Public Health England

Sterilization for operating theatres – *The UK experience*

Peter Hoffman
Consultant Clinical Scientist
Public Health England

Public Health England

History

The approach to sterilization in the UK has largely been shaped by two events:

- A significant sterilization failure in the 1970s
- The emergence of prions as a significant infectious agent

In addition to these, both European Standards (“EN”) and International Standards (“ISO”) have been influential.

Public Health England

UK 1970s sterilization failure

Industrial production of dextrose saline in glass bottles.

Poor air removal resulted in layering of steam at the top of a manually operated autoclave

Bacteria were killed on the top shelf but survived on the lower shelf.

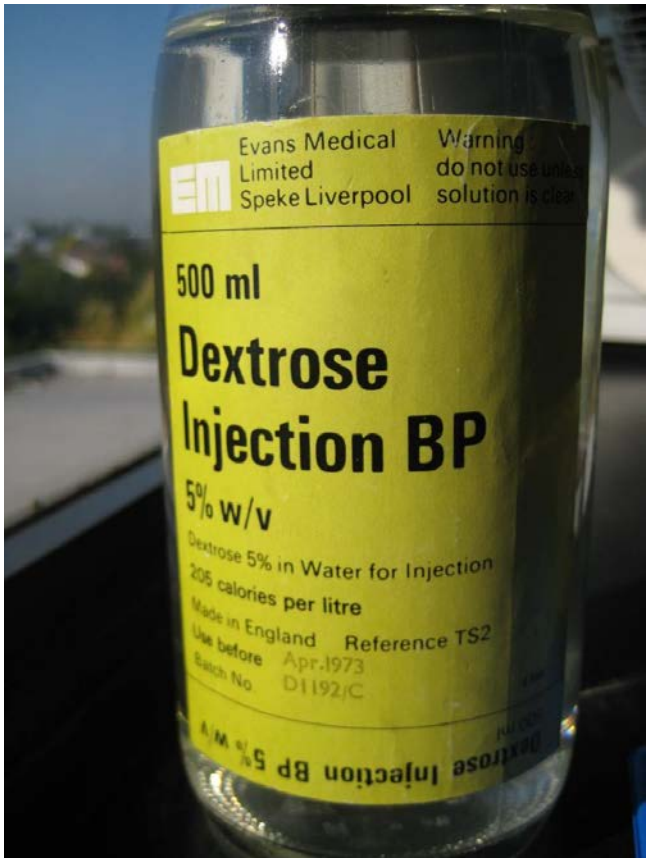
Sterility was assured by sterility test of bottles, but these were taken from the top shelf – the only one that got hot.

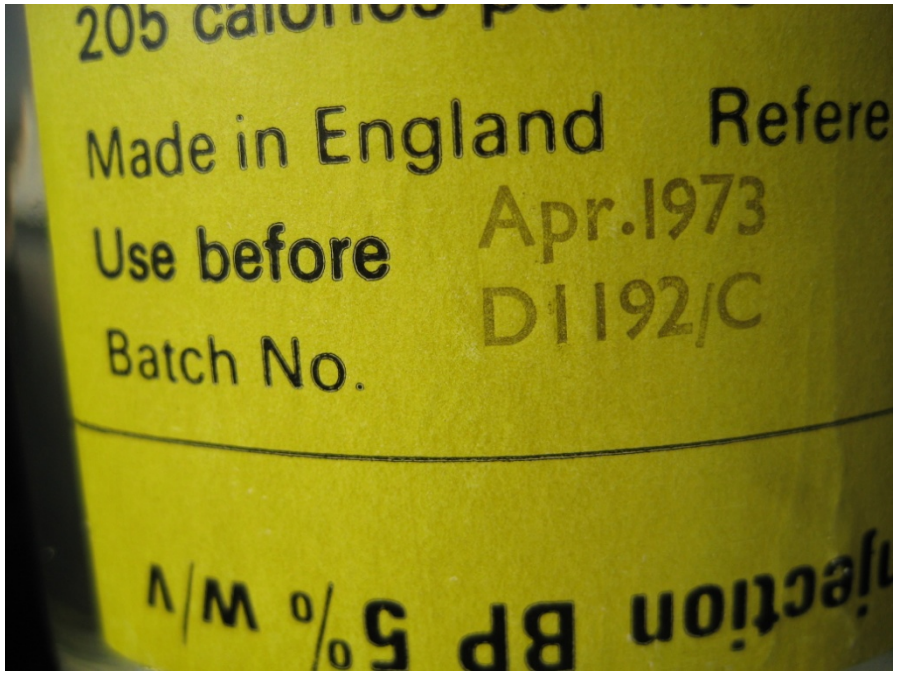
Patients died from endotoxic shock – the result of infusion of gram negative bacteria.

The resulting enquiry (The Clothier Report, 1972) set quality assurance standards for UK sterilization

Public Health England

Bottles from batch 1192





Public Health England

Bottles from batch 1192

Public Health England

The UK approach to sterilization - 1

Control and monitor the process parameters, not the product.

- **“Parametric” product release as sterile**

There are multiple problems with sterility testing, mainly:

- Poor detection of low levels of contamination
- Operator contamination
- Delay in product release
- Inability to test large objects

Public Health England

The UK approach to sterilization - 2

The UK does not use biological monitors for heat or irradiation sterilization

- Delay in product release
- Easiest to place test pieces in positions easily accessible to heat
- Will only indicate comparatively major failures
  - e.g. if 10^6 spores per test piece and want a 10^{12} reduction, would need 10^6 biological indicators per load.

Biological indicators are only used for processes where multiple interrelated make it impossible to assure via parameters e.g. ethylene oxide and hydrogen peroxide.

Public Health England

The UK approach to sterilization - 3

The UK allows use of thermochemical “integrating” indicators as secondary to process control

- These are most often on the outside of packs – the easiest place for steam to reach.
- If on the inside of packs, can only see them once the pack is opened.

They are used but normally to indicate a pack has been processed and not as the main determinant of sterilization.

Public Health England

UK guidance

Health Technical Memorandum (HTM) 01-01 (2016)

5 volumes:

a) Management & provision (46 pages)

b) Common elements (36 pages)

c) Steam sterilization (88 pages)

d) Washer-disinfectors (97 pages)

e) Alternatives to steam (8 pages)

Total: 275 pages of guidance

Available at: www.gov.uk

Public Health England

HTM 01-01

Covers:

- Design & procurement
- Validation
  - Installation, performance and operational qualifications
- Verification
  - Test details
  - Schedule of periodic testing
- Revalidation

For steam sterilisers and washer-disinfectors

Public Health England

Prions

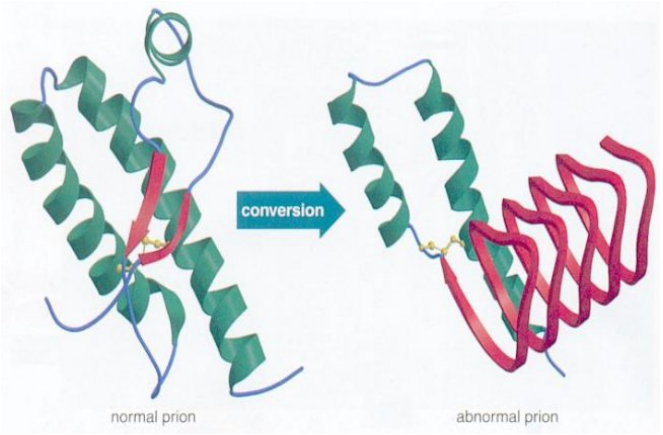
There exist on the surface of mammalian cells, particularly nerve cells, “prion proteins” whose function is unknown.

The function of these proteins depends on their shape.

They can change shape and lose their function.

When one prion protein changes shape, it causes nearby prion proteins to similarly change their shape – and so on.

It is this progressive loss of function that leads to disease: transmissible spongiform encephalopathy



Public Health England

Human prion disease

There are a number of human prion diseases.

It is thought that an epidemic of cattle prion disease (bovine spongiform encephalopathy), mainly in the UK in the 1990s, transmitted to people via food resulting in “**variant Creutzfeld-Jakob Disease**” (**vCJD**) (less than 200 deaths so far).

It is though to be transmissible person to person by blood and other tissues (and derivatives of blood and tissue), and by surgical instruments, particularly those that make contact with tissues with a high concentration of prion proteins – mainly central nervous systems and some immunological tissues.

Public Health England

vCJD – the surgical problem

Prions are hydrophobic

- When surrounded by water molecules they do not attach to surfaces, but when dried they stick very firmly

Prions are infectious by contact

- Prions on a surgical instrument can start the wave of protein shape change that leads to disease

Prions are very heat stable

- Prions are not reliably inactivated by steam sterilization

Surgical instruments can be a risk for prion disease transmission.

Public Health England

Prions, surgical instruments and infection prevention

Identify high risk patients and identify high risk tissues.

- If surgical instruments are used on high risk tissues in high risk patients, they are not reused on any other patients.

For all other instruments, the removal of prion proteins by efficient cleaning in washer-disinfectors before sterilization has become very important.

This includes not allowing instruments to dry (particularly neurosurgical instruments).

- These instruments should be processed in a washer-disinfector within 2 hours or kept moist (e.g. in high humidity).
- Keeping instruments moist does not have to be complex – tap water on a cloth in a closed bags is OK.

Public Health England

Protein measurement

UK hospital sterilizer departments are being encouraged to measure protein residues on instruments after cleaning.

The results will be monitored and used to progressively refine the whole cleaning process

This will involve not just the washer-disinfector but also things like transport times between use and cleaning and the efficiency with which instruments are kept moist.

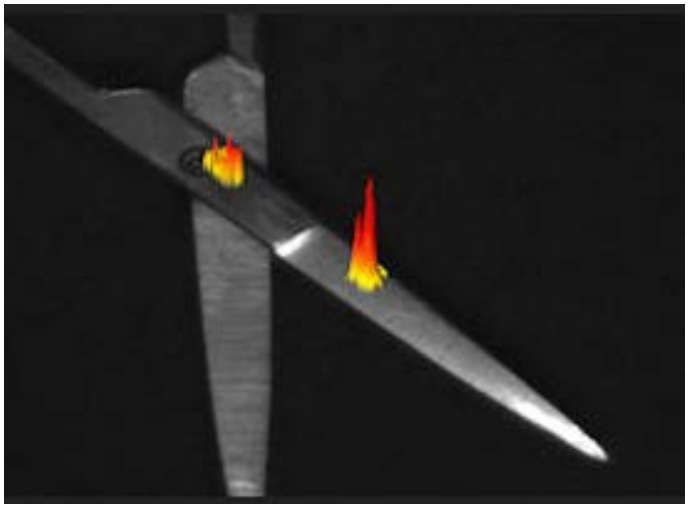
This can only be done on a small samples of instruments processed.

Public Health England

Protein measurement

As the most relevant proteins are hydrophobic (will stick firmly to instruments and will not come off on a swab), and the most difficult places to clean are also the most difficulty places to swab, methods that measure them in situ are being developed.

Only one such method that uses a fluorescent labelled othopthaladehyde is currently available; more are being developed.



Public Health England

New technology

Robotic surgery arms that will not withstand heat sterilization are becoming more common.

These need sterilization at or near ambient temperatures

Hydrogen peroxide vapour sterilizers are used for this.

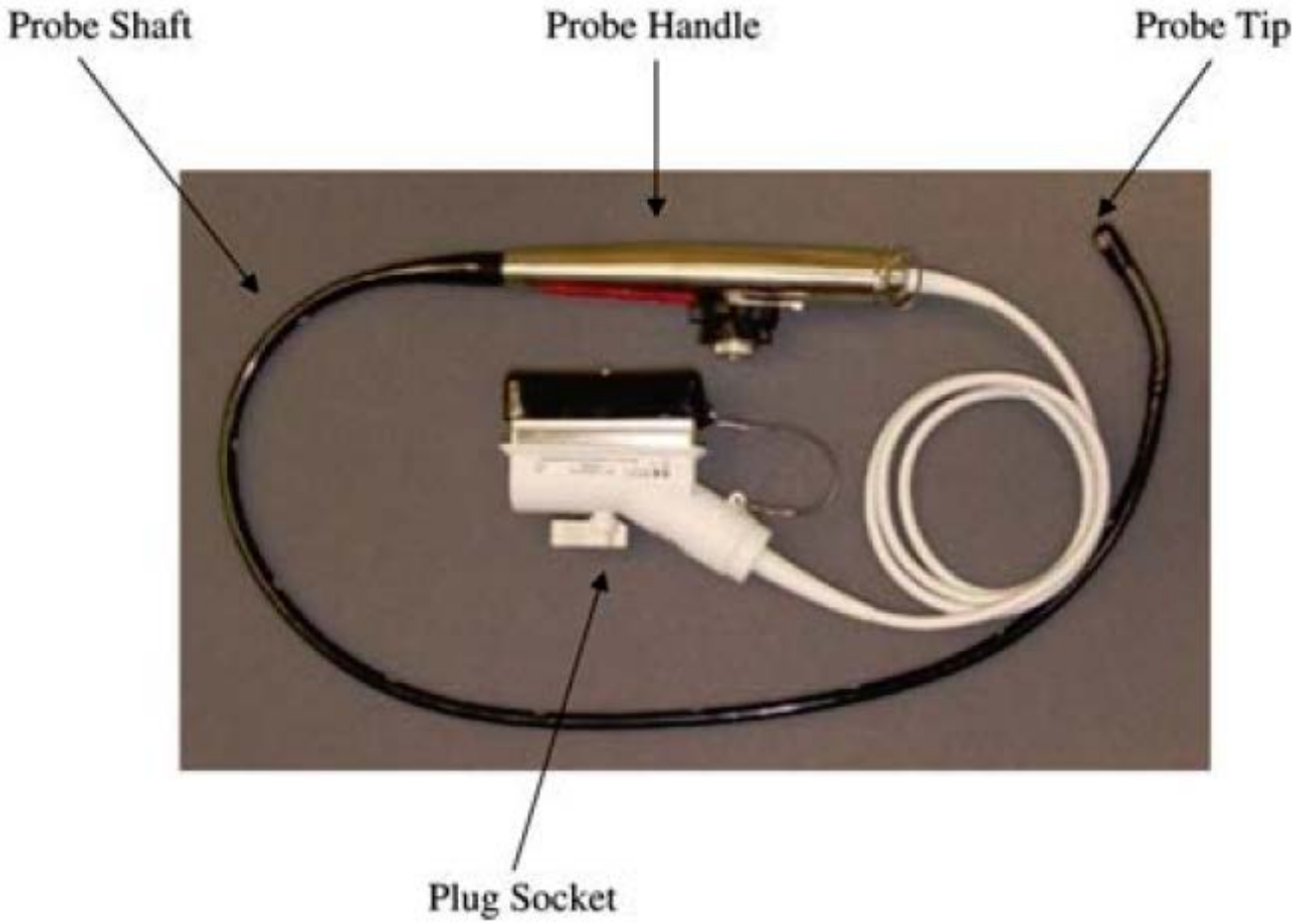
The validation and periodic assessment of these processes is more difficult than for steam.

This is still a developing area but one that cannot be ignored.

European standards are being developed to cover this area.

Public Health England

Transoesophageal echo (TOE/TEE) probe



Public Health England

TOE probes

5 April 2012 Last updated at 13:17

Morriston Hospital hepatitis B death: Lessons learned, says ABM health board

A cardiac patient who died after contracting hepatitis B at a Swansea hospital did not receive a high standard of care, say health chiefs.

An independent external review panel was asked to investigate the circumstances surrounding the hepatitis B infection.

The panel has made several recommendations about decontamination, infection prevention and control, staff training and auditing procedures.

It found that the most likely cause of the infection was a contaminated probe.

ABM University Health Board Headquarters,

One Talbot Gateway,

Baglan Energy Park,

Baglan,

Port Talbot,

SA12 7BR

Expert External Report on the transmission of hepatitis B between two patients who underwent cardiac surgery at Morriston Hospital in Swansea in March 2011

Prepared by the Expert External Review Panel

January 2012

Patient identifiable information redacted report at:
http://www.wales.nhs.uk/sitesplus/863/opendoc/189315

Public Health England

European Journal of Echocardiography (2011) **12**; i17 – i23

European Journal of Echocardiography (2011) **12**, i17–i23
doi:10.1093/ejechocard/jer095

Guidelines for transoesophageal echocardiographic probe cleaning and disinfection from the British Society of Echocardiography†,‡

P. Kanagala[1], C. Bradley[2], P. Hoffman[3], and R.P. Steeds[4]*

[1]Glenfield Hospital, Leicester, UK; [2]Hospital Infection Research Laboratory, Queen Elizabeth Hospital, Birmingham, UK; [3]Laboratory for Healthcare Infection, Health Protection Agency, London, UK; and [4]Department of Cardiology, University Hospital Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Birmingham B15 2TH, UK

Accepted after revision May 2011

The clinical utility of transoesophageal echocardiography (TOE) is well established. Being a semi-invasive procedure, however, the potential for transmission of infection between sequential patients exists. This has implications for the protection of both patients and medical staff. Guidelines for disinfection during gastrointestinal endoscopy (GIE) have been in place for many years.[1,2] Unfortunately, similar guidance is lacking with respect to TOE. Although traversing the same body cavities and sharing many similarities with upper GIE, there are fundamental structural and procedural differences with TOE which merit special consideration in establishing a decontamination protocol. This document provides recommendations for TOE probe decontamination based on the available evidence, expert opinion, and modification of the current British Society of Gastroenterology guidelines.

Public Health England

TOE probe use

- In cardiac surgery:
  - Good facilities and adequate time for probe decontamination in OR use
- In outpatients examination:
  - Usually bad facilities for probe decontamination and little time between patient uses.

Public Health England

Summary

- The conventional sterilization of traditional theatre instruments in the UK is done on a large scale with very few incidents
- Prions are a minor problem for most of the world but a very specific UK problem whose precise details are still not fully established.
- The problematic areas are mainly those where instruments are not amenable to steam sterilization – in theatres and elsewhere in healthcare.

➢ **This is a global problem**.