London Ambulance Service NHS Trust

Policy for the Management of Medical Devices

DOCUMENT PROFILE and CONTROL

Purpose of the document: To ensure that Medical Devices are procured, used, maintained and disposed of in accordance with relevant legislation, guidelines and best practice.

Sponsor Department: Fleet and Logistics

Author/Reviewer: Corporate Logistics Manager / Deputy Medical Director
To be reviewed by February 2018

Document Status: Final

Amendment History			
Date	*Version	Author/Contributor	Amendment Details
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
12/01/17	0.10	Deputy Medical Director	Minor Changes, formatting and EQIA
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.

For Approval By:	**Date Approved**	**Version**
PMAG	02/02/2017	1.0

Ratified by (if appropriate)		
ELT	07/02/2017	1.1

Published on:	Date	By	Dept
The Pulse (v1.3)	12/05/17	Governance Administrator	G&A
LAS website (v1.3)	12/05/17	Governance Administrator	G&A
Announced on:	**Date**	**By**	**Dept**
The RIB	16/05/17	IG Manager	IG

Equality Analysis completed on	By
12/01/17	EA Screening Team
Staffside reviewed on	**By**

Links to Related documents or references providing additional information		
Ref. No.	**Title**	**Version**
TP/027	Infection Prevention & Control Policy	2016
	Infection Prevention & Control Training Workbook	2016
OP/025	Procedure for the Scheduled Maintenance and Exchange of Ambulance Equipment	2016
HS/011	Incident Reporting Procedure	2016
HS/011	Trust Policy for Processing Medical Device Alerts and Other Hazard Notices	2016
TP/057	Waste Management Policy	2015
TP/089	Policy & Procedure for Personally Issued Equipment	2015
HS/008	Provision and use of work equipment procedure	2017
TP/029	Records Management and Information Lifecycle Policy	2016
	Managing Medical Devices Guidelines For Healthcare And Social Services Organisations Medicines and Healthcare Products Regulatory Authority,	April 2015
	Medical Devices Regulations	2002
	Health and Social Care Act 2008: Code of Practice for the Prevention and Control of infections and related guidance	2015
	MHRA Medicines and Healthcare products Regulatory Agency (MHRA). Single-use medical devices- implications and consequences of re-use	2013

1. Introduction

1.1. Medical devices play a key role in healthcare and are vital for diagnosis, therapy, monitoring and care. Effective management of this important resource is required to meet the Trust objectives of high-quality patient care, clinical and financial governance, including minimising the risk of adverse events. Good medical device management will assist in reducing the potential for harm to patients and staff.

1.2. The London Ambulance Service NHS Trust is responsible for ensuring that the management of all medical devices complies with appropriate legislation, regulation and guidance.

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

1.4. The purpose of this document is to outline a systematic approach to life-cycle management of medical devices addressing the requirements of the Medicines and Healthcare Products Regulatory Authority (MHRA) document 'Managing Medical Devices Guidelines for Healthcare and Social Services Organisations (April 2015)'. Life-cycle includes:

- Selection, trial and acquisition
- Training and implementation
- Cleaning
- Maintenance and repair
- Reporting adverse incidents and monitoring manufacturer's recommendations
- Decommissioning and Disposal

2. Scope

2.1. 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

3.1. 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.

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

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

4. Responsibilities

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

4.2. Chief Executive
The Chief Executive has overall responsibility for having an effective policy for the Management of Medical Devices in place and for meeting all related statutory requirements.

4.3. Medical Directorate (Quality Governance)
The Medical Director is responsible for
- 4.3.1. Identifying a medical requirement
- 4.3.2. Ensuring that devices meet this requirement
- 4.3.3. Ensuring that devices comply with the Trusts clinical, quality and safety policies and procedures, including compliance Infection Prevention and Control guidelines.

4.4. The Clinical Equipment Working Group (CEWG)
CEWG are responsible for the selection and approval of medical devices, and for decisions relating to withdrawal of devices.
- 4.4.1. The Terms of Reference and Membership of CEWG are detailed in the appendices. Health, Safety and Security Department
  Are responsible for working with CEWG to ensure that equipment complies with current legislation and that appropriate risk assessments have been carried out.

4.5. Clinical Education and Standards
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

4.6. Infection Prevention and Control Committee (IPCC) (Assurance Group)
IPCC 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.

4.7. Procurement Department
The Procurement Department is responsible for ensuring that all medical device procurement complies with relevant procurement legislation and NHS and Standing Financial Instructions

4.8. 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.

4.9. Operational Staff
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.

5. Definitions

5.1 The Trust accepts the Medical Devices (2002) Regulations definition of a medical device as
An instrument, apparatus, appliance material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:

a. *is intended by the manufacturer to be used for human beings for the purpose of:*
    i. *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
    ii. *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
    iii. *investigation, replacement or modification of the anatomy or of a physiological process*
    iv. *control of conception*
b. *does **not** achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means"*

6. Policy Statement

6.1. The London Ambulance Service is committed to maintaining the health and safety of staff and patients, and is committed to delivering high-quality clinical care. The Trust recognises that it is responsible for ensuring that staff have access to the most efficient and appropriate equipment and that staff receive appropriate guidance in its use.

6.2. This policy covers the management of all medical devices within The Trust. It applies to all staff who work with medical devices or are involved in the procurement, maintenance, decontamination, training, monitoring, incident reporting and disposal.

6.3. All 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.

7. Selection, trial and acquisition of new medical devices

7.1. The procurement of new medical devices will be undertaken in accordance with relevant legislation, national and Trust policies and Financial Instructions.

7.2. New Medical Devices

7.2.1. 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. This standard applies equally to trials as it does to outright purchase.

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

7.2.3. All medical equipment that is provided free of charge, for a loan, trial or on a permanent basis must have the relevant indemnity, liability and insurance cover in place before it is used within the Trust. The Procurement Department will, in the first instance, ascertain whether the supplier is registered under the Department of Health Master Indemnity Agreement (MIA) and if not, ensure that this is arranged or an equivalent agreement is in place.

7.2.4. 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.

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

8. Training and Education

8.1. This policy recognises that there are varying levels of training needed to use medical devices, ranging from familiarity with the device that can be

undertaken supported by a bulletin, to complex end-user education requiring assessment and / or certification prior to use.

8.2. Clinical Standards and Education are represented on CEWG and will provide advice as to the level of education and training needed to ensure safe and competent use of new devices, and for ensuring that where formal training, assessment or certification is required, a relevant educational package is produced.

8.3. Where formal training, assessment or certification is required, Education and Standards will keep a record of training, and track requirements for on-going education and certification as needed.

9. Implementation

9.1. Reusable equipment and equipment requiring regular maintenance will be appropriately labelled to enable tracking

9.2. Roll-out of new equipment will be planned and delivered in conjunction with Logistics and operational managers

10. Cleaning

10.1. Wherever possible, single-patient-use items will be procured. Where this is unavoidable, consideration will be given to ease of decontamination and risk of infection transmission during appraisal of new equipment.

10.2. Medical devices will be cleaned and decontaminated in accordance with manufacturer's recommendation and Trust IPC Policy and Procedures.

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

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

11. Packing and Loading Lists

11.1. Packing lists for standard equipment bags will be developed and maintained through CEWG and Fleet and Logistics.

11.2. Vehicle Loading lists for standard vehicles (Ambulances, Fast Response Units etc.) will be developed and maintained through CEWG, Vehicle and Equipment Working Group (VEWG) and Fleet and Logistics

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

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

12. Asset Management, Maintenance and Repair

12.1. The Trust will develop and implement an asset Management process that records key maintenance events throughout the operational life-cycle of the equipment, including commissioning, servicing, repair and disposal.

12.2. The 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.

12.3. The 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.

12.4. Free equipment and items provided on loan will be subject to the same asset management requirements; in addition, Finance will be advised of the cost if purchased new.

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

12.6. Equipment that does not show up as 'seen' by the 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.

12.7. 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:

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

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

12.7.3. Manual handling equipment should be inspected for damage before use.

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

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

13. Decommissioning and Disposal

13.1. CEWG will identify a need to remove a particular medical device from the Trust catalogue. This will be done following an appraisal of current evidence, risk and need for and availability of a suitable replacement device.

13.2. All re-useable medical devices will be formally decommissioned by Logistics prior to disposal. This includes:

- Removal of any stored patient-identifiable data, ensuring that data is securely and permanently erased, or storage cards, for example, are destroyed.
- 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

13.3. Medical Devices not deemed safe for future patient care must not be re-sold or donated. Where sale of devices that are surplus to requirements is contemplated, contract arrangements must include consideration of matters relating to assurance of serviceability and liability.

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

14. Records

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

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

14.3. 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 asset register held by Logistics

14.4. Where appropriate, all staff that have undergone training for a medical device, will be registered on the Trusts training database

15. Monitoring and Compliance

15.1. The monitoring of this policy will be through reports to the Clinical Equipment Working Group, It will receive reports on audits, Trust's incident reporting system and reports from key managers, staff and

stakeholders. Further detail is provided in the Monitoring Table in the appendices.

15.2. 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.

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:				
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 CSSC and Finance / Audit Committees	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 CSSC	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

				training materials as needed
Effectiveness of Procurement of medical equipment	6 months Reports from Procurement Department	Head of Procurement Clinical Equipment Working Group	CSSC, Finance	Improve systems where deficiencies are identified
Compliance with MHRA Alerts	Quarterly Audit of Medical Device Alerts	Head ofHealth, Safety and Security Clinical Equipment Working Group	CSSC, Clinical Education and Standards	Ensure that the Trust acts on relevant alerts and the changes to inventory, use and education are disseminated .

Appendix 1

Terms of Reference

January 2017

Clinical Equipment Working Group

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 Governance Committee

1.2 The group is authorised by the Quality Governance Committee 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 Governance Committee 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 Governance Committee.

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.

3.1.9 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.

4.2 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)
- Advanced Paramedic Practitioner
- Representation from the Procurement department
- Clinical Advisor to Procurement
- Cycle Response Unit representative
- Motor Cycle Unit representative

- 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 Governance Committee 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 Committee through the Clinical Safety and Standards Committee.

6.3 The Chair of the Clinical Equipment Working group will draw the attention of the Clinical Safety and Standards Committee and Quality 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

8.1 The quorum will be:

- 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 Committee each quarter.

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

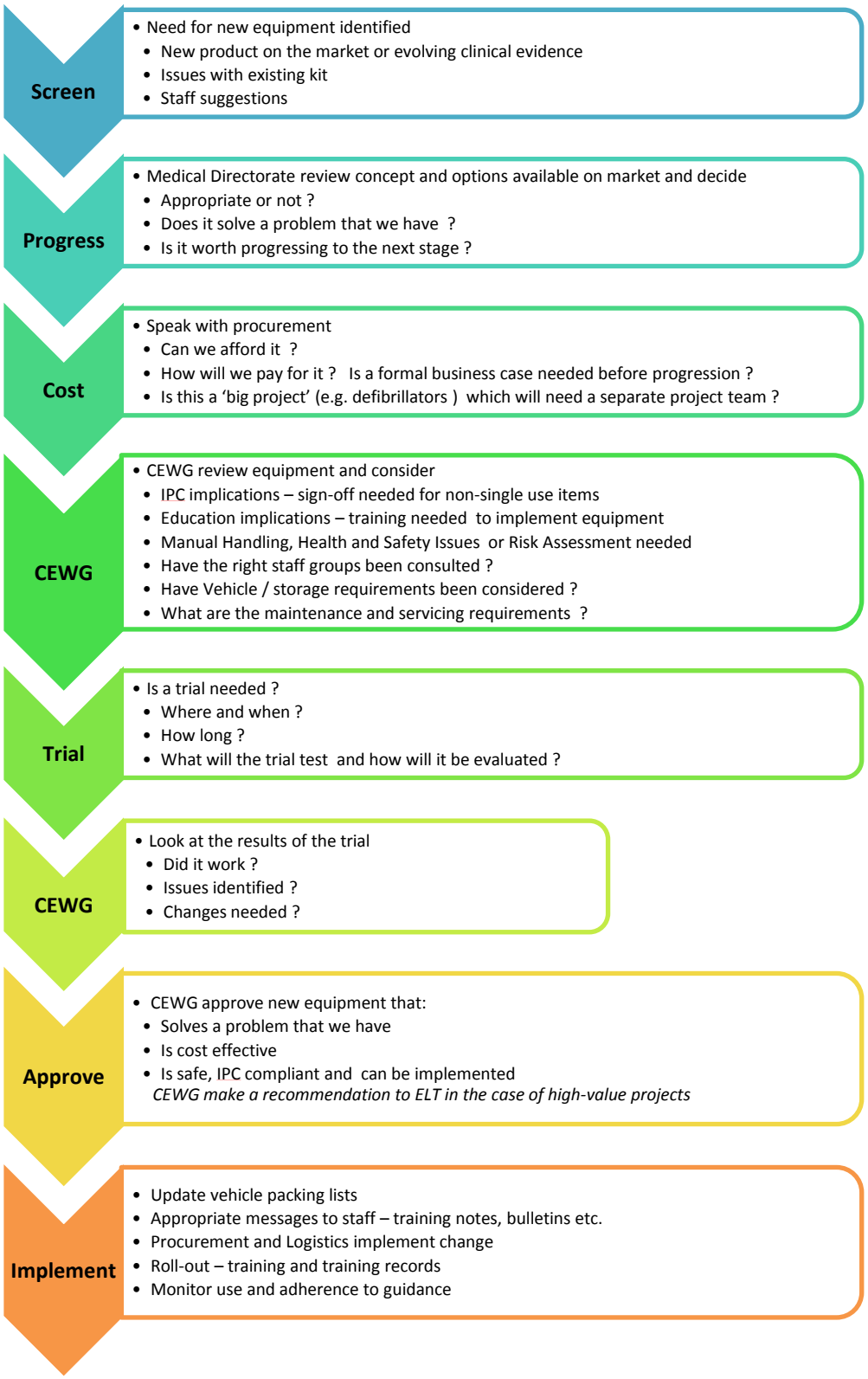
10. Review of Terms of Reference

10.1 The Clinical Safety and Standards Committee 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.

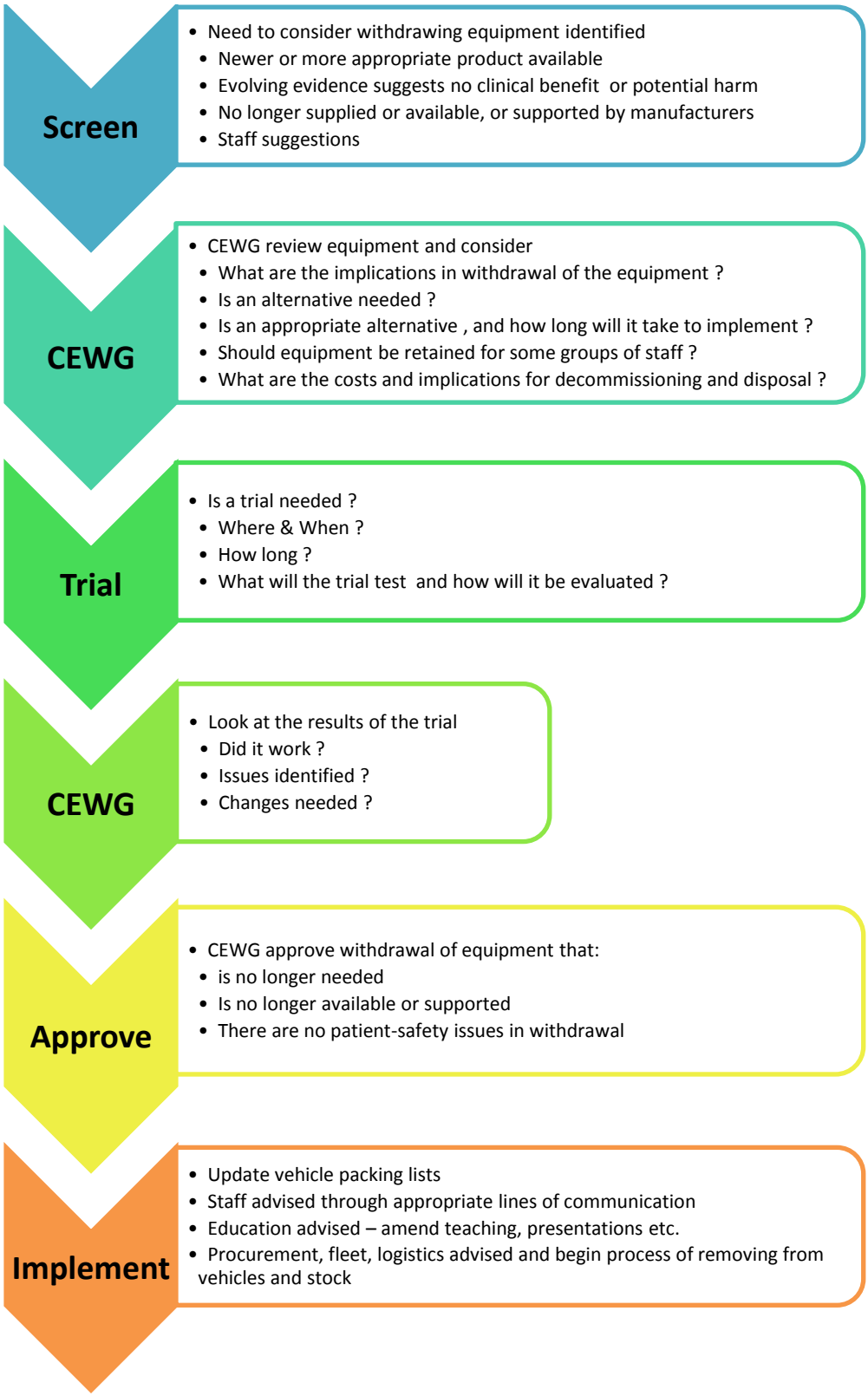
Appendix 2

CEWG Process for introducing medical devices & clinical equipment



Appendix 3

CEWG Process for withdrawal of medical devices & clinical equipment



Appendix 4

CEWG Process for urgent withdrawal of medical devices & clinical equipment due to a product recall or safety issue