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Sussex Partnership NHS Foundation Trust

INFECTION PREVENTION AND CONTROL POLICY AND PROCEDURES
Sussex Partnership NHS Foundation Trust (The Trust)

IPC4

DECONTAMINATION OF MEDICAL EQUIPMENT

INTRODUCTION

This guidance outlines the procedures for the disinfection and decontamination of medical devices / healthcare equipment that must be implemented to prevent the transmission of infection by contaminated equipment. It applies to all Sussex Partnership NHS Foundation Trust staff involved in the handling of medical devices.

AIM

All medical devices / healthcare equipment which comes into contact with body fluids or other potentially hazardous material must have a certificate with it stating that the equipment has undergone an appropriate decontamination process and is considered safe for handling before inspection, repair /servicing or re-use.

BACKGROUND

Any medical device / healthcare equipment used in either a hospital or community environment may become contaminated with biological, chemical or radioactive material and thus present a risk to anyone handling or using it. Such equipment must undergo decontamination prior to being repaired, serviced or reused to ensure that personnel who come into contact with it during transit and subsequent handling are not exposed to any such hazard.

Decontamination requires the implementation of a number of processes, from purchasing equipment through to delivery and use, cleaning and disinfecting, packing, sterilizing, repair and disposal. To be effective it needs standards to be set for all elements of the device life cycle.

The vast majority of equipment used in Sussex Partnership NHS Foundation Trust will not require more than cleaning and occasionally disinfection.

The decision about the level of decontamination required depends not only on how the item is used, but also the risk of the equipment transmitting infection or acting as a reservoir or source of infection.

DEFINITION OF A MEDICAL DEVICE

Medical Devices includes medical and laboratory equipment, consumables and materials used in the treatment, assessment, diagnosis and care of service users.

A medical device is any instrument, apparatus, appliance, material or other article used alone or in combination and intended by the manufacturer to be used for humans for any of the following purposes:

- Control of conception
- Monitoring, diagnosis and investigation
- Treatment, alleviation or compensation for injury or incapacity
- Replacement or modification of anatomy and physiology.

The vast majority of equipment used in service user care will be defined as a medical device.

Implementation of this guideline will lead to:

CLINICAL RISK MANAGEMENT

Effective management of clinical risks will be achieved by ensuring that cross infection from potentially infected equipment / devices to service users, staff and visitors is minimised.

COMPLIANCE WITH STATUTORY LEGISLATION

- **Health and Safety at Work etc. Act 1974**, which require employers to assess the risks to their staff and service users
- **Control of Substances Hazardous to Health (COSHH) Regulations 2002**, which provide a framework of actions designed to control the risk from a wide range of substances, including biological agents (micro-organisms)
- **EU Council Directive 93/42/EEC 1993 - Medical Devices Directive and EU Council Directive 93/34/EEC 1998 - Product Liability Directive**, are wide-ranging European Regulations that govern all aspects of medical devices production, management and use / re-use and form the basis of the directives used in the UK
- **Health Technical Memorandum 01-01 Management and decontamination of surgical instruments (medical devices) used in acute care** (DH, 2016) (HTM 01-01) - provides comprehensive guidance on all aspects of device decontamination in compliance with European Legislation (as above)

SERVICE IMPROVEMENT

The quality of services to users and the public will be improved by adopting safe decontamination practices for equipment and the environment.

DUTIES

It is the responsibility of all healthcare staff to ensure that all equipment that is used in the care of service users is appropriately decontaminated and fit for purpose. Staff in charge of a service user area have direct responsibility for ensuring that cleanliness standards of medical devices are maintained throughout that shift to minimise the risk cross-infection. See The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (DH, 2015) criterion 2.

RISK ASSESSMENT

Medical equipment is categorised according to the risk that particular procedures pose to service users and by assessing the microbial status of the body area being manipulated during the procedure. For example, items that come into contact with **intact** mucous membranes are classified as intermediate risk and require disinfection between each use as a minimum standard. Items that enter normally sterile body areas, or items that come into contact with broken mucous membranes, are classified as high risk and must be sterile before use.

See Appendix 1 for Risk assessment for decontamination of equipment.

DECONTAMINATION - DEFINITIONS

DECONTAMINATION OF RE-USABLE DEVICES

Decontamination is a process used to make a re-usable item safe for handling and further use. Decontamination is the term widely used to collectively describe the combination of processes of cleaning, disinfection and sterilisation to make a re-usable device safe for further use on patients and safe for the user. The effective decontamination of re–usable devices is essential to reduce these infection risks. Decontamination methods used will depend on the nature of the micro-organisms present and the infection risk associated with the surface, equipment, device or procedure.

CLEANING

Cleaning is a process which physically removes contamination but does not necessarily destroy micro-organisms. The reduction of microbial contamination will depend upon many factors including the efficiency of the cleaning process and the initial contamination. A further reduction will occur on drying, as some micro-organisms cannot multiply on a clean dry surface. Cleaning is the first step in the decontamination process. It must be carried out before disinfection and sterilisation to make these processes effective. Thorough cleaning is extremely important in reducing the possible transmission of all micro-organisms, including the prion protein that causes Variant Creutzfeldt-Jakob Disease (vCJD).

Liquid detergent and warm water is an effective cleaning agent. Hot water should not be used, as it will coagulate proteins (body fluids) making it more difficult to remove from the equipment. Hard surface detergent wipes are also available for equipment cleaning.

DISINFECTION

Disinfection is defined as a process used to kill or remove pathogenic micro-organisms but which cannot usually kill bacterial spores. Disinfection processes, if used appropriately will reduce micro-organism counts to safe levels.

Disinfection processes can be used on both equipment and environmental surfaces and usually involves the use of either a disinfectant solution or a structured process using equipment such as bed-pan washer-disinfectors, dishwashers and washing machines where temperature of water or steam provides the disinfection process.

Disinfection using antiseptic solutions is the process used to reduce microbial contamination of the skin, mucous membranes and other body tissues and cavities.

STERILISATION

Sterilisation is a range of processes used to render the device free from viable micro-organisms, including spores. Processes include moist and dry heat using autoclaves and / or hot air ovens; low temperature steam and formaldehyde; gamma radiation; ethylene oxide and gas plasma.

In healthcare, sterilisation processes are usually confined to the application of moist heat using autoclaves.

There should be no equipment within Sussex Partnership NHS Foundation Trust which requires sterilization. There are no facilities within this Trust to undertake sterilization. In the event of a query over sterilisation processes, staff should gain the involvement of the Infection Prevention and Control Service at the local acute trust.

DECONTAMINATION ADVICE FOR STAFF

If the method of decontamination is in doubt, then advice may be sought from:

- The device supplier and/or manufacturer of the equipment
- Local decontamination lead and/ or infection control lead

SAFE SYSTEMS OF WORK

All medical devices and equipment, including that loaned, rented or leased to a service user for use in the community, must be treated with the same level of care and preparation.

Staff handling used medical devices and equipment should assume that they are contaminated and take adequate precautions to reduce the risk to themselves and

others. The use of personal protective equipment (PPE) is required when undertaking any decontamination activity – this includes disposable aprons and gloves as a minimum, and should include visors / safety glasses for eye protection.

CLEANING AND DECONTAMINATION SOLUTIONS

The following products are suitable for the decontamination of the majority of care equipment and surfaces. Specialised equipment should be decontaminated following manufacturers' instructions.

Neutral detergent (low-foaming washing-up liquid) – a mild detergent that is adequate for most cleaning of equipment and surfaces and will mechanically remove (by cleaning) the majority of micro-organisms contaminating equipment. Refer to bottle before use, but usually 5ml in 1 litre of warm water is sufficient.

Hard surface wipes – There are two main types of wipe. Some contain 70% alcohol or other disinfectants and others contain a detergent. Wipes are cheap and effective and are portable (in drums / packs) and require no access to water. They can also be used on large items of equipment. Detergent wipes can be used instead of detergent and water. Alcohol wipes can be used for surfaces requiring disinfection as well as cleaning e.g. dressing trolleys. Where gross soilage / contamination is present a detergent wipe is preferable as alcohol is inactive in the presence of soil. There is no benefit in purchasing wipes that contain other chemicals or disinfectant agents.

Alcohol by itself is not a cleaning agent. Alcohol wipes should not be used to clean an item but can be used following cleaning to disinfect an item.

Chlorine-releasing agents – These contain a chlorine-releasing agent and are often referred to as bleach solutions or hypochlorite. They are used for spillages of blood and high risk body fluids such as faeces and can be used to disinfect service user contact surfaces in an isolation room and also during outbreaks of infection e.g. diarrhoea and vomiting for cleaning of both the environment and equipment such as commodes. Staff using such products must be familiar with COSHH regulations and have access to the product's data sheet. Apron and gloves must be worn for preparation and use. Reference should be made to the container for correct dilution. Do not use on acids (e.g. vomit, urine) as chlorine gas may be liberated. Do not use on stainless steel, as it will discolour. See Spillages of Blood and Body Fluids policy for further guidance.

Non-abrasive cream cleaner – Mild cleaner for general hard surface use e.g. sinks

Toilet cleanser / sanitizer – cleanser which can contain bleach and / or lime-scale remover

Thermal washer / disinfector - e.g. bedpan washer / dishwasher / washing machine. Designated machinery for thermal (heat) disinfection of articles where a higher temperature and controlled method of cleaning are required e.g. bedpans; cutlery / crockery and laundry items.

COMPATIBILITY OF PRODUCTS WITH DEVICES

An alert was issued to all manufacturers MDA/2013/019 by MHRA in 2013 regarding the use of detergent and disinfectant wipes used on reusable medical devices with plastic surfaces.

This alert warns that:

- Damage to the plastic surface may occur if the product (used for cleaning) is not compatible with the surface material
- Products may compromise the users' ability to decontaminate the device adequately and / or interfere with device function

The alert recommends that users':

- Ensure compatibility of product with device
- Follow manufacturers' instructions
- Examine devices for signs of damage
- If instructions (for decontamination) are inadequate, report to MHRA and the manufacturer

The alert also provides guidance on the use of pre-purchase questionnaires and emphasises the importance of adequate staff training in device decontamination.

MEDICAL DEVICE CLEANING PROCESSES – GUIDANCE NOTES

- Comprehensive guidance on cleaning of both medical devices and other service user specific equipment is available in two publications:
    - The National Specifications for Cleanliness in the NHS: a framework for setting and measuring performance outcomes (NPSA, 2007)
    - The Revised Healthcare Cleaning Manual (AHCP, 2013).
- Cleaning of medical devices and other service user specific equipment should be subject to regular, on-going monitoring of the standard of cleaning
- Cleaning schedules specifying the frequency of cleaning should be devised incorporating all medical devices / equipment used locally. These schedules should be available for all staff and a simple check-list should be devised for staff to sign after completion of cleaning
- Re-usable medical devices must be decontaminated between each service user use. Some larger items of equipment e.g. IV stands, notes trolleys etc. should be cleaned weekly as a minimum. Frequency of cleaning is specified in the documents above

- The user of the device is responsible for ensuring that it is visibly clean and free from contamination with blood and/or body fluids following each procedure or care episode and prior to sending for service or repair internally and externally.

- Dirty equipment awaiting cleaning, should be stored separate from clean items and should be cleaned as soon as possible after use and then stored appropriately

- Cleaning of equipment should take place in a designated area e.g. dirty utility or away from clean items that could become contaminated during the cleaning process

- Personal protective equipment (PPE) should be worn when cleaning medical devices. Disposable gloves (or household gloves) together with a plastic apron should be worn to protect hands and clothing.

See Appendix 2 for examples of the Recommended Decontamination Methods and Frequencies for commonly used medical devices / healthcare equipment.

DECONTAMINATION OF EQUIPMENT PRIOR TO LOAN, SERVICING OR REPAIR

- It is the responsibility of the person / department using the equipment to ensure that it is visibly clean and free of surface contamination with blood and / or body fluids if being sent for service, maintenance or repair either on or off site (HSG(93)26).
- A decontamination notice must be attached to the equipment to warn others of the type of contamination it may have been exposed to and whether it has been possible to decontaminate it. Many manufacturers provide their own decontamination certificates with their equipment and will not accept returned equipment without an accompanying certificate. This is appropriate practice and should also apply to equipment being repaired or serviced on-site.

- The ward manager or head of department has the responsibility for ensuring that all equipment has been cleaned, that adequate decontamination has been carried out and that the appropriate paperwork has been completed prior to it being passed on for repair, service or inspection.

CERTIFICATE OF DECONTAMINATION

The declaration of contamination status should be readily accessible to the recipient of the equipment in the event of needing repair, servicing, disposal or transportation. In the event that equipment subject to a decontamination certificate is required to be sent away from the hospital for inspection, service or repair, then a copy of the certificate must be enclosed in an envelope clearly marked and affixed to the outside of the packaging.

See Appendix 3 for an example of a Decontamination Certificate.

ITEMS THAT CANNOT BE DECONTAMINATED (e.g. equipment that is the subject of a complaint or investigation)

Where the decontamination of equipment could remove evidence of fault or hinder any subsequent investigation, advice on transportation must be sought from the manufacturers, repair organisation or investigating body as it may require the use of a specialist courier. In this event:

- Double package all devices in appropriate packing material
- Give prior warning to the intended recipient
- Clearly label equipment to indicate that it is contaminated.

APPENDIX 1 RISK ASSESSMENT FOR DECONTAMINATION OF EQUIPMENT

Risk	Application of Item	Minimum Standard	Definition
Low	• In contact with healthy skin. • Not in contact with patient.	Cleaning	Cleaning - Physical removal of organic matter and infectious agents
Medium	• In contact with mucous membranes. • Contaminated with particularly virulent or readily transmissible organisms. • Before use on immunocompromised patients.	Cleaning followed by sterilization / disinfection or Single-Use NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.	Disinfection - Reduction in viable infectious agents
High	• In close contact with broken skin or broken mucous membrane. • Introduced into sterile body areas.	Cleaning followed by sterilization or Single- Use	Sterilization - To render an object free from all viable infectious agents

APPENDIX 2 DECONTAMINATION METHOD AND FREQUENCY

This list contains common use healthcare equipment only and is not an exhaustive list.

EQUIPMENT	RECOMMENDED DECONTAMINATION PROCEDURE
Auriscope ear pieces	Single Use pieces are recommended. If reusable then wash with neutral detergent and dry, then wipe with 70% alcohol wipe and air dry.
Baby changing mats	Always replace mat if ripped or damaged Protect with disposable paper and change after each use Clean mat after each use, at the end of the session or when contaminated with neutral detergent and warm water Follow with a hard surface disinfectant wipe if contaminated with blood or body fluids
Baths	Clean after each use with non-abrasive cream cleanser Follow with a Sodium Hypochlorite 1,000 ppm solution if soilage occurs e.g. incontinence.
Bath mats	Clean under running water after use Hang up to dry between uses Monitor and replace if mould is present.
Bed frame and accessories	Wash with detergent and dry.
Bed pans, commode pans	Disposable or Decontaminate in washer-disinfector after each use.
Bed pan shells (holders for disposable bed pans)	Wash in warm detergent and water, rinse and dry with paper towels.
Bowls (washing)	Wash with neutral detergent and dry. Store inverted and separated.
Mattresses (bed and cot)	Follow manufacturers' instructions. Mattress covers should be wiped with a detergent and warm water solution and dried thoroughly with paper roll. Alternatively a detergent wipe can be used. Do NOT use alcohol spray or other disinfectant solution as these may damage covers – mattress cleaning regimes should contain details of mattress inspection and records kept locally.
EQUIPMENT	**RECOMMENDED DECONTAMINATION PROCEDURE**
Nebulisers	Do not share between residents. Clean all parts thoroughly with detergent and warm water between each use. Ensure all parts are thoroughly dried. Refill with sterile water only.

Pillows	Cover with impermeable cover and decontaminate as per mattresses (above). If impermeable covers are not suitable for other risk management reasons e.g. potential of self-harm, then pillows should be single patient use.
Shaving equipment	Use patient's own equipment; do not allow sharing. If not available use disposable razors. Dispose of in sharps container after single use.
Sphygmomanometer cuffs	Follow manufacturer's recommendations.
Suction bottles	Disposable liners and/or containers should be used and incinerated as clinical waste. Non-disposable containers should also be regularly cleaned with detergent and warm water and dried with paper towels prior to storage and insertion of new disposable liner. Ensure filters are changed regularly.
Suction catheters	Single use only. Dispose of as clinical waste after single use. This includes Yankuer catheters.
Suction tubing	Use disposable tubing and change after individual patient use. If in regular use on same patient, change at least weekly.
Telephones	Detergent wipes.
Tympanic Thermometers (clinical)	Disposable single use covers. Clean hand piece with neutral detergent and warm water or detergent wipes.
Toys	Clean plastic / wooden toys with neutral detergent and hot water and dry thoroughly. Soft toys must not be used due to risk of contamination and cross infection.
Treatment couch	Ensure cover intact. Protect with disposable paper and change after each use Clean at the end of the session or when contaminated, with neutral detergent and warm water. Follow with a hard surface disinfectant wipe if contaminated with blood or body fluids.
EQUIPMENT	**RECOMMENDED DECONTAMINATION PROCEDURE**
Trolleys (dressing)	Daily, wash thoroughly (all surfaces including underneath) with neutral detergent and dry. Before use and between dressings wipe top with 70% alcohol impregnated swabs and allow to dry If visibly contaminated wash with neutral detergent and dry thoroughly prior to alcohol wipe.

Urine bottles	Disposable or Decontaminate in a washer-disinfector.
Water cooler	Clean and maintain as per manufacturer's instructions.
Work surface	Clean at the end of the session or when contaminated, with neutral detergent and hot water Follow with an alcohol wipe if contaminated with blood or body fluids.

APPENDIX 3 DECONTAMINATION CERTIFICATE

(DECLARATION OF CONTAMINATION STATUS – to be completed prior to inspection, servicing, repair or return of medical and laboratory equipment)

From:		**To**:	
Address:		Address:	
Reference:		Reference:	
Emergency telephone no:		Manufacturer:	
Description/type of Equipment:			
Model No:		Serial No:	
Fault:			
Please state level of risk (see guidance)	**Low** ☐	**Medium** ☐	**High** ☐
State type of contamination, i.e. blood, body fluid, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard.			
Has the item been decontaminated?	**Yes** ☐	**No** ☐	**Don't know** ☐
What method of decontamination has been used? Please provide details: Cleaning …… …… Disinfection …… …… Sterilization …… ……			

Please explain why this item of equipment has NOT been decontaminated:-

Contaminated items must not be returned without prior agreement of the recipient

This item has been prepared to ensure safe handling and transportation

Name: _____ Position: _____

Signature: _____ Date: _____