Decontamination facilities and requirements in the Welsh Health Service

By
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Where do we carry out decontamination of medical devices that need correct facilities?
Medical Devices in Use

- Chiropody
- Cardiac
- Trauma
- Dental instruments
- Clinics
- General surgery
- A & E
- Outpatients
- Endoscopy
- Orthopaedics
- Primary care
The Enemy

MICROBES

PRIONS
- Proteinaceous infectious particles
- CJD, vCJD, BSE etc

BACTERIA
- Few are pathogenic—which means that they can cause illness in humans
- 1-5 microns

VIRUSES
- Can grow on living tissue
- 1/10 the size of bacteria

 FUNGI
- Complex life style
- Most are harmless to humans—*but!*

PROTOZOA
- Single cell animals
- More common abroad—*however!*
What is decontamination of Medical Devices all about?

- What needs to be decontaminated?
- What departments and end users are to be included?
- What is the turn around time for each user?
- Transportation requirements?
- Best location or locations?
- On site or off site?
- Extra instrumentation costs?
- Who needs to be involved in planning?
- Secure a good advisory team?
- What facilities are required?
- What layout and design?
- What standards do we use?
- Where do we carry out the service?
- Who is responsible?
All soiled re-usable medical devices should be regarded as contaminated and are potential hazards to handlers until correctly cleaned.
### Categorisation of infection risk to the patient from contact with an item

<table>
<thead>
<tr>
<th>Risk</th>
<th>Application of item</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>• In close contact with a break in the skin or mucous membrane</td>
<td>Sterilization</td>
</tr>
<tr>
<td></td>
<td>• Introduced into sterile body areas</td>
<td></td>
</tr>
<tr>
<td><strong>Intermediate</strong></td>
<td>• In contact with mucous membranes</td>
<td>Sterilization or disinfection required</td>
</tr>
<tr>
<td></td>
<td>• Contaminated with particularly virulent or readily transmissible organisms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prior to use on immunocompromised patients</td>
<td></td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>• In contact with health skin</td>
<td>Cleaning</td>
</tr>
<tr>
<td></td>
<td>• Not in contact with patient</td>
<td></td>
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</tbody>
</table>

Microbiological Advisory Committee [MAC Manual] - MHRA
Prions

- The abnormal protein associated with prion deceases are very resistant to all conventional methods of decontamination.
- Prions are infectious agents, smaller than viruses and unlike other pathogens, contain no DNA or RNA. Their only known component is an abnormally conformed protein and accumulate in the central nervous system where they can trigger neurological symptoms.
- Most chemical and physical means of cleaning, disinfection and sterilization of medical devices are only partially effective at inactivating prion proteins.
Inactivation of Prions on Medical Devices

• **Chemical means** – detergents have almost no effect when used in concentration that are safe in healthcare settings. Exposure to EO for four hours only reduces the infectious nature of the prions by less than 10%. Immersion in gluteraldehyde for three weeks is only partially effective and both hydrogen peroxide and peracetic acid are ineffective. Research has shown that sodium hypochlorite and sodium hydroxide are the most effective chemicals for reducing inactivity of prions. Unfortunately these are dangerous and very corrosive chemicals for metals, materials and us!

• **Physical means** – Abnormal proteins are very resistant to the common physical methods of decontamination.

• Hence WHC[99] 157 and 158 and SEAC as issued by WAG in October 1999
WHC(99) 157

- Implementation of existing guidance on cleaning and sterilization of medical devices
- Validate washer disinfectors using HTM 2030 with particular attention to the cleaning process
- Validate and manage sterilization equipment using HTM 2010
- Never re-use medical devices designated for single use.
- Develop a programme to upgrade or replace decontamination equipment that does not meet the standards and test methods
• Reinforcing existing safeguards
  All cases where CJD of any type ...should be reported to the National CJD Surveillance Unit [CJDSU]
• Effective and thorough cleaning of surgical instruments to remove as much organic debris as possible before sterilization.....
• Instruments designated for single episode of use should be discarded after use and never reprocessed
• Use mechanical Washer Disinfectors
After the issue of the WHC’s, an audit was undertaken in England, and the findings were poor.

WAG set up Project Board to review, audit and improve the Sterilization Departments of Wales.

October 2001 the work began by the Project Board to ensure that all Sterile Service Departments of Wales were to achieve the MDD Directive 93/42/EEC – this was achieved in April 2005, and Wales is the only unit within the UK to achieve this standard.

Now the real work has to begin to maintain and improve the standards within Trusts. This must include reviewing the Primary Care sectors decontamination policies and standards.
Design What do we need to consider?

- How do we clean the equipment and instruments after use?
- Accredited Sterile Service Department?
- What volume of instruments required, and when?
- What type of procedures are to be planned and carried out?
- Do we need to disinfect?
- Do we need to sterilize?
- Storage methods and space / segregation?
- Equipment design and capacity, standards and testing
- Relative locations of decontamination areas within unit
- Environment, ventilation, air quality and design
- Infection Control advice
- Room design and surface finishes
- Emergency back-up systems required?
- Room layout and flow paths
- Transportation needs, building design for access of vehicles
- Staff, equipment and patient flow paths
- Patient safety
- Cross contamination issues
- User protection
- Trust / unit policy
- **Who do we consult with as a team – very important!**
Existing documents
Sterile Service
Departments

Welsh Health Estates

DOCUMENT STATUS NOTE

HEALTH BUILDING NOTE 13
Sterile Services Department
2004 edition

This Document APPLIES in Wales

The following points should be noted

Page 3: The last bullet point in paragraph 1.7 should read: “Reprocessing flexible endoscopes and heat-tolerable accessories. However, the design principles and standards of this document apply when planning new and refurbished units for the decontamination of flexible endoscopes.”

Page 10: The use of single-ended porous autoclaves referred to in paragraph 2.62 is preferred, due to technical and cost issues associated with double-ended autoclaves. The appropriate layout is illustrated in figure 1 on page 14.

If you have any queries on the status of this document, please contact info@whe.wales.nhs.uk or telephone 029 2031 6672.
Policies and principles
Health Technical Memorandum 00: Best practice guidance for healthcare engineering
Infection in the built environment

“It is imperative that infection control is “designed-in” at the planning and design stages of a healthcare-facility, new build or renovation project and that input continues up to the final build stage.”

We should ensure that this principle is carried through with all projects in potential patient treatment areas, and decontamination facilities with clear continued consultation with the end users.
Principles of HSDU layout designs

- Dirty returns
- Washroom
- IAP Cleanroom
- Sterilizers Loading area
- Sterile store
- General plantroom
- Bulk materials store
- Offices and administration
- Sterile products

Expansion area for growth of service – *Ground floor location*
Segregation of clean and dirty

Clear flow paths of products and staff

Preferred layout diagram for a new Hospital Sterilization and Disinfection Unit [HSDU]

Document contains sizing criteria

Single door sterilizer design is preferred in Wales
Porous Load Sterilizers

Llandough HSDU

BMM Weston Ltd.

Bronglais HSDU

Thermocouple testing
2.51 Consideration should be given to the benefits of having sterilization equipment with interchangeable loadhandling equipment. There is an advantage in choosing a common size of chamber for all steam sterilizers. Enough sterilizers should be installed to maintain production, but their regular servicing and maintenance should be ensured without disruption to production. It is important to locate sterilizers in such a way as to facilitate the installation of additional machines should workloads increase.

2.52 Experience suggests 0.6 m³ or 0.8 m³ single-door sterilizers are particularly suited to hospital-type loads. Before considering alternative sterilizer sizes and configurations, issues such as loads, frequency of use, working practices, load types and mass should be addressed to ensure performance requirements will be consistently met.
Washer Disinfectors

Cabinet type
-pass through design

Bronglais HSDU
Washroom area

Llandough HSDU
washroom area
SSD design

Transfer hatch
HBN 13 [2004]

Smaller typical HSDU layout, more common as TSU’s

Follows the basic Standard layout Principles and flow paths
Central Hospital

Boiler Plant

Local steam generation in the HSDU

Pure steam generation plant [small units]

Central Hospital Boiler Plant
Air handling plants for IAP room and other service areas

**Roof mounted plant**

Large spaces required with good clear access

**Dedicated plant room within the unit**
Plant room spaces required

- All Hospital units require plant to operate
- Plant rooms must be correctly positioned and well sized for the task
- Good access for maintenance and plant replacement
- Allow for growth
- Allow for new standards

Reverse osmosis water treatment {Ro}
## Sterile Service Department work loads

### Llandough HSDU
**Nov. 2005 figures**
- Soft packs: 1352
- Singles/supplement instruments: 1703
- Trays/sets: 2555
- Ward packs: 41
**Total 5651/month**

In 2006 4 new orthopaedic theatres
Approx. 50% increase in sets

### Wrexham Maelor HSDU
**Nov. 2005 figures**
- O.T. and soft packs: 7872
- Single instruments: 2548
- HSDU sets: 1898
- Holloware: 126
- Theatre instruments: 3072
- Theatre trays: 3046
- LN packs: 681
- Loan sets: 96
**Total 19699/month**

### Royal Gwent HSDU
- Sets: 1043 per week

May 2006, 4 new orthopaedic theatres = 600 extra instrument sets /week
Facilities, Primary Care or Clinics – The reality

- Single room used for all, decontamination and storage
- Often shared with other clinical functions
- No segregation process of clean and dirty
- No segregated storage of sterile and non-storage items
- Not isolated from general patient areas
- Insufficient space for safe decontamination
- No automated wash processes [WD’s] as recommended
- Can be in “cupboards” or under the stairs or dirty corridors
- Shared sink with other facilities!!!!
- Room finishes inadequate for the purpose
- Education and formal training ?
- Etc……………………………
Setting Up a Decontamination Area

*Use a dedicated decontamination area, separated from the patient treatment area, preferably in another room or rooms.*

If, through lack of space, decontamination has to be carried out in a patient treatment room, minimise the risk to patients by deferring decontamination until the room is unoccupied and ensure that rigorous environmental cleaning is carried out between clinical and decontamination activities. As this takes time and will inevitably affect the frequency of patient appointments, plan to move towards a separate dedicated decontamination area as soon as possible.

When setting up new premises or planning significant modification to existing premises, consider having two rooms for decontamination that are separate from the patient treatment area(s): one for dirty activity (cleaning instruments) and one for clean activity (inspection, sterilization and wrapping instruments). This is the preferred arrangement.

*Scottish Dental Clinical Effectiveness Programme SDcep*
Physical segregation means using different areas for different activities.

Regard temporal separation as a temporary arrangement and plan to increase the space for the decontamination area to enable physical segregation of decontamination activities as soon as possible.
Facilities – Ideal or the way to go!

If reprocessing on site or clinic

- **Dirty room**
  - Dedicated for the purpose
  - Automated washer disinfector(s)-validated
  - Ultrasonic pre-cleaner if required.
  - Two deep sinks for cleaning, one for cleaning, one for rinsing.
  - Setting down areas for washed instruments - and one for rinsed instruments
  - Separate wash hand basin
  - Appropriate detergent, brushes and PPE

- **Clean Room**
  - Dedicated for the purpose
  - Appropriate sterilizer(s)- validated and correctly tested
  - Sufficient worktop and work space for inspection etc.
  - Secure storage, clean and orderly for instruments not in use.

- PPE
- Infection Control policy
Cleaning facilities

Hand washing facilities

Double sinks set up for manual cleaning of soiled medical devices
Small Decontamination Unit
Alternative design [1] for Dental

Segregation of dirty decontamination activity from patient area;
Single treatment room + Decontamination area (Option B)

Product flow:
- Hatch
- Treat room & Clean decon
- Dirty Decon
- Treatment zone eg dental chair
- WD/Ultrasonic
- Sink

Sterilizer B&I or Vac
WHB
PPE
Bench Top Machines

Do we need them?

Bench top autoclaves – Non-vacuum and vacuum types

Bench top Washer Disinfectors
Endoscopes and facilities

- How many users are there in a Trust?
- Theatres, outpatients, endoscopy clinics, X ray, maternity, Dental units, ENT clinics etc etc....
- Where are they being used?
- How are they being cleaned?
- Are you sharing rooms for dual purposes, AER’s in a store cupboard for example.
- Are disposables being used, or reprocessing?
- How and where are the scopes being stored.
- Who is responsible for the process?

This is a very fast growing method of diagnosis and treatment
Segregation
Dirty to Clean

Endoscopy Decontamination Room in principle

Work surface
Deep sinks
/+ve air pressure
Clean area for inspection and assembly
/-ve air pressure
Double ended Washer Disinfectors

WASH ROOM

Storage and supplies

Gowning area
Dirty returns
Double ended Hatch

Storage area for scopes
Gowning area

controlled access
New Endoscope Departments

Service             staff                corridor
Staff
areas
Wash room
Cleanroom
'scope storage
Ward and treatment
Theatre
Cleanroom
Patient and clean corridor
Theatre
Patient waiting reception area
Staff areas
Plant room
Plant room
Store
Ward and treatment
Theatre
Cleanroom
‘scope storage
Patient and clean corridor
Patient
waiting
reception
area
Office
Endoscope AER’s
Automatic Endoscope Reprocessors

All different shapes and designs
Future planning is essential
Mobile Units for Endoscopy

Provision for services, space and links to existing structures

Mobile unit for specialist services

Very expensive option!
A Sterile Services Department is a factory unit handling the core services of the Health Service.

If a large unit was shut down for more than a period of 8 to 10 hours, the Hospital would have to cancel operations and possibly refer trauma patients to other units, including transfers.

Service strategies need to be agreed with other units for shut down periods or disaster planning [eg Lockerbie].

Good planning is essential.
How to proceed

• Consult with the end “user” at the initial planning stage, and all the way through the scheme
• Examine the needs of Decontamination- what procedures!
• Explore the equipment for production needs and volume
• Service and maintenance needs – and costs!
• Correct selection and specification of decontamination equipment
• Testing requirements and sustainability of equipment
• Employ the latest guidance and standards
• Consult with specialists in the field
• Consult with the Infection Control Team
• Use “best practice”
• Use a strong team approach
• Allow for flexibility of change due to Healthcare needs
• Allow for procedure growth
• Allow for department growth to meet the needs of the future – do not locate Sterile Service Departments on the fifth floor!
Thank you for listening

Consultation is the key with good early planning

Do not work in isolation

Use WAG and WHE for advice

Teamwork is essential for the future – keep asking questions

Include all specialists and “users” in the team for success