# Current Issues & Controversies

Causes for concern…….?

# Where to start?

- Education for all personnel
- No requirement to be trained
- Training providers – are they biased?
- Training providers – are they competent?
- Who decides on the syllabus?
- Personal belief

# Single use

- Single use device v. single patient use – the same icon
- Single use device – or single sterilization process?
- Opened in error – I didn’t use it
- Who decides?
- Cost effectiveness?
- Easy option….

# Manufacturers instructions

- BS ISO 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the re-processing of re-sterilizable medical devices

- Do manufacturers know/understand, what we need to know?

- “Rinse the somewhat inaccessible holes in the head (1) and around the ratchet wheel (2) by injecting hot water with a syringe without a needle. And if in doubt, you can perform a supplementary wash in an autoclave, which will provide thermal disinfection”.

# HTM 01-05: Decontamination in Dental Practice

- 4.24 b. with a displacement steam sterilizer instruments may be wrapped immediately after removal from the sterilizer in suitable sealed view-packs. Instruments should be dry before being packed and may be stored for up to 21 days.

- 1.24 Preliminary research finding indicate that where instruments are wrapped prior to sterilization in a validated vacuum sterilizer – the storage period can be extended to 60 days.

- My storage time period in a validated vacuum sterilizer is one year – what is the difference??

# CFPP 01-06: Reprocessing of flexible endoscopes: management and decontamination

- Choice Framework for local Policy and Procedures – Final consultation draft 30 August 2011
- Essential Quality Requirements (EQR) and Best Practice (BP)
- “BP is a risk assessed goal rather than a universal goal”
- 242 pages – 1.43 Cystoscopy – “a sterile endoscope is ideal for this purpose, but not essential”
- 1.47 – “if endoscopes are intended for use on highly immunocompromised patients, they may require rinse water with very low levels of contamination.”
- 2.29 “The manual cleaning area should be designed to protect the Operator from splashes created during the cleaning process”

# CFPP 01-06: Continued

- 16.127 Table 12 Total viable count results guide – gives advice on how to understand water test results.
- Page 200 – first mentioned  on page 19 but no indication where to find it – the document is only easy to read if read ‘on line’
- Policy needs to be clear and easy to understand
- Who has time?
- Training days

# Conflicting requirements

- Health Technical Memoranda 2030 specifies  0 colony forming units (cfu's)
- ISO 15883 Part 4 specifies 10 cfu's
- National standards/guidance or International standards
- Tracking and tracing of all RIMD's
- National guidance – developing a national risk evaluation protocol v. ISO 14971- Risk Management

# RIMD's and cleaning

- Clinicians work with instrument manufacturers
- Instrument manufacturers do not seem to consider decontamination
- Why design a product that cannot be cleaned effectively?
- Heat labile equipment
- Sterilization v. disinfection – Spaulding Classification

# Loan Sets -

- Time – no decontamination instructions – decon certificate
- 23 trays for a new knee
- Bespoke packaging cases
- Washer disinfector & sterilizer capacity
- Technician learning
- User recognition

# Lack of user knowledge/understanding

- It’s only a fancy dishwasher
- Lack of equipment – any costly RIMD
- Fast track – how long? (5 hours off site?)
- Arthroscopy
- But I didn’t use it!
- Back to cost

# Round 2

- Why do you need manufacturers instructions?
- Just use a different chemistry
- The ph factor
- MHRA – Medicines and Healthcare products Regulatory Agency
- Product failure investigation

# Round 3

- The process damaged it
- The law and the ‘picket fence’
- The manufacturer – didn’t know you did that
- Everyone else is using it
- The surgeon  owns it - You are harming the patient

# Personal experience

- At a hospital in England, an orthopaedic surgeon went shopping….

# Sterilization or disinfection?

Spaulding – disinfection if not in contact with sterile body tissue – who decides?

- Laryngoscope handles
- Vaginal speculum
- Dental instruments
- Podiatry equipment

# Investment

- Not patient visible
- Not seen as a ‘sexy or a high tech’ service
- New patient beds or a sterilizer
- Contract out the service?
- Who manages, who protects the patient?

# Other considerations

- Money v control
- Once gone?
- Flexible service?
- New innovation?
- Sales pitch v staff perceptions & loyalty

# The ‘great & the good – research’

- Financially controlled
- Snapshot
- Percentages
- Accuracy
- Panorama

# What next?

- Joy of decontamination
- Sophisticated surgery
- Innovation in Endoscopy
- Maintaining standards
- Maintain relationships

# New developments

Provide sterile flexible endoscopes

Anglia Ruskin University

Acknowledge the skills

Plan theatre lists considering RIMD's availability

Work in partnership

# Passion

- Patient safety
- Service provision
- Knowledge
- Teamwork
- Audit – 0.009% - 17 theatres

# Causes for concern?

- Does Hong Kong have the same issues?
- Human body
- Decontamination processes
- What else is out there?
- Communication – WFHSS  and e-mail

# Thank you for listening

- Any questions?
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