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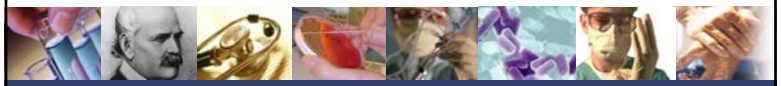

Accreditation of your endoscopy room

Isabel Leroux-Roels, MD PhD
Microbiologist – Infection Control Physician

BSGIE Annual Meeting
10 september 2014

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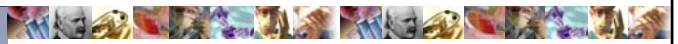

Overview

- **Inspection and accreditation of hospitals**
- **Risks associated with inadequate endoscope reprocessing**
- **Recommendations for qualitative endoscope reprocessing**
- **Considerations**
- **Conclusion**

 2

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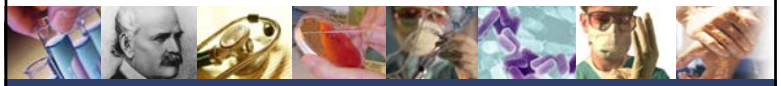

Inspection and accreditation of hospitals

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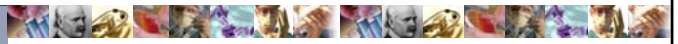

Nieuw inspectiemodel van de Vlaamse Overheid

Agentschap Zorginspectie

Externe accrediterende instanties

Eisenkaders:
zorgtrajecten
• Chirurgisch (2013)
• **Internistisch**
• Moeder-kind
• Geriatrie-revalidatie
• Psychiatrie

NALEVINGSTOEZICHT
• Toets op concreet geleverde zorg (S, P, R)

SYSTEEMTOEZICHT
• Toets op de organisatie van de zorg

Bevraging eind 2012:
• Positief advies RvB en MR
• ISQua gecertificeerde instantie
• Accrediteringsbesluit vóór 2018

Acute, categorale en universitaire ziekenhuizen

 4

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Accreditation organisations

Haute Autorité de Santé (HAS)	France	HAS
Joint Commission International (JCI)	USA	Joint Commission International
Accreditation Canada International (ACI)	Canada	
Nederlands Instituut voor Accreditatie in de Zorg (NIAZ)*	Netherlands	NIAZ

* May 2013: Franchise agreement between ACI and NIAZ.
NIAZ adopted Qmentum guidelines (NIAZ 3.0)

Qmentum International

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JCI standards

Joint Commission International

- **PCI 7.1 'The organization reduces the risk of infections by ensuring adequate equipment cleaning and sterilization** and the proper management of laundry and linen'
- **Measurable elements of PCI 7.1**
  - 1. Equipment cleaning and sterilization methods in a central sterilization service are appropriate for the type of equipment
  - 2. Equipment cleaning, disinfection, and sterilization methods conducted outside a central sterilization service are appropriate for the type of equipment

 6

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NIAZ Qmentum standards

Qmentum International

- **Standard 13.0 'The organization follows specific requirements to reprocess endoscopy devices'**
  - 14 substandards (13.1 → 13.14)
  - 10 golden elements (minimal accreditation level)
    - *Training/competency, separation patient and reprocessing areas, daily cleaning, immediate start of reprocessing, check for damages, manual cleaning, rinsing and drying, flushing with 70% alcohol, rinsing sterile/filtered water, correct storage*
  - 4 platinum elements (medium accreditation level)
    - *Separation clean/dirty work areas with separate plumbing/drains, good ventilation, traceability (endoscope reprocessing, repairs, clinical procedures)*

 7

AGENTSCHAP ZORG & GEZONDHEID

Standards for the internistic patient

Eisenkader voor de internistische patiënt

Het "eisenkader voor de internistische patiënt" is nog een ontwerp, dat nog kan gewijzigd worden (zij het in beperkte mate). In het eisenkader staan alle eisen vermeld die door de sector en de overheid weerhouden werden als cruciaal voor de kwaliteit van zorg.

Het internistische eisenkader is opgebouwd uit 4 onderdelen:

- De D-dienst en de functie niet-chirurgische daghospitalisatie (XLS) - Download als pdf
- De functies gespecialiseerde spoedgevallenzorg, eerste opvang spoedgevallen en MUG (XLS) - Download als pdf
- De functie voor intensieve zorg (XLS) - Download als pdf
- De functie ziekenhuisapotheek (XLS) - Download als pdf

Het onderdeel m.b.t. high level desinfectie van warmtegevoelige flexibele endoscopen met lumen, moet nog verder uitgeklaard worden. Het wordt nog niet gepubliceerd. Het zal in de eerstvolgende inspectieronde ook niet worden meegenomen als te inspecteren onderdeel in functie van erkenning (toe te voegen).

Standards for high level disinfection of flexible endoscopes have not been published

www.zorg-en-gezondheid.be

 8

AGENTSCHAP ZORG & GEZONDHEID

Standards for endoscopy rooms (not published)

- **Training of non-medical staff**
- **Infrastructure**
  - Separation clean-dirty in the reprocessing area and during transport
  - Tagging (ID nr) of all devices involved in reprocessing
  - Drying cabinets
- **Cleaning and disinfection**
  - Manual pre-cleaning in endoscopy room
  - Traceability
  - Accessories and brushes: single use or if reusable, manufacturers' approval needed
  - Transport containers
  - Rinse water bottles
- **Maintenance and microbiological controls**

 9

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Guidelines

Society	Country/Region	Year of publication	Recommendations based on…
HGR/CSS	Belgium	2010	Consensus
SFERD	Netherlands	2011	Best practice Common sense
WIP	Netherlands	2009	Consensus
ESGE/ ESGENA	Europe	2007 (2) 2008 (1)	Consensus
ASGE/ SHEA	USA	2011	Level of evidence (IA/B/C, II, unresolved issue)

+ NEN standards, ISO 15883-1, 15883-4, 15883-5, …

 10

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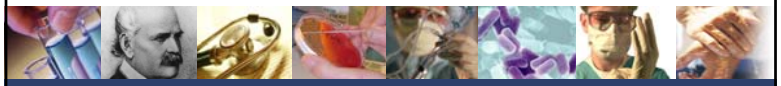

Risks associated with inadequate endoscope reprocessing

 11

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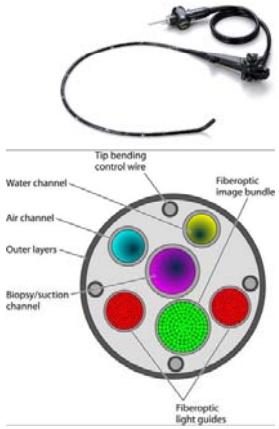
Flexible endoscopes

- Semi-critical/critical instruments
- Heat-sensitive
- Complex structure: small lumina, narrows channels
- Disinfection and drying procedures often fail
- Biofilm can easily grow



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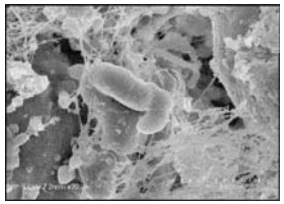
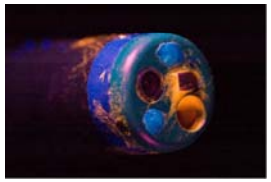
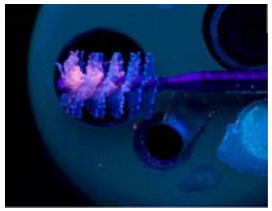
Biofilm in endoscopes







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Transmission of infection

- **Bacterial transmission during endoscopic procedures is underestimated**
- **Factors related to endoscope contamination:**
  - Ineffective cleaning
  - Ineffective disinfection
  - Insufficient rinsing and drying
  - Errors in the endoscope design
  - Use of a damaged endoscope

Kovaleva et al. *Clin Microbiol Rev* 2013; 26: 231

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Endoscopy related infections

- **Endogenous (own) microflora**
  - *E. coli, Klebsiella spp., Enterobacter spp., Enterococci*
  - Cannot be prevented by a good disinfection procedure
- **Exogenous microflora**
  - Gramnegative bacteria (*P. aeruginosa, S. marcescens, Salmonella spp.*), mycobacteria, yeasts
  - Transmission to patients through contaminated endoscopes and accessories
  - **Strict adherence to disinfection procedures is essential!**

Kovaleva et al. *Clin Microbiol Rev* 2013; 26: 231

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Risks of gastro-intestinal endoscopies

- **Lower rate of post-procedure infections as compared to bronchoscopies**
- **ERCP scopes: increased infection risk!**
- ***P. aeruginosa* is the most common causative pathogen**
  - *P. aeruginosa* biofilm is very hard to eliminate
  - Outbreaks of *Pseudomonas* infections are related to failed disinfection procedure or insufficient drying of the channels
- **Recent outbreaks of post-ERCP sepsis by multiresistent *K. pneumoniae* or *E. coli* (ESBL, CPE)**

Aumeran 2010; Carbonne 2010

Infection (2014) 42:15–21
DOI 10.1007/s15010-013-0544-6

REVIEW

Klebsiella spp. in endoscopy-associated infections: we may only be seeing the tip of the iceberg

P. Gastmeier · R.-P. Vonberg

- **Review of endoscopy-related outbreaks with *K. pneumoniae***
- **6/9 *K. pneumoniae* outbreaks ~ duodenoscopes (ERCP)**
  - 2 outbreaks 1979-2008
  - **7** outbreaks 2009-2013
- **Due to emergence of highly resistant strains**
  - Carbapenemase producing *Enterobacteriaceae* (CPE)
- ***"Insufficient reprocessing of the endoscope was the main reason for subsequent pathogen transmission"***

Gastmeier et al. *Infection* 2014; 42: 15-21 17

Morbidity and Mortality Weekly Report

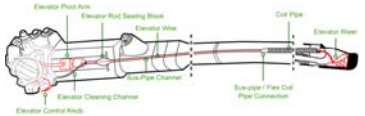
Notes from the Field

New Delhi Metallo-β-Lactamase–Producing *Escherichia coli* Associated with Endoscopic Retrograde Cholangiopancreatography — Illinois, 2013

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE)* are increasing among patients in medical facilities (*1*). CRE that produce *Klebsiella pneumoniae* carbapenemase (KPC) have been responsible for much of the increase in the

were recovered from the terminal section (the elevator channel) of the device.§ The *E. coli* isolate was highly related (>95%) to the outbreak strain by PFGE. Retrospective review and direct observation of endoscope reprocessing did not identify lapses in protocol. Previous studies have shown an association between ERCP endoscopes and transmission of multidrug-resistant bacteria; the design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection (*2*,*3*).

- 69 patients colonized/infected with **CPE+ *E. coli* (NDM)**
- Strong association between CPE positivity and a previous **ERCP** (OR 78; 95% CI 6 - >999.99)
- Positive samples of the **elevator channel**
- Since **ethylene oxide sterilization** of ERCP scopes, no new cases



NDM: New Delhi metallo-betalactamase
MMWR 2014; 62: 1051 18

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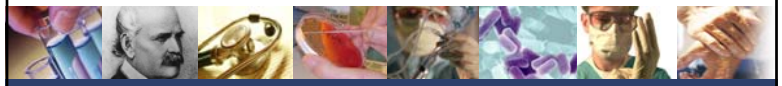

Recommendations for qualitative endoscope reprocessing

 19

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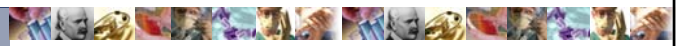
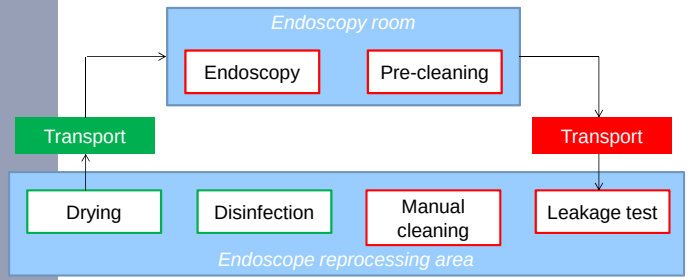


Process of endoscope reprocessing



 20

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Pre-cleaning on site by the operator

- **Purpose:**
  - Remove visible blood, mucus, soil and prevent drying
- **Method:**
  - Cleaning the exterior with a single use tissue/gauze/spunge
  - Flush air/water and biopsy channels
    - Tap water (HGR/CSS), sterile water versus detergent solution?
  - Disconnect and transport the endoscope to the reprocessing area
    - In a container if not immediately adjacent

 21

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Endoscope reprocessing area

- **Separation of clean and dirty areas**

"The ideal world"

 22

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Endoscope reprocessing area

"The real world… at UZ Gent"

 23

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Manual pre-cleaning

- **Purpose:**
  - Remove biofilm!
  - Lower the bioburden with ± 4 log (99.99%)
  - Pre: 10^5-10^6 CFU/ml → Post: 10^1-10^2 CFU/ml
- **Method:**
  - Leakage test
  - Complete immersion in clean sink, with clean (filtered?) water, **flush and brush** valves, channels and connectors
  - Ultrasonic cleaning of accessories/components may be needed
  - Enzymatic (HGR/CSS) vs non-enzymatic detergent
  - Respect the manufacturers' concentration, contact time and t°
  - Brushes and rinsing solution should not be reused

 24

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High level disinfection

- **Automated procedure (AER) >> manual procedure**
  - Cave! Contaminated (biofilm) or defective AER
- **Glutaraldehyde vs peracetic acid vs OPA vs…. ?**
- **Automated endoscope reprocessor (AER):**
  - Rinsing step with bacterium-free (sterile/filtered) water
  - **Model-specific reprocessing protocols,** e.g. elevator channel of duodenoscope cannot be disinfected by most AER → manual
  - Maintenance
  - **Validation by an external organisation using dummy scopes (cfr. SFERD)**

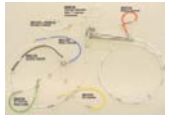


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TABLE 1 Advantages and disadvantages of commonly used high-level disinfectants

High-level disinfectant	Advantage(s) (reference[s])	Disadvantage(s) (reference[s])
Glutaraldehyde	Excellent biocidal properties (5, 33–35) Many studies published	Slow action against mycobacteria (35, 38) Irritant to the respiratory tract, eyes, and skin; development of allergic reactions, contact dermatitis, asthma, acute colitis (36, 37)
	Does not damage endoscopes and processing equipment; noncorrosive to metal (5, 33) Relatively inexpensive (5)	Development of biocide resistance (39–42) Coagulation and fixation of proteins (5)
ortho-Phthalaldehyde	High biocidal activity (inclusive of mycobacteria) (5, 44) Does not damage endoscopes and processing equipment	Slow action against bacterial spores (5) Staining of the skin, clothing, instruments (46) Irritation of the respiratory tract and eyes; development of "anaphylaxis-like" reactions after repeated use (5, 36, 45) Expensive
Peracetic acid	Excellent and fast biocidal activity at low concentrations (5, 7) Can be used at low temperatures (5, 7) No development of resistance reported	Irritant to the respiratory tract and eyes (5, 7, 36) Corrosive action depending on the pH value and concn (7) Limited efficacy in biofilm removal and in killing bacteria within the biofilm (47–49)
Electrolyzed acid and superoxidized water	Excellent and fast biocidal activity (15) Nontoxic to biological tissues; nonirritant to the respiratory tract, eyes, and skin (15) Relatively inexpensive	Reduced efficacy in the presence of organic soil after inappropriate cleaning (50)

Kovaleva et al. *Clin Microbiol Rev* 2013; 26: 231

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Drying and storage

- **Drying is a critical step (humidity → bacterial growth +++)**
  - Within AER or with medical dry air/alcohol (level IA)
  - In a vertical position (level II)
- **Storage**
  - To prevent recontamination
  - Preferably in a drying (or storage) cabinet
- **Endoscope shelf life or hang time: unresolved issue**
  - Open air: 4 hours
  - Drying cabinet: 1 month (Z&G) vs 10-14 days vs 5-7 days (duodenoscope, immunosuppressed patients) (ASGE)

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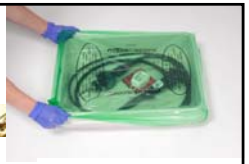

Transport

- **In containers (unless reprocessing area is adjacent to endoscopy area)**
- **Indication of clean vs contaminated**
- **Disinfection of container after each use**

- **Handhygiene prior to manipulation of disinfected endoscope**
- **New: touch-free endoscope handling trays**

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Accessories

- **Brushes: single use, if reusable ultrasonic cleaning + HLD**
- **Valves and caps: (ultrasonic) cleaning + HLD**
- **Biopsy forceps, sphincterotomes, … are critical devices: sterilisation**
- **Water bottles, flushing catheters, waste vacuum canister**
  - Single use or daily sterilized
  - Filled with sterile water
  - Replacement frequency: per procedure or per day?

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Training and protection of staff

- **Training**
  - On a regular basis (e.g. annual)
  - Content: techniques, standard precautions (incl. PPE)
  - Regular evaluation of competencies!
- **Protection**
  - HBV vaccination
  - **Personal protective equipment** (masks, safety glasses or splash shields, gloves, plastic aprons) should be **available** and **compliance** of wearing should be checked!

 30

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Traceability and log books

- **At level of**
  - Patient, procedure
  - Endoscopes (e.g. reparations)
  - AER (e.g. validation, maintenance) and disinfectant
  - Reprocessing process, incl. manual steps
  - Disinfection of transport containers, drying cabinet, …
- **In case of an outbreak (e.g. Cidex incident)**
- **Priority?**
  - At least as important: good procedures and processes, staff training and evaluation, audits…
  - Omentum: platinum norm, level II evidence in ASGE

 31

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Role of microbiological surveillance testing

- **Rapid and simple method to monitor effectiveness**
- **Limitations:**
  - Surveillance cultures: 24-48h
  - Efficient sampling hindered by complex endoscope design
  - No standardized sampling protocol for surfaces and channels

- **Frequency of sampling?**
  - On a routine basis vs to validate a new method or to investigate an outbreak?
  - Duodenoscopes 1x/month ➔ all endoscopes 1x/year

 32

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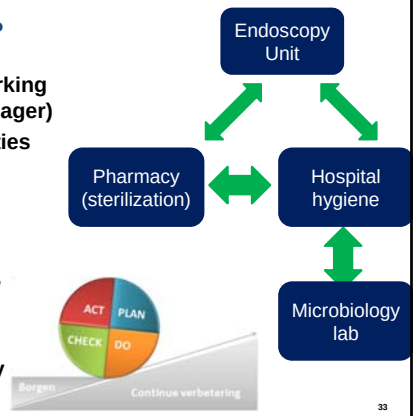
How to implement?

- **Multidiscplinary working group (incl. QC manager)**
- **Define responsabilities**
  - Procedures
  - Training
  - Validation
  - Microbiological samples, outbreaks,
- **Risk assessment**
- **Regular audits**
- **Balance cost-quality**



 33

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Conclusion

- **Inadequate reprocessing of GI endoscopes poses a real risk**
  - Duodenoscopes (ERCP)
  - Multiresistant bacteria (CPE!)
- **The multitude of standards and guidelines is not facilitating implementation**
- **Accreditation should be an opportunity to improve patient safety and quality of care**
- **Endoscopy staff, pharmacy and infection control team should join their forces!**

 34