High level disinfection of endoscopes

A central vision
Summary

• Introduction
• Responsability
• New tendencies
• Organisation
• Conclusion
Introduction

• ↑ Importance of endoscopy

• ↑ Complicated technology

• ↑ Complicated cleaning/disinfection
  – ↑ National & international standards
  – ↑ Manufacturers & products
Introduction

“State of the art”

Variation in compliance

Responsibility?
• Contractual
  – No contractual outcome
  – State of the art
  – Pressure of quantity
Pharmacist

• Not contractual
  – Sterilization
  – Disinfection
    • Products
    • Method?
Team infection control

• Not contractual
• State of the art
  – Literature
  – National working groups
  – Provincial working groups
• Advisory
Nurses

- Not contractual
  - State of the art
  - Pressure of quantity
Missing link

• Quality system
  – Following standards
  – Policy supported
    • Reproduceable
    • Traceable
  – Standardised control and improvement
“State of the art”

• Spaulding classification
• Standards
  – EN ISO 14971
  – EN ISO 15883-1
  – EN ISO 15883-4
  – EN ISO 17664
Spaulding

- Critical
  - Bloodvessels, sterile tissues: sterilization
- Semi critical
  - Intact mucuous membranes: high-level disinfection
- Not critical
  - Intact skin: cleaning
Spaulding

Flowchart Spaulding classification

- Yes: Patient immuno-compromised
- No

- Yes: Sterile tissue
- No

- Yes: Mucuous membrane intact
- No

- Yes: Skin intact
- No

- Sterilization
- High-level disinfection
- Cleaning
Spaulding

Beslissingsboom sterilisatie en high-level desinfectie (na adequate reiniging)

- CSA mogelijk
  - Ja
    - Hulpmiddel stoomsteriliseerbaar
      - Ja
        - CSA (stoom)
      - Neen
        - CSA (gas)
    - Neen
      - Gebruksfrequentie te hoog
        - Ja
          - Extra aankoop mogelijk
            - Ja
              - Stoomsterilisator op afdeling
                - Ja
                  - Decentrale stoomsterilisatie (4)
                - Neen
                  - Was- en desinfectie-toestel haalbaar
                    - Ja
                      - Gebruksfrequentie te hoog
                        - Ja
                          - Extra aankoop mogelijk
                            - Ja
                              - Onderdompelbaar
                                - Neen
                  - Neen
                    - Gebruksfrequentie te hoog
                      - Ja
                        - Extra aankoop mogelijk
                          - Ja
                            - Desinfecterende opl. mogelijk
                              - Neen
                                - Steriele overtrek haalbaar
                                  - Ja
                                    - Steriele overtrek (7)
                                  - Neen
                                    - Hulpmiddel vervangen door alternatief dat zo hoog mogelijk in de beslissingsboom kan
                          - Neen
                            - Cidex OPA® 20 min (6)
                              - Ja
                                - Steriele overtrek (7)
                              - Neen
                                - Steriele overtrek (7)
            - Neen
              - Steriele overtrek (7)
EN ISO 14971

• Application of risk management to medical devices
  – Predictable risks for total lifetime
  – No influence on clinical decisions
    • Permanent risks vs advantages

(Registration?)
EN 17664

Sterilization of medical devices

Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN 17664

- Reprocessing instructions
  - Limitations
  - Validation of the provided information
  - Risk analysis
  - Exclusion of textile devices
EN ISO 15883-1

- Washer-disinfector, general requirements
  - Not for laundry or general catering
  - Only loads intended by manufacturer of WD
  - Automatic control parameters
  - All surfaces meet parameters
  - Installation-, operational- & performance qualification
EN ISO 15883-4

Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
EN ISO 15883-4

- Not intended for heat stable endoscopic accessories
- Not intended to ensure inactivation or removal of TSE
- Each channel/cavity meets all requirements
EN ISO 15883-4

• Cycle:
  – Leak testing
  – (pre-) Cleaning
  – Rinsing
  – Disinfecting (self disinfection $A_0$ 600)
  – Removing toxic residues
  – Drying (when appropriate)
Comparison of the cleaning and disinfection efficacy of four washer-disinfectors (WD) for flexible endoscopes

2 of 4 WD don’t detect blocked endoscope channels and continue the process

New influences

- CJD
  - Gastro-enterology
  - ORL
- Cleaning- & disinfection products
  - PAA
  - Chlorine dioxide
Disinfection

Prions

Biofilms

Toxicity
TSE (vCJD)

- Irish TSE Infection Control GuidelinesSept 2004:
  - Quarantaine and destruction endoscope
  - Gastro-intestinal endoscopy
  - Otolaryngologic endoscopy
TSE (vCJD)

- Pelckmans P, Cras P. (UZA)

“Each endoscope should be identified and traceable in each population”
Disinfection

- EN ISO 15883-4
  - Log $10^6$ vegetative germs
    - Mycobacteria, yeasts & fungi
  - Log $10^4$ spores
    - Fungal spores and viruses
Desinfection

- Glutaral aldehyde
- Peracetic acid (Fr)
- Chlorides (Eng)
Disinfection

• Kampf G, Bloss R, Martiny H.
  (Journal of hospital infection 2004 Jun;57(2):139-43.)
  – Fixation by glutaraldehyde en PAA
  – Effective cleaning is a must

• Henoun Loukili N. et al
  (Journal of hospital infection 2004 58:151-54.)
  – Aldehydes & mycobacteria,…?

• Vadrot C. et al
  (Zentral Sterilisation 2006 (1):22-29.)
  – Fixating properties of PAA
Cleaning

- EN ISO 15883-4
  - Manual precleaning
  - Prerinsing of channels is recommended
  - Detergent is obligable
  - No reuse of detergent solution
  - Quality of rinsing water specified by manufacturer (≥ drinking quality)
  - Testsoils
Cleaning

• Rutala WA, Weber DJ
  (Journal of hospital infection 2004 Apr;56 Suppl 2:S27-39.)
  – Log $10^4$
  – Immediately after use

• Vickery K, PajkosA, Cossart Y.
  (American Journal of Infection control 2004 May;32(3): 170-6.)
  – Removing biofilm
    • Not enzymatic product as cleaning product
      (Matrix, Whiteley Medical)
Final rinsing

• EN ISO 15883-4
  – $\text{H}_2\text{O}$
    • $\geq$ Drinking quality
    • Free of micro-organisms including;
      – Legionella
      – Mycobacteriae
Drying

• New disinfection after 4 hours
  (WIP)

• 72 hours in drying cabinet
  (Wassenburg)

• 5 days in dustfree cupboard
  (Gastrointestinal endoscopy, 2004 Jul;60(1): 76-8.)
Conclusion

- Washer-disinfector recommended
- Connections
- Quality of water
- Increasing importance of collaborating manufacturers
  - Endoscopes
  - Automats
  - Detergents & disinfectants
Quality system

- Connected with hospital policy
- Dossier per medical device
- Traceable
- Standardised follow-up and improvement
Appointing responsibilities

• 1 Coordinator (Pharmacist/representative)
  – Quality assessment
    • Identification inconformities (registration?)
    • Identification solutions
      – Strategy
  – Follow up
    • Planned
    • Contact per unit
Appointing responsibilities

- Team infection control
  - State of the art (cleaning/disinfection), standing orders
  - Teaching
  - Budget (?)

- Endoscopy doctor/nurse
  - State of the art
  - Adjusted devices
Dossier medical device

- “Administrative data”
- Theoretic disinfection level (Spaulding)
- Actual disinfection level
  - Direct solutions
  - Long term solutions
    - Planning tasks
    - Planning evaluation
Dossier medical device

- Evaluation
- Information/approval doctor
- Information/approval pharmacist
- Information/approval direction
- Next evaluation
Dossier medical device
Traceability

- Registration
  - Patient
  - Employees
  - Endoscope
  - Proces parameters

- Centralisation
  - Project
  - Manufacturers
Conclusion

• Central vision
  – Awareness
  – Budgetting (long term vision)
  – Equal level for each discipline
  – Collaboration central sterilization
  – Collaboration external players