NHS National Services Scotland

National Decontamination Guidance on Loan Medical Devices (Reusable): Roles & Responsibilities GUID 5002

Health Facilities Scotland
Decontamination Services

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Contents

Page

1.0 Executive summary

Healthcare facilities are using reusable loan medical devices to provide needed inventory to perform procedures. An obligation of healthcare facilities is to ensure these loan medical devices have minimal contamination and are appropriately processed at time of use. Additionally national initiatives exist to minimise Healthcare Associated Infections (HAIs) and harm to patients and staff.

The effective control of loan medical device decontamination presents challenges to theatres, clinics, sterile services, manufacturers and suppliers. Loan medical devices must be managed in a consistent way to ensure patient and staff safety.

Clear national guidance is required to define roles and responsibilities required in the decontamination process of loan medical devices. The Sterile Service Department Consultative Group (SSDCG) requested the development of such guidance. The new guidance will reduce risks associated with loan medical devices and deliver positive health impacts.

Contained within the guidance are roles and responsibilities for theatres/clinics, Central Decontamination Units (CDUs) and manufacturers/suppliers. The guidance encompasses the entire loan cycle from the decision to order a loan medical device to the returning of the loan medical device to the supplier.

The guidance ensures loan medical devices are delivered to theatre fit for purpose, in a timely manner and returned safely to the supplier.

Managing Medical Devices was published in 2014 by MHRA. It outlines a systematic approach to the acquisition, deployment, maintenance, repair and disposal of loan medical devices and medical device training.

2.0 Background

2.1 The lack of clear reusable loan medical device guidance introduces risks of delayed and cancelled patient treatment and of injury and cross infection. MHRA guidance Managing Medical Devices 2014 set the requirements to have clear roles and responsibilities of those involved in managing loan medical devices. The Safety Action Notice, SAN(SC)00/30 'Handling of Surgical Instruments on Loan from another Organization' sought to bring awareness and forward implementation of documented and controlled processes.

2.2 Loan medical devices often consist of trays with many types of sometimes complex instruments. With advances in medical technology, loan medical devices are sometimes new and unfamiliar to the facility. Reported incidents have identified that loan devices arrived at CDUs in an unsuitable condition e.g. dirty, corroded etc. This is of particular concern to Central Decontamination Unit (CDU) staff who are responsible for inspecting, processing, storing and issuing loan medical devices.

2.3 Lapses in planning, policies, communications and instructions ultimately increase the risks associated with loan medical devices, including:

- patient, staff and supplier safety;
- cross infection;
- injury from defective loan medical device;
- damaged or missing loan medical devices;
- cost of replacements;
- disputes with suppliers;
- cancellation or delay of surgical procedures;
- financial burdens to rectify these risks.

2.4 Through the established stakeholder network, the Sterile Service Department Consultative Group (SSDCG) requested that national loan medical device guidance regarding roles and responsibilities be developed. The introduction of this guidance and its subsequent implementation would deliver a positive health impact. Adverse incidents related to loan medical devices are documented, reported to Incident Reporting and Investigation Centre (IRIC) and therefore clear guidance defining roles and responsibilities will aid this process.

3.0 Objective

3.1 The objective is to produce national decontamination guidance on reusable loan medical devices to be used across NHSScotland with clearly defined roles and responsibilities for the theatres/clinics, Central Decontamination Units (CDUs) and suppliers.

The guidance aims to ensure loan medical devices are:

- safe and fit for purpose;
- available at the designated time;
- managed by staff trained in reprocessing loan medical devices;
- reprocessed, packaged and transported in a manner to comply with Medical Device Regulations, relevant standards and guidance;
- reprocessed, packaged and transported in a manner to prevent damage to instruments and risks to staff;
- returned to the supplier in a safe and decontaminated state.

4.0 Scope

4.1 This guidance is applicable to reusable loan medical devices from all suppliers. The loan medical devices being reusable medical devices subjected to decontamination processes in a CDU or a supplier of contract sterilization services.

Loan endoscopes and Endoscope Decontamination Units (EDUs) are not within the scope of this guidance.

5.0 Theatre/Clinic roles and responsibilities

5.1 The overall responsibility for management of reusable loan medical devices resides with Theatres. This covers assessing the requirement for loan medical devices to returning them to the supplier.

5.2 Staff education and training:

- ensure a full understanding of loan medical device policies and procedures;
- for unfamiliar items - Recognise the additional time that may be required for loan medical devices that are unfamiliar to the CDU and provide information on them for training and processing. Refer to MHRA Managing Medical Devices April 2014 for further guidance on training;
- ensure the manual handling regulations are included in the training;
- coordinate with all interested parties to enable the supplier's trainer to deliver training and update as required.

5.3 Establish Service Level Agreements (SLAs) with suppliers. All medical devices on loan from manufacturers should be subject to a written agreement which defines the loan medical device management requirements i.e. the acquisition, deployment, maintenance, repair and disposal of medical devices, responsibilities and liabilities. (refer to MHRA Managing Medical Devices April 2014).

5.4 Ordering loan medical devices and checking the indemnity agreement with supplier:

- surgeons' designee should organise matters at least 1 week prior to surgery;
- specify quantities and time of delivery;
- inform CDU at least 24 hours before delivery;
- raise purchase order. Refer to MHRA Managing Medical Devices April 2014 on factors to consider before acquisition.

5.5 Acceptance checks of loan medical devices and documents from supplier before forwarding to CDU for decontamination and sterilization:

- advise supplier of discrepancies immediately;
- allow CDU at least 48 hours for processing;
- inform CDU of any delays.

5.6 Introduction of loan medical devices onto the theatre register/IT system (preferred) for traceability:

- identify and tag as: 'On Loan';

- theatre should track loan medical device details to the patient;
- prevent loan medical device migration in theatre.

5.7 Pre and post operative checks of loan medical device and documents:

- ensure packaging is intact and sterility is not compromised upon delivery from CDU;
- ensure loan medical device and documents are complete and in order.

5.8 Returning loan medical devices to supplier with decontamination certificates and traceability information:

- allow CDU at least 24 hours to process and issue decontamination certificates;
- check and package appropriately to prevent damage of loan medical devices on return to supplier;
- arrange uplift by supplier as agreement and sign off in the theatre tracking system.

5.9 Reporting other non-conformances, complaints and incidents:

- report non-conformances to the relevant parties (CDU manager and/or supplier) within 48 hours;
- raise complaints directly to the relevant parties (CDU manager and/or supplier) within 48 hours;
- in the event of an incident/defect, notify immediately:
  - the manufacturer/supplier;
  - CDU manager and any local reporting system;
  - IRIC (Incident Investigation and Reporting Centre).

5.10 Receiving a complaint from CDU or supplier:

- acknowledge within 1 working day;
- agree plan of corrective actions;
- action must be completed within the agreed timescale with the complainant.

5.11 Maintain and archive paper and electronic records.

5.12 In emergency or trauma cases:

- if applicable immediately inform CDU of loan medical devices requirement and specify that they be regarded as ‘fast track’ and a high priority;
- expedite ordering, supply, checking and processing.

5.13 Additional responsibilities for ‘high risk’ potential CJD/vCJD patients:

- prior to any request for invasive loan medical devices for a procedure which may involve contact with tissue deemed as “high risk tissue” as listed in Appendix 3 in the NICE guidelines (2006), theatre staff must identify patients who have been “notified that they are at increased risk of CJD/vCJD and the appropriate infection control procedures and ADCP guidelines (Annex J 2014) are followed;
- in the event that the patient, family member or representative cannot provide a definitive answer regarding CJD/vCJD status, then the procedure should proceed but all invasive loan medical devices should be quarantined after use until the patient’s status is clear;
- theatre/clinic must inform the CDU of the CJD/vCJD status of the patient to allow the loan medical devices to be processed guaranteed in the appropriate manner.

6.0 CDU roles and responsibilities

6.1 Prior to agreeing to process loan devices, the CDU should ensure that all reusable loan medical devices are compatible and can be processed with their existing decontamination processes.

6.2 Staff education and training:

- ensure a full understanding of loan medical device supplier's reprocessing procedures;
- inform theatre when unfamiliar loan medical devices are received as these require longer training and processing time.

6.3 Confirm and check upon arrival:

- that all loan medical devices and documents are present;
- disassemble complex loan medical devices and inspect;
- notify theatre within 30 minutes if discrepancies occur;
- quarantine loan medical devices and arrange for theatre and/or supplier to inspect.

6.4 The CDU should consider loan medical devices as contaminated upon delivery and personal protective equipment (PPE) should be worn throughout.

6.5 Tracking:

- enter details onto CDU tracking system;
- prevent loan medical device migration throughout process.

6.6 Decontamination Process:

- decontaminate using CDU procedures and in accordance with written manufacturer's processing instructions;
- loan medical devices should be sent sterile and appropriately packaged to theatre, accompanied with a list of items;
- loan medical devices should be cleaned and disinfected/sterilized as agreed in the SLA, prior to returning to suppliers, accompanied with a decontamination certificate. Ensure that loan medical device trays have been secured and there are no loose loan medical devices in the bottom of any packing case. Packaging should be appropriate to prevent damage on transport back to the supplier.

6.7 In emergency or trauma cases:

- expedite checking, processing and delivery;
- regard devices as ‘fast track’ and prioritise;
- notify theatres of delays.

6.8 Reporting other non-conformances, complaints and incidents:

- report non-conformances to the relevant parties (Theatres and/or supplier) within 48 hours;
- raise complaints directly to the relevant parties (Theatres and/or supplier) within 48 hours;
- in the event of an incident/defect, notify immediately;
  - the manufacturer/suppliers;
  - theatres and any local reporting system;
  - IRIC (Incident Investigation and Reporting Centre).

6.9 Receiving a complaint

- acknowledge within 1 working day;
- propose corrective actions ;
- action to be completed within the agreed timescale with the complainant.

6.10 Maintain and archive paper and electronic records.

7.0 Supplier roles and responsibilities

7.1 Suppliers are responsible for providing safe, fit for purpose and traceable reusable loan medical devices to agreed timescales.

7.2 Provide loan medical devices meeting the required standard and quality as follows:

- ensure the cleanliness, functionality and completeness of loan medical device sets;
- package appropriately;
- ensure compliance with the facility's handling policy;
- loan medical devices should be CE marked (unless exempt e.g. custom made);
- include training and documentation on 'new' devices.

7.3 Staff education and training – Roles/Responsibilities

- ensure training in the handling, use and reprocessing of unfamiliar devices, is provided for CDU/Theatre staff;
- provided CDU/theatre staff with training for other loan devices as requested.

7.4 Provide full supporting documentation:

- a delivery note should be provided;
- reprocessing instructions should conform to EN ISO 17664;
- a decontamination certificate should be provided;
- include a detailed tray lists for the loan medical devices;
- provide product codes and photographic documentation as necessary.

7.5 Ensure weight of the loan medical device does not present a manual handling risk.

7.6 Ensure loan medical devices are controlled on a robust tracking system.

7.7 Rectify supply discrepancies:

- ensure an immediate supply of replacements is provided; or
- inform theatre and CDU of the length of any delay.

7.8 Check, uplift loan medical devices and sign off request, as agreed with customer (theatres or CDU as relevant). Follow the master indemnity agreement terms and conditions if a signed agreement is in place.

7.9 Reporting other non-conformances, complaints and incidents:

- report non-conformances to the relevant parties (Theatres and/or CDU) within 48 hours;
- raise complaints directly to the relevant parties (Theatres and/or CDU) within 48 hours;
- in the event of an incident/defect, notify immediately;
  - CDU;
  - theatres;
  - IRIC (Incident Investigation and Reporting Centre)/MHRA.

7.10 Receiving complaint:

- acknowledge within 1 working day;
- propose corrective actions;
- action to be completed within the agreed timescale with the complainant.

7.11 Maintain and archive paper and electronic records.

8.0 Glossary

Medical Device - means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Abbreviated from the directive 2007/47/EC.

Tray – a container for a set of medical devices. Often interchanged with the term ‘set’.

Tray List – A list of the expected contents of a tray.

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