Clean care is safer care

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Our problem

• Dutch law places responsibility for sterility of medical devices with hospital directors ➔ this responsibility is delegated to ‘DSMH’ ➔
• DSMH is responsible for quality of decontamination processes
  but
• DSMH controls from a distance…
The real problem

- Patient safety is compromised if decontamination is not performed properly!
  - Sterility
  - Functionality
  - Safety
    - Patient
    - User

Clean care is safer care

Soil spoils
Decontamination problems

Soiled before and after cleaning

Packaging problems

damaged paper caused by nuts sticking out
Wet loads

Heavy metal & silicone inserts causing wet load

Not submersible

Internal defibrillator paddles
Responsibility for decontamination quality

Can only be accepted by DSMH when
• processes are validated
• staff is qualified

Therefore:
• no deviant processes allowed

Validated processes means

• Equipment validation
  – Sterilizers
  – Washer/disinfectors
  – Heat sealers
• Fixed load configuration
• Fixed programmes
  – Fixed time/temperature combinations ($F_0$, $A_0$)
  – Sterilization: Pre-vacuum cycles
Qualified staff

- Education
  - School
  - Vocational training
  - Life-long learning
- Motivation
- Appreciation
- Sterilization technician
- Team leader
- Manager
- DSMH

"willing people make failing systems work, unwillingly, people make working systems fail!"

Guidelines

- MDD 93/42/EEC revision → MDD 07/47/EC
- UK: CJD committee:
  "Improve design for better cleanability"
- EN-ISO 17664:2004
  - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- NL:
  - NEN standards
  - RIVM reports
Problems in reprocessing

• Meetings of experts and managers of the CSD from all university hospitals resulted in:
  – recognizing problems in reprocessing
  – development of the “grey list”: a list with problem causing instruments
    • question: which criteria do we use for placing instruments on the list?

Assessment criteria for new reusable medical devices (RMD)

• 2006: developed by AZO
• April 2007: accepted by the VDSMH
Assessment criteria for new reusable medical devices (RMD)

• General:
  - CE marking
  - information manual

• Instrument design:
  - lumen
  - visual inspection
  - submergible

Assessment criteria for new reusable medical devices (RMD)

• Tray / container
  - mesh tray
  - size
  - weight
  - arrangement

• Properties:
  - reprocessable in Dutch CSD's?
Next step

• Today:
  – Assessment criteria in your conference bag
  – On the website VDSMH www.cscnl.net/divers/vdsmh

• Nearby future:
  – Dutch Technical Specification (NTA)?
  – Translation in English?

Other developments

• Loaner instruments:
  – a field standard and a list of requirements
  – december-07: a meeting with all parties concerned
  – NTA (Dutch Technical Specification)?

• Re-sterilization of disposable medical devices
  – NEN 301.08104: NPR (Dutch Technical Report)?
Conclusion

• Criteria are available for:
  – loaning
  – buying and
  – re-sterilization of single-use MD

• These criteria will help to make the right decisions for safer care to patients and for protecting employees

or

One small step…

for man(ufacturer),
one giant leap for mankind
(patient safety)

Neil Armstrong,
the Moon,