INFECTION CONTROL and STERILIZATION UNIT

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Hospital acquired infections

- 3 – 10 / 100 hospitalized patients

  USA → > 2 million patients / year
- Cross-infections → 11 – 35%
- At least 20% → preventable
- Percentage of infections related to the sterilization units → ??

  Zero risk should be the standard

MMWR, 1992

Harbarth S, J Hosp Infect, 2003

Outline

- Sterilization failures
  - Complex surgery equipment
  - Endoscopes
  - Reprocessing single use devices
  - Prions

Goal of infection control

- Reduce infection risk
  - Patients
  - Employees
  - Others

Sterilization Unit + Infection control team

Sterilization unit

Cleaning

Decontamination

Inspection

Assembly

Packaging

Sterilization → Principles, Methods, Agents, Limitations, Regulations

Storage

Delivery

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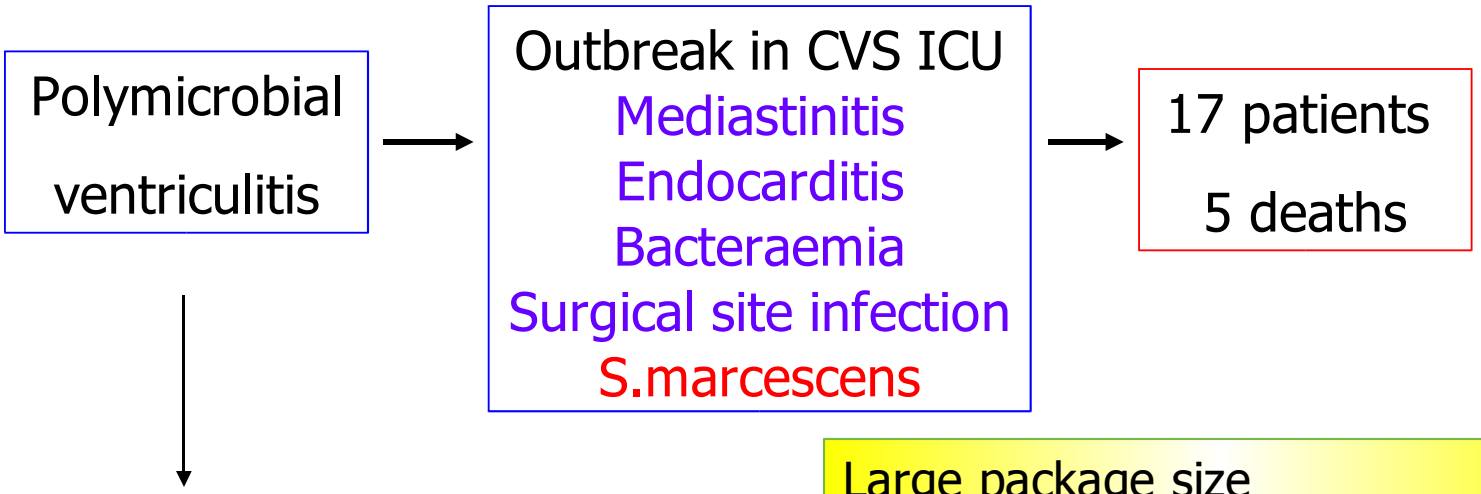
Properly prepared, sterile medical devices

Sterilization failure



Large package size

Irregular Bowie-Dick tests

No biological indicator

Improper humidity control

Lack of proper infection control

Esel D, J Hosp Infect, 2002

Complex structured devices

- Narrow and long lumens
- Twisted structure with crevices
- Heat-sensitive material, lubricants
- Small pieces, difficult to detach

Disinfection / Sterilization

- Difficult
- Labor-intensive
- Requires attention to details

Complex structured devices

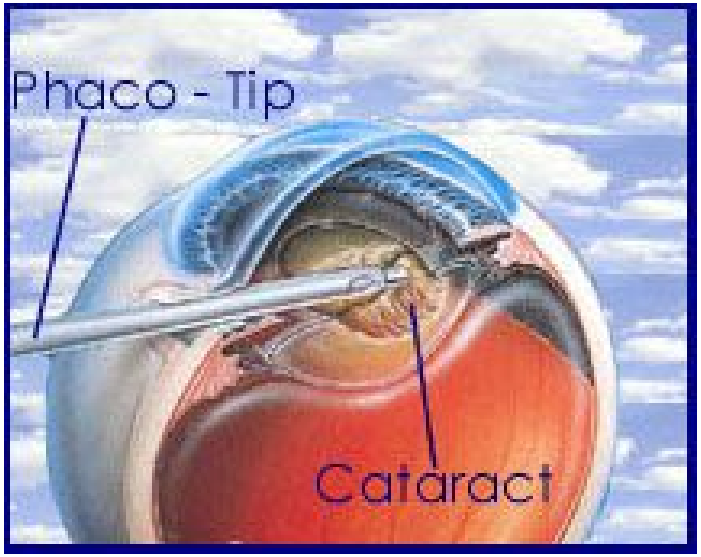
Phacoemulsification instruments

32 sets

16% moderately contaminated

22% severely contaminated

- lens capsule
- man-made fibres
- squamous cells
- bacteria and fungal elements
- red blood cells
- proteinaceous material.



Leslie T, Eye

Endoscopes

PATIENT

Normal flora
- E. coli
- Klebsiella spp.

Colonizing organism
- Serratia spp.

Infection
- Salmonella spp.
- M.tuberculosis
- Hepatitis B or C virus
- HIV

ENVIRONMENT
- Pseudomonas spp.
- Atypical mycobacteria

→ Failure of cleaning and disinfection → Infection transmission

Ann Intern Med, 1993

Am J Infect Control, 2000

Endoscopes - Problems of disinfection

- Complex structure of endoscopes and accessories
- Compliance with established reprocessing guidelines

Endoscopy, 2000

Infect Control Hosp Epidemiol, 2003

Disinfection of endoscopes

- 26 hospitals in USA
- 78% → failure to sterilize biopsy forceps
- 71 GIS endoscopes

  ↓ bacterial cultures of internal channels after disinfection

  24% grew $\geq 10^5$ colonies

Kaczmarek RG, Am J Med, 1992

Endoscopes - Failures of disinfection

- Inadequate manual CLEANING
  - Cleaning of all channels (flushing, brushing)
- Inadequate disinfection
  - Lack of full immersion in the disinfectant solution
  - Short duration of immersion
  - Unappropriate disinfectant
- Inadequate rinsing and drying
- Lack of sterilization of accessories
- Use of automated endoscope reprocessors
  - Contaminated reprocessor (water bottles and tubes)
  - Improper connection / usage

Endoscope-related transmission

- Colonoscopy – HCV
  - Biopsy suction channel was not cleaned
  - Accessories were not autoclaved
  - 5 min. immersion in 2% gluteraldehyde
- Bronchoscopy – M. tuberculosis
  - Poor manual cleaning
  - Partial immersion in the disinfectant
  - Failure to sterilize biopsy forceps
- Gastroscopy – HBV, H.pylori, Trichosporon spp.

Langenberg W, J Infect Dis, 1990
Bronowicki JP, NEJM, 1997
Michele TM, JAMA, 1997
Agerton T, JAMA, 1997
Wenzel R, JAMA, 1997
Larson JL, Infect Control Hosp Epidemiol, 2003

Endoscope related pseudo-infections

Patient is not infected but the culture of the sample taken by the endoscope is positive

Pathogens

- P. aeruginosa, S. marcescens,
- M. tuberculosis and atypical mycobacteria

Possible results

- Transmission → Colonization or infection
- Unnecessary investigations
- Unnecessary treatment

Silva CV, Infect Control Hosp Epidemiol, 2003

Bennett SN, Am J Respir Crit Care Med, 1994

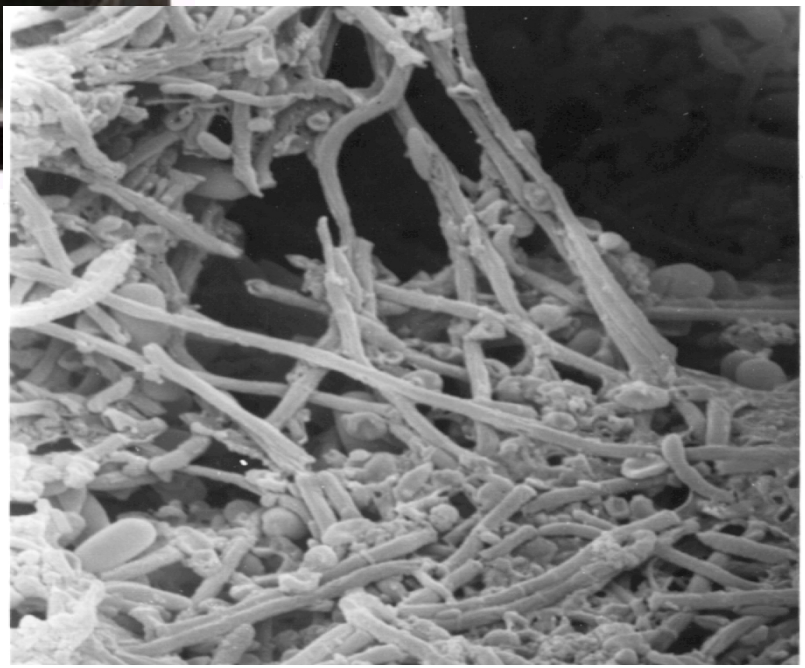
Microbial reservoirs

- Biofilm formation
  - Layer of bacteria (tightly attached to each other and the underlying surface) and extracellular material
  - Difficult to clean
  - Protection from disinfection and sterilization

☞ Importance of mechanical cleaning

A biopsy forceps after cleaning, demonstrating residual organic soil

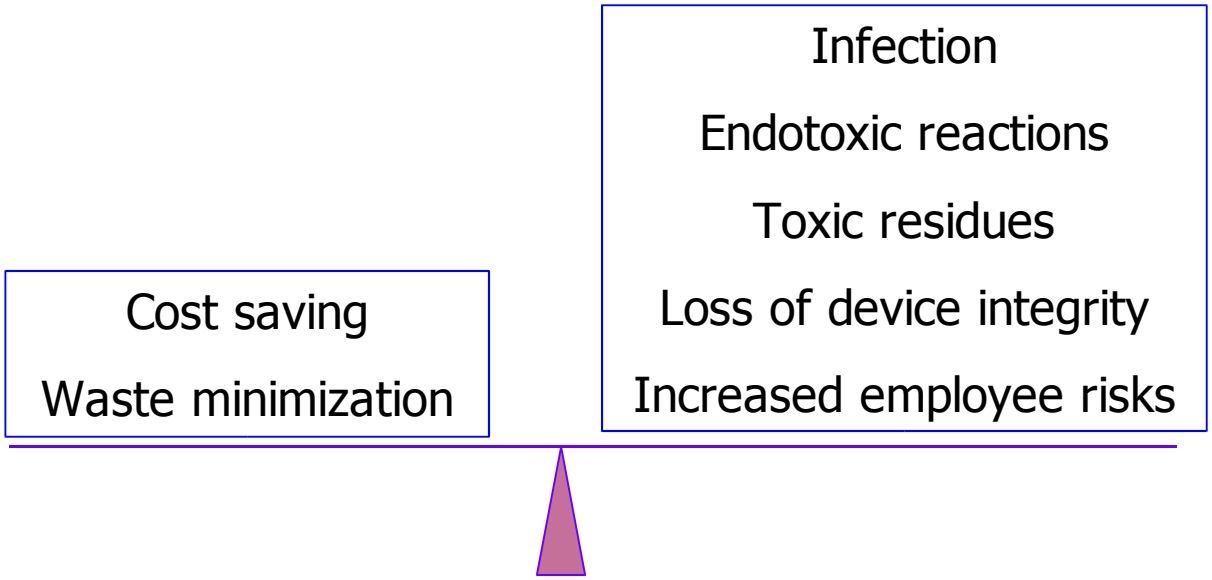
Am J Infect Control, 2000



Biofilm: Microbial life on surfaces

commtechlab.msu.edu

Reuse of single use devices (SUD)



Controversial but common practice

Collignon PJ, MJA, 1996 and 2003

Muscarella LF, Gastroenterol Nurs, 2001

Studies related to reuse

In favor

Catheters → Bloom,1997; Kozarek, 1996 Browne, 1997; Druce 2003

Sphincterotomes, papillotomes → Cohen,1997; Wilcox 1998

Coagulation probes → Roach,1999

Spinal needles → Penna, 2000

Against

Endoscope stopcocks → Wilson,2000

Biopsy forceps, papillotomes, stone baskets → Heeg,2001; Hambrick, 2001

Laparoscopic devices → Roth,2002

Reuse-related infections

- Frequency is unknown
- May be undetected
  - Long incubation period,
  - Asymptomatic nature of blood-borne viral infections
- Difficulty to trace infections back to reused device

Reuse of catheters

Balloon catheters

contaminated with viruses (echo- and adenovirus)

↓

Culture and PCR

↓

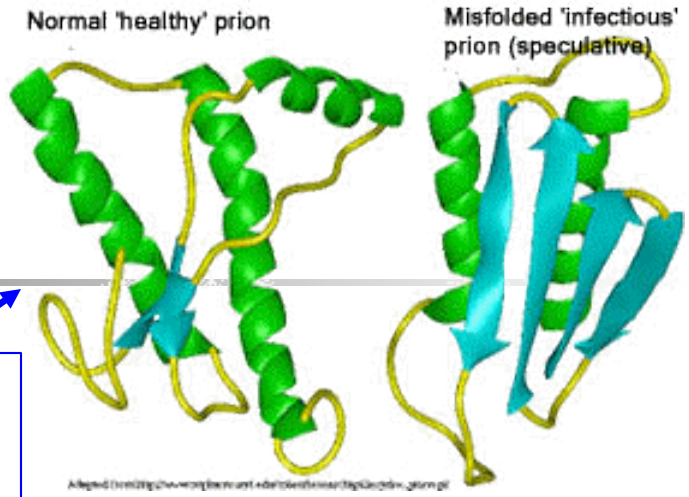
Detectable virus after cleaning + sterilization (glutaraldehyde)

Luijt DS, Eur Heart J, 2001

Reuse - Questions

- Which device is suitable for reuse? (instructions of the manufacturer, decision of a central body, etc)
- Is it cost effective?
- What are the risks? (quality assurance and research)
- What are the standards and regulations?
- Is the patient informed?
- Is there a validated cleaning / sterilization process and a guideline?
- Is there a standardised assessment process?
- Is there a tracking system for the outcome?

Prion



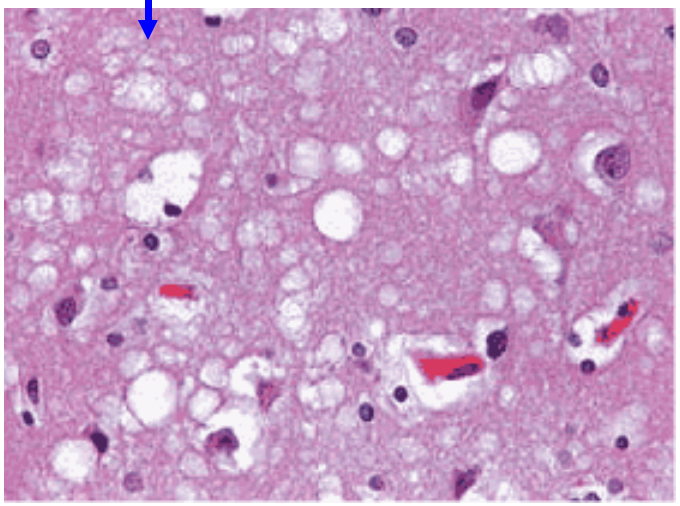
www.chem.tue.nl

Abnormal isoform of a host encoded pr

Accumulation within the CNS

Spongioform changes in the brain

Dementia and death



- Lack of nucleic acid
- Resistant to currently used sterilization methods
- Transmission - cornea, human GH, dura mater grafts, neurosurgical instruments - electrodes

vCJD protein

- Present in lymphoid tissue starting from early (asymptomatic) stages of disease
  - Tonsil
  - Spleen
  - Lymph nodes
  - Appendix
- Incubation period : years

vCJD pr - Risk of transmission

UNKNOWNS

- Number of infected people (prevalence)
- Quantity of prions that can cause cross-infection
- Infectivity of the tissues involved in procedures
- Amount of reduction of infective tissue with the decontamination / sterilization procedures

Possibility of cross-infection with surgical instruments contaminated with lymphoid, neural, ocular tissues

Lowering the risk of transmission

- Using disposables (may be only in UK)
  - Which procedures?
  - Are the disposables as effective as reusable equipment?
- Special decontamination – sterilization methods
  - How to decide when to use them?
- Separated equipment for diagnosed patients
  - Endoscopes

Method of sterilization for prion

Combinations of

- Immersion in NaOH or sodium hypochlorite (at different temperatures and durations)
- Autoclaving at 121°C (30 min – 1 hour) or ≥ 132°C

www.who.int/emc-documents, 2003

Type of operation, tissue involved, risk level of the patient

↓

Collaboration between the surgery team, infection control group, sterilization unit

Summary

- Sterilization units' success has a leading role in the prevention of health-care associated infections.
- Problems
  - Sterilization of the complex surgery equipment and endoscopes
  - Reprocessing single use devices
  - Inactivating prions

Success of the sterilization unit

- Skilled personnel
  - Asepsis, cleaning, disinfection, sterilization
- Adequate space and equipment
- Standardized written protocols
- Quality control - assurance
- Continous education
- Communication and collaboration between departments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