorised by the Quality Oversight Group to obtain outside legal or other independent professional advice and to secure the attendance of outsiders with relevant experience and expertise if it considers this necessary.

2. Purpose

2.1 The Clinical Equipment Working Groups prime purpose is to ensure that the LAS through effective use and management of clinical equipment and where appropriate other equipment not covered by other groups is delivering high quality patient care and meets the CQC Essential Quality Standards Outcome 8 and 11.

2.2 The group will look at all aspects of the introduction of proposed new clinical equipment and also review existing clinical equipment.

2.3 The agenda will routinely include a focus on a clinical issue/risk for discussion and recommendations for improving practice and this will be informed and led by the Quality Oversight Group.

3. Objectives

The Clinical Equipment Working Group will:

3.1 Ensure that criteria are set for approving the future funding of potential high cost (>£5K) clinical equipment, to include some cost benefit and clinical risk analysis.

3.1.1 Ensure existing clinical equipment which are outliers for high cost, low usage or high wastage are reviewed for cost benefit and clinical risks of alternatives.

3.1.2 Ensure that the clinical need(s) for new equipment within the LAS is established prior to the introduction, with due cognisance to the available types / models / manufacturers / configurations. As well as costs and impact upon existing use of clinical equipment and application of clinical care within the LAS.

3.1.3 Ensure where appropriate that expert advice is sought on matters relating to Infection Prevention and Control, Decontamination and Manual Handling.

3.1.4 Ensure that matters concerning staff training and communications strategies are formally addressed for the introduction of new clinical equipment.

3.1.5 Ensure that guidelines are developed, published and communicated to the staff to support the safe implementation and use of new equipment.

3.1.6 Ensure that recommendations or requirements from other audits / inspections of clinical equipment within the LAS are dealt with by the Clinical Equipment Working Group or referred onwards to the correct group or committee. Review the risks associated with the LAS clinical practice and ensure that appropriate action plans have been put in hand to reduce the number of untoward clinical events.

4. Membership and attendance

4.1 Membership of the Clinical Equipment Working group is determined by the Executive Leadership Team and the Chair of the Committee.

The following core membership applies

- Deputy Medical Director (Chair of the group)
- Assistant Director of Operations (Vice Chair)
- Deputy Director – Fleet and Logistics
- Education & Development representative at PLM/ECM level.
- Emergency Planning Resilience & Response representation (HART & Tactical Response Unit)

4.2
- Advanced Paramedic Practitioner
- Representation from the Procurement department
- Clinical Advisor to Procurement
- Cycle Response Unit representative
- Motor Cycle Unit representative
- H&S / Medical Devices Manager
- Head of IPC
- Fast Response unit representative
- Nominated staff side representative from Unison and GMB (one each)

4.3 The members listed above will be expected to attend every meeting or send a formally nominated deputy who has the authority to contribute to discussions and support decisions made by the group.

4.6 Other representatives may be invited to attend as relevant to the agenda and work programme to provide expert opinion and guidance.

5. Accountability

5.1 The Clinical Equipment Working group is accountable to the Quality Assurance Committee (QAC) which is a Trust Board committee.

6. Reporting

6.1 The minutes of the Clinical Equipment Working Group meetings will be formally recorded and approved minutes submitted to the Quality Oversight Group.

6.3 The Chair of the Clinical Equipment Working group will draw the attention of the Quality Assurance Committee to any issues that require disclosure to the full Trust Board.

7. Administration

7.1 Requests for agenda items shall be forwarded to the Chair no later than 8 days before the date of the meeting.

7.3 The draft minutes and action points will be available to Group members within two weeks of the meeting.

7.4 Papers and 'Any other Business' will be tabled at the discretion of the Chair of the Clinical Equipment Working Group.

8. Quorum

The quorum will be:

8.1

- The Chair or vice chair;
- Minimum of 4 other members.

8.2 Committee members' attendance will be recorded in the minutes of each meeting and reviewed at the end of the year to ensure that this requirement is met.

9. Frequency of Meetings

9.1 The Clinical Equipment Working Group shall meet every month and this will be scheduled at least two weeks prior to the Quality Oversight each quarter.

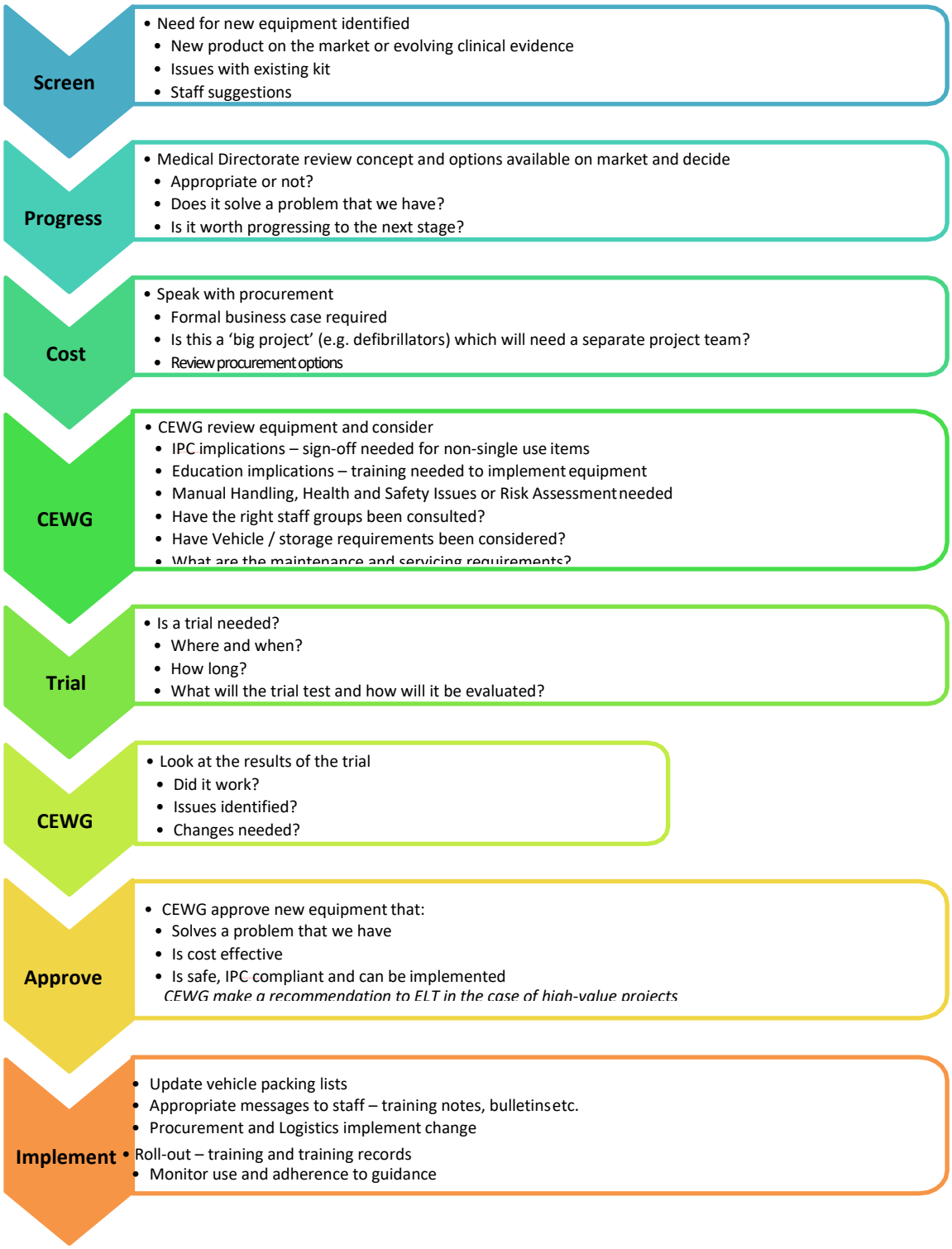
9.2 The Chair of the Chair of the group may request an extraordinary meeting outside of these times if required.

10. Review of Terms of Reference

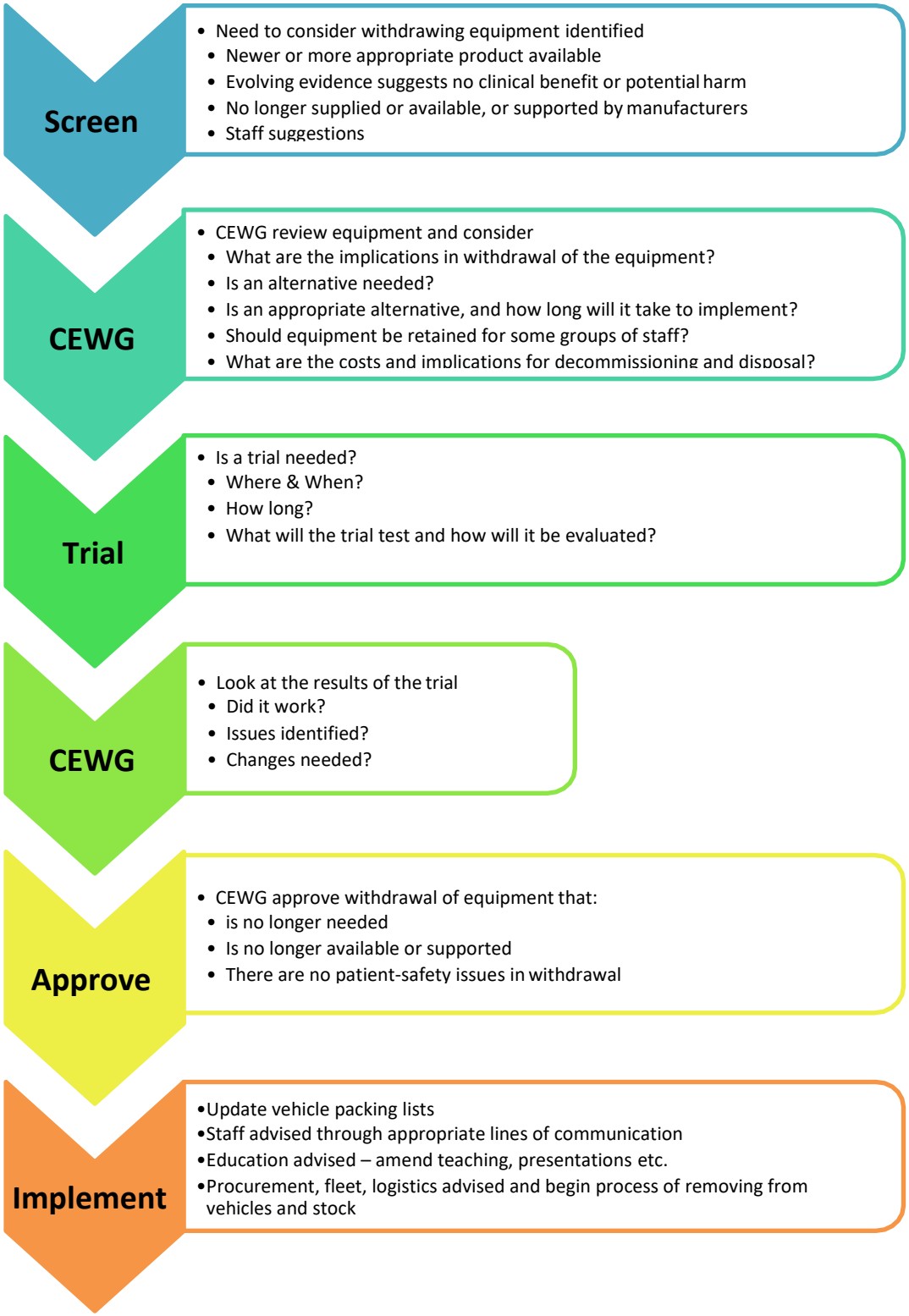
10.1 The Quality Oversight Group will review these Terms of Reference in six months' time in the first year of operation and then annually thereafter.

10.2 The Chair or the nominated deputy will ensure that these Terms of Reference are amended in light of any major changes in committee or Trust governance arrangements.

Appendix D – CEWG Process for introducing Medical Devices & clinical Equipment



Appendix E – CEWG Process for withdrawal of Medical Devices & Clinical Equipment



Appendix F – CEWG Process for urgent withdrawal of Medical Devices & Clinical Equipment due to a product recall or safety notice