Pan American Health Organization

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Webinar Recommendations

- Please turn off your microphones
- There will be a one hour presentation and one hour of questions and answers
- Questions should be sent in writing, through the chat or by email to: Infectioncontrol@paho.org
- The presentation will be available on PAHO website in 48 hours

Acknowledgement

The webinar is made possible by the auspices and cooperation of the Infection Control Center(CDC), according to the cooperation agreement CDC-RFA-CK13-1302. “BUILDING CAPACITY AND NETWORKS TO ADDRESS EMERGING INFECTIOUS DISEASES IN THE AMERICAS”

High level disinfection: challenges in procedures

Silvia Guerra
Epidemiologist
Specialist in Hospital Infection Control

TOPICS

- Definitions
- Disinfection methods
- Disinfectants and its characteristics
- Disinfection process
- Problems of high level disinfection (HLD) in endoscopy
- Common errors in HLD
- Conclusions

Sterilization

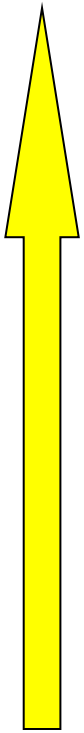
•Destruction or elimination of any type of living organisms from materials under process, including spores.

High Level Disinfection

Disinfection process that destroys all organisms from inanimated objects, except bacterial spores, by a complete immersion of an article in a germicidal compound for a definite period of time.

Levels of resistance

Greater resistance



Less resistance

PRIONS (proteins)

SPORES
(Bacillus subtilis, Clostridium sporogenes)
MYCOBACTERIAS
(Mycobacterium tuberculosis var bovis)
LIPOPHYLIC OR SMALL VIRUS
(Polio virus, Coxsackie virus, Rhinovirus)
FUNGI
(Trichophyton spp, Crytococcus spp, Cándida spp)
BACTERIAS
(P. aeruginosa, S. aureus, Salmonella)
LIPOPHYLIC OR HALF SIZED VIRUSES
(Herpes simplex virus, Cytomegalovirus, Respiratory syncytial virus, HBV, HIV)

Spaulding classification

Sterilization

Critical items

Surgical equipment, central line catheters, urinary catheters, intravenous fluids among others.

High level disinfection or sterilization

Anaesthetics machine circuits and endoscopes

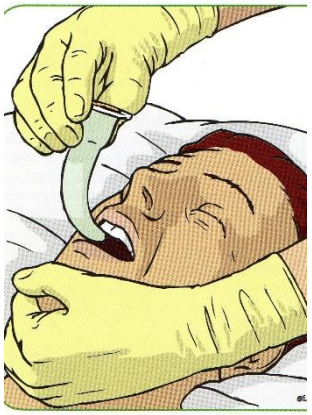
Low level disinfection

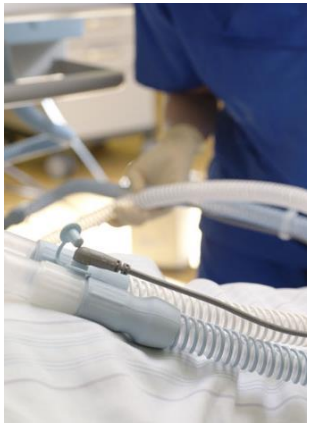
Non-critical

Bed spreads, blood pressure devices, incubators and tableware

Difficulties with Spaulding classification

- Oropharyngeal cannulas, thermometers, tableware, mechanical ventilators' corrugated tubing, and endoscopes are all classified as "semi-critical" and….**they don't have the same risk**





Over- simplification of Spaulding Classification

It does not consider different risks for items in the same category.

Decision in reprocessing should depend in the nature of the item in itself and the type of procedure in which is going to be used.

Spaulding classification needs some changes…

When Spaulding designed his scheme 50 years ago, semi-critical items where rarely introduced in sterile tissues and lacked of an adequate risk assessment associated with reprocessing of endoscopes, mainly those to be reused for surgical purposes (ECRP).

It should be changed into « item with direct contact or secondary/indirect with sterile tissues»

Disinfectants assessment

- Consider:
  - Type of materials (Spaulding classification)
  - Microbiological challenge (design and other problems)
  - Possible damage to equipment (compatibility)
  - Occupational risks in healthcare workers

Methods of disinfection

Thermal disinfection

Pasteurization

- Originally implemented by Louis Pasteur.
- HLD uses this process. Water is heated up to 77°C and kept in that temperature for approximately 30 minutes.
- Destroys all organisms, except bacterial spores.

Chemical disinfection

- Items or surfaces are kept in contact with chemical agents classified as high level disinfectants.

Disinfectants: Ideal characteristics

- Wide spectrum
- Stable in organic residues
- Compatible with equipment materials
- Measurable activity and concentrations
- Fast action
- Prolonged half-life
- Odorless
- Degradable in environment
- Low toxicity
- Cost-efective

High level disinfectants approved by FDA

Germicides	Concentration
Glutaraldehyde	≥ 2%
Orto-phtalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and y Peracetic acid*	1.0%/0.08%
Hydrogen peroxide and y Peracetic acid*	7.5%/0.23%

*Risk of cosmetic and functional damage

- http://www.fda.gov/cdrh/ode/germlab.html
- ANSI-AMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities

HIGH LEVEL DISINFECTANTS

FDA approves a product defining:

1. Active ingredient concentration
2. Contact time
3. Temperature
4. Maximum number of reuses

Regulations for High level disinfection

FDA	European community
Efficacy test simulating worst conditions, without washing Times are longer than for EC Information of compatibility with equipment and job security is required	Efficacy tests simulating clean equipment Times are shorter than for FDA Compatibility studies under discussion.

Factors affecting high level disinfection process

- Pre-cleaning of equipment
- Type and level of microbial contamination.
- Concentration and exposure time to disinfectant
- Physical characteristics of equiopment under disinfection
- Process pH and temperature.

Peracetic acid + Hydrogen peroxide

- Stabilized solutions of hydrogen peroxide, acetic acid and peracetic acid
- HLD 25 min, reuse: 14 days
- They have a strong odor
- Buffers, anticorrosives and surfactants can be included
- Limited experience with endoscopes
- Fumes can irritate nose, throat and lungs
- Contact with solution can cause skin burns and eye damage

Peracetic acid

- ✓Formula for automatic processes at 35% which is diluted with a buffer, surfactants and anticorrosives. It is used at 0.2%
- ✓Time needed for mechanical sterilization: 12 min. a 50-56º C. Total cycle: 30 minutes.
- ✓During the cycle time, temperature and concentration are under automatic control.
- ✓Rinse with sterile water, through 0.2 micron filters
- ✓Uses chemical and biological indicators
- ✓Suitable for endoscopes and submersible laparoscopes

Peracetic acid

For MANUAL processing:

- ✓HLV: 30 min.
- ✓Can corrode surfaces with copper, bronze, steel, and galvanized metals
- ✓Highly irritant
- ✓Its action can be reduced by additives and pH changes
- ✓To be discarded after its use → expensive

Peracetic acid + Hydrogen peroxide

- Available in ready-to-use dilutions: 1% hydrogen peroxide and 0,08% peracetic acid.
- At 20º C, esterilizes in 8 hours and HLD in 25 min.
- Reusable for 14 days.
- Non-irritant and free of skin damage.

HYDROGEN PEROXIDE

- ✓7,5% hydrogen peroxide, 0.85% phosphoric acid andy 91,65% inert ingredients.
- ✓Reuse: 21 días, does not require activation.
- ✓ Minimum effective concentration for hydrogen peroxide is 6,0%.
- ✓HLD in 30’ at 20º C and sterilizes at 20º C in 6 hours.
- ✓Can be used in automatic and manual processing.
- ✓Can cause discoloration of equipment.
- ✓Suitable for disinfecting contact lenses and respirators.

2% GLUTARALDEHYDE

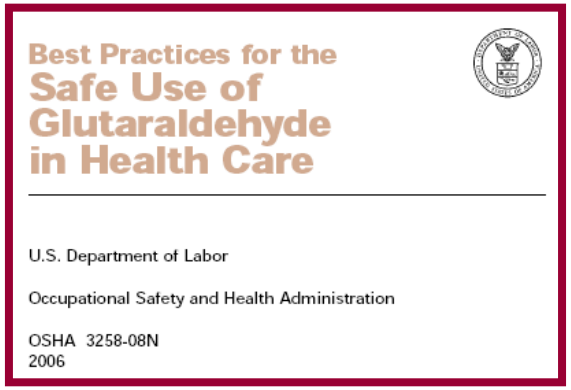
- ✓Wide compatibility.
- ✓ Duration: 14 days without surfactants, and 28-30 days with surfactants
- ✓Formulas with surfactants are not compatible with automated endoscopes reprocessors (AER) due to foam production.
- ✓ Heat cycles in AER must guarantee reaching adequate temperature in reprocessing chamber.

Glutaraldehyde, concentrations and conditions for HLD, according to FDA

Glutaraldehyde	Contact conditions
1,12% glutaraldehyde, 1.93% phenol-phenate	25° C , 20 min
2,4 a 2,6% glutaraldehyde without surfactants	20-25° C , 45 min
2,4 a 2,5% glutaraldehyde with surfactants	20-25° C , 45-90 min
2,5% glutaraldehyde without surfactants	35° C , 5 min (only in AER, keeping temperature)
3-4% glutaraldehyde without surfactants	20-25°C , 20-90 min
3,4% glutaraldehyde, 20,1% isopropanol	20°C , 10 min

http://www.fda.gov.uy/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm

Occupational risks using glutaraldehyde



Throat and lungs irritation
Asthma like symptoms
Breathing difficulties
Nose irritation,
Sneezes
Nose bleeding
Eye irritation and conjunctivitis
Skin rash
Alergic or contact dermititis
(chemical dermatitis)
Spotting of hands
Urticaria
Headaches
Nausea

¿CÓMO ACTUAR EN CASO DE **CONTACTO** O **DERRAME** DE **SUSTANCIAS QUÍMICAS?**

Productos peligrosos en contacto con la piel o los ojos.

¿QUIÉNES DEBEN CONOCER ESTA INFORMACIÓN?

» El **personal médico** del sector debe familiarizarse con el uso y composición del principio activo de estos productos y saber asistir las intoxicaciones.
» El **personal de Enfermería** y las **Instrumentadoras quirúrgicas** deben conocer el uso adecuado de cada producto químico y asistir en intoxicaciones.
» El **personal de Hotelería y Mantenimiento** debe capacitarse en el uso de estos productos y de los primeros auxilios en caso de intoxicación.

PRODUCTOS QUÍMICOS QUE SE ENCU

Es importante saber qué sustandas se **contacto o derrame.** Todos los product

PRODUCTO	PRINCIP
Enfermería	
Agua Oxigenada	Peróxid
Alcohol 70%	Alcohol
Hotelería	
Gif crema limón puro	Carbona sulfonat
Detergente Alcalino	Hidróxid Pirofosfa
Lavandina Pura	Hipoclor
Lavandina Dilución 1:10	
Limpiador Neutro R9 Puro	Sulfonat
Limpiador Neutro R9 Dilución 1:50	
Virex 256 II Puro	Cloruro amonio
Virex 256 II Dilución 1:256	
Alpha HP Puro Es incoloro, no confundir con agua	Peróxid
Alpha HP Dilución 1:64 o 1:128 Es incoloro, no confundir con agua	
Limpia metales Puro	Solvente
Limpia vidrios Puro	Dilayent
Limpia vidrios Dilución 1:40	
Quitasarro Puro	Ácido n
Los Soles	
Onda Puro	Alquil-d
Onda Diluido	Butoxi E
S.G. Argentina	
Crew Puro	Cloruro
Crew Diluido	Isoprop
Mantenimiento	
Glicol	Etilengl
Otros (Completar en el caso de que se utilice	

» Evitar mezclar sustancias químicas e caliente! porque pierden efectividad y o

Más información

Depto. de Seguridad, Higiene y Protecci
Int. 4482, 8739
www.hospitalitaliano.org.ar/intranet/

¿CÓMO ACTUAR EN CASO DE **CONTACTO** O **DERRAME** DE **SUSTANCIAS QUÍMICAS?**

Productos peligrosos en contacto con la piel o los ojos.

PRIMEROS AUXILIOS EN CASO DE CONTACTO

Para **todos** los productos de la lista se debe actuar de la misma manera en caso de:

» Salpicadura en los ojos y mucosas:
- Enjuagar con agua la zona afectada durante 15 minutos con el **lavaojos ubicado en el Kit combinado de derrame de líquidos** del sector.
NOTA: Si utiliza y es posible, quitarse los lentes de contacto
- Luego **buscar atención médica inmediata.**

» Contacto con la piel:
- **Lavar con abundante agua** la zona contaminada durante varios minutos.
- Si la irritación persiste solicite atención médica inmediata.
- Quitarse la ropa en el caso de que se haya salpicado la misma.

» Ingesta:
- En ningún caso se debe indudr el vómito.
- Beber uno o dos vasos de agua.
- Acudir de inmediato al médico.

» Inhalación:
- Retirarse del lugar de inmediato.
- Si las molestias continúan procure atención médica inmediata.

¿QUÉ HACER FRENTE A DERRAMES?

» Si la sustancia está **pura**:

- NO LIMPIARLO, NO TIRARLE AGUA. **Evacuar el área afectada**, cerrar la puerta de ser posible y **dar aviso al 8700.**

- Si el accidente ocurre en áreas abiertas o pasillos se debe **llamar de inmediato al 8700 y arrojar polvo absorbente hasta que lleguen al lugar.**
NOTA: El polvo se encontrará en el kit de derrames.

» Si la sustancia está **diluida** :
- Limpiar el derrame con un paño descartable.

PASOS PARA EL MANTENIMIENTO DEL LAVAOJOS PORTÁTIL

La estación de lavaojos portátil está conformada por **botellones con solución salina 0.9% con conservantes**, que debe permanecer libre de contaminación y **descartarse a los noventa días (90)** luego del llenado:

1. Sobre una superficie limpia, **separar la copa del botellón y vaciarlo.**
2. **Lavar el botellón y la copa con abundante agua destilada estéril.**
3. **Desinfectar utilizando alcohol 70%.** Para la copa, utilizar una gasa. Para las paredes interiores, colocar aproximadamente 100 cc y circular el alcohol por la zona.
4. Dejar **secar.**
5. **Higienizarse las manos.**
6. **Destapar el frasco con solución salina 0.9% con conservantes nueva y traspasarla** sin apoyar el borde sobre el botellón.
NOTA: La solución para el llenado debe solicitarse a Centro de Distribución con el código D30726.
7. **Colocar la copa y cerrar el botellón.**
8. Inscribir **fecha de carga y fecha de descarte** (Seguridad e Higiene controla la fecha y da aviso a personal de Enfermería del sector).

MÁS INFORMACIÓN SOBRE CADA SUSTANCIA:

- **Carpeta amarilla de Seguridad e Higiene** con las fichas se seguridad de los productos, en el office de Enfermería de cada sector.

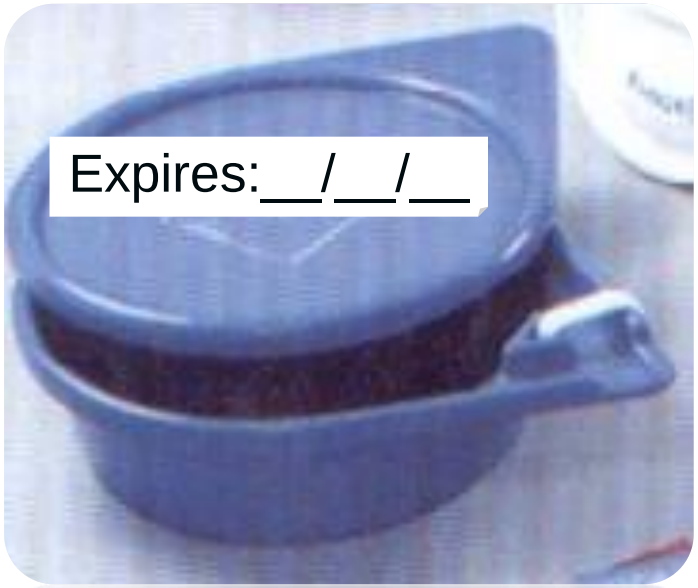
- **Hojas de seguridad de los productos,** en INTRANET *(Menú izquierdo / Seguridad e Higiene).*
Centro de Emergencias Toxicológicas **0800-444-4400**

0.55% Ortophtalaldehyde

- ✓Excelent microbicidal activity.
- ✓Great stability in pH ranges of 3 – 9
- ✓Dose not require activation, stable for 14 days.
- ✓Does not bind to blood or proteins.
- ✓High compatibility with equipments.
- ✓No nose or eye irritation.

HIGH LEVEL DISINFECTION PROCESS

HLD in manual processing



1. Instrument and equipment should be free of any organic residues.
2. Was rinsed and dried thoroughly.
3. HLD must be approved by IPC Committee.
4. Solution must be in its valid period.

High level disinfection controls

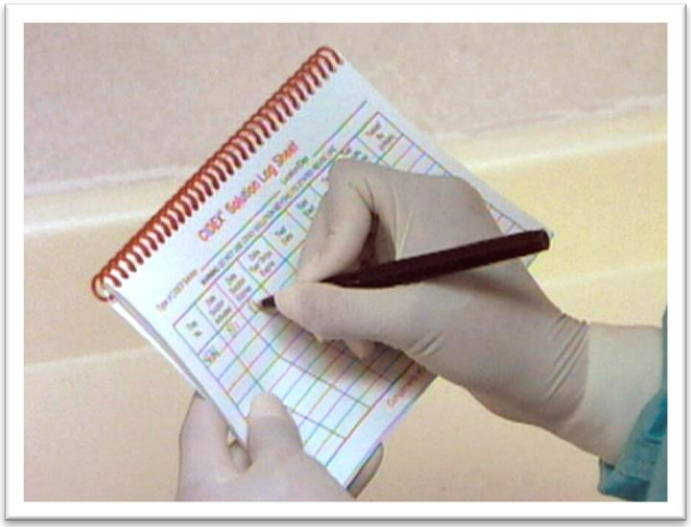
- Reactive strips or electronic meters needed to check **minimum effective concentration** (MEC) of its active principle, needed to eliminate *Mycobacterium tuberculosis.*

- Checking must be done on a daily basis or according to disinfectant use

MEC

OPA >= 0,30%
Glutaraldehyde>= 1,5%
Hydrogen peroxide: 6,0%

MEC controls registration



Each test result must be registered.

HLD manual processing

5. Solutions must be handled with an adequate protection.

6. Inmersion time and temperature for HLD must agree manufacturer's recommendation, according approval for each product by regulatory agencies.

HLD manual processing

7.

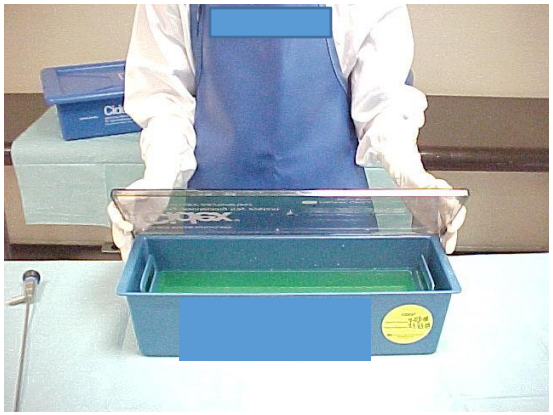
Immerse COMPLETELY all materials to be disinfected, check entrance of disinfectant through lumens. Size of container and volume of disinfectant must guarantee complete immersion.

HLD manual processing

8. Containers must be kept covered to avoid evaporation of toxic fumes into the environment.
9. Once immersion time required is accomplished, withdraw equipment with aseptic technique and rinse with sterile water. No agreement on ideal rinse. Rinsing is essential to reduce chemical residues to safe levels.

10. Dry with sterile cloth.

HLD manual processing



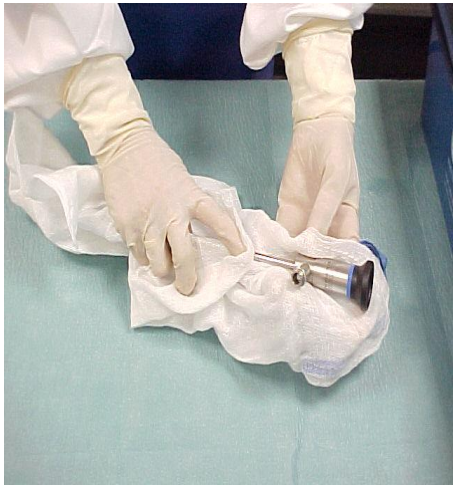
1. Uncover

2. Immerse and irrigate equipment

3. Time

4. Withdraw equipment

5. Rinse through immersion for 3 min. x 3 min, repeat with adequate water



6. Dry

High level disinfection in automated endoscope reprocessors

- Diminishes variability and errors in processing.
- Difficulties in its use are related to:
  - Contamination of AER/ Biofilm
  - Inadequate connections of channels

- Outbreaks associated with contamination of these equipments with Gram negative rods and non- tuberculous Mycobacteria have been reported, due to biofilm or resistance to disinfectant.

Infection risks using AER

- Defective and contaminated AER can result in an improper reprocessing and endoscopes contamination. It has been associated with infection outbreaks. (Gastroenterology 92 : 759-763, ICHE 22 : 414-418, JHI 46 : 23-30).

- Biofilms in AER have been detected in these outbreaks.

  (A.m. J. Med. 91 (3B : S272-S280), ICHE 22 : 414-418, J Hosp Infect 46 : 23-30)

10 frequent problems with high level disinfection

1 High level disinfection is done but not adequately managed in all facilities and areas within.

- No thorough list of all areas in which HLD is done in a hospital.

→ Who's responsible of the supervision?

- A list identifying all areas with HLD must be kept and known. Uniform protocols and supervision.

10 frequent problems with high level disinfection

2 Processes are not standardized in all the organization

Standardized policies and procedures for decontamination, transport, storage and HLD must be developed in all the organization.

Processing records and stardandized quality controls should be developed. Flexibility in record reports can be allowed as long as they provide necessary data (can improve accomplishment and sustainability)

10 frequent problems with high level disinfection

3 Clean and dirty are not separated.

- Separate clean and dirty areas.
- Signage for clean and dirty areas wil be helpful in keeping separation.
- Work flow should go from dirty to clean.
- Always make sure that no splashes from dirty area might contaminate clean area.
- If necessary clean or dirty areas should be kept in separte rooms to provide a safe division

10 frequent problems with high level disinfection

4

Teams do not follow manufacturers' use instructions (IFU) to decontaminate and process properly all instruments and equipments.

Soaking times and temperatures must be fulfilled with no variations.

Manufacturer's indications and specifications must be applied to guarantee that the process brings out a desired outcome.

Help the correct process be done easily.

5 Reporting of processes' quality control is not adequate.

Quality control tests should be done as the manufacturer indicates and its results should be kept in a quality control report.

Place instructions in a visible place in the working area.

Make sure that MEC strips corresponds to product been used, time of immersion and reading.

Makes sure that quality control forms include a place where to record solution temperature (if manufacturer mentions it) and reporting when a new solution is being prepared.

10 frequent problems with high level disinfection

6 Teams do not keep records of processing that are required

1. These records should include patient's identification, doctor, the procedure and all information needed to track instruments to a patient.
2. Initials of technician in charge of the procedure and recording of AER for every process done. Or detail report of the manual processing.

10 frequent problems with high level disinfection

6 Teams do not keep records of processing that are required

Omission of records of HLD in endoscope happens frequently

3) Keep records of disinfectants, validity, MEC, day/hour/procedure and patient for each endoscope
4) Keep records of preventive maintenance and repairing of endoscopes and reprocessing equipment (ie, leak testers, automated endoscope reprocessors, sterilizers).
5) Data should include investigation of critical events such as failures of AER.
6) Keep records according to local policies of storage of information in the facility. This should include data for AER and withdrawn endoscopes.

7 The processed equipment is stored improperly.

Equipments processed under HLD must be stored assuring it is saved in optimal conditions for its use in a next patient.

A clean cover, such as a plastic clean and transparent bag. For endoscopes, they must be stored hanging completely dry in all its length.

8 Facilities do not assess capabilities done by qualified personnel.

«Personnel with training, experience or knowledge related with skills that are assessed evaluates capabilities»

«Train the trainer» and teach a small group of people on how to assess capabilities to perform HLD.

10 frequent problems with high level disinfection

9 **Supervisor are not trained in HLD and sterilization processes.**

10 **There is no supervision process to guarantee a constant compliance.**

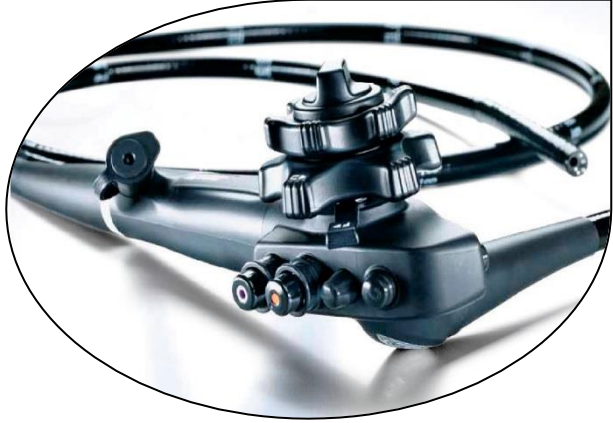
An important critical element is to specially assign a person, committee or responsible team in charge of monitoring and assessing, and to guarantee that improvement measures are applied when necessary. Each organization must define how to settle responsabilities in supervision.

HLD in endoscopy wards.

- Consider potential hazards associated with medical devices.
- Endoscopes are always in the list.

AAMI Highlights problems dealing with maintenance and reprocessing of endoscopes.

Important aspects



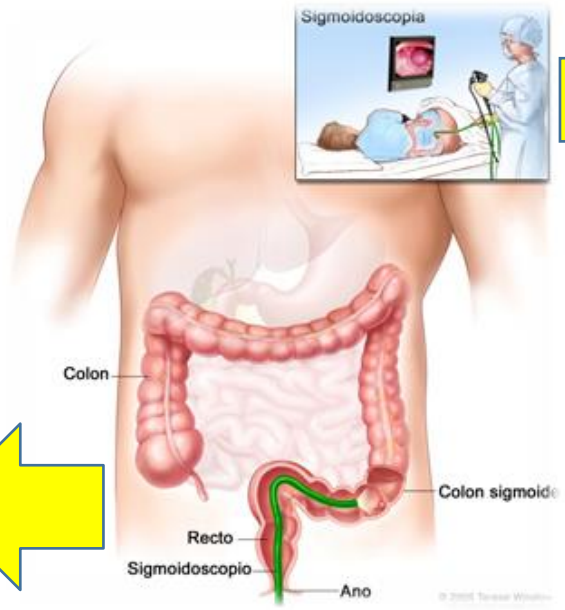
Contaminated endoscopes are the medical devices most frequently related to outbreaks in hospitals

Duodenoscopes have been ften related with trasmission of carbapenemase-producing Enterbacteriaceae

Damage
Costs
Discredit

Infections due to flexible endoscopes

EXOGENOUS INFECTIONS



ENDOGENOUS INFECTIONS

Albornoz H & Guerra, S. Manual Prevención de infecciones en procedimientos endoscópicos. COCEMI. 2008

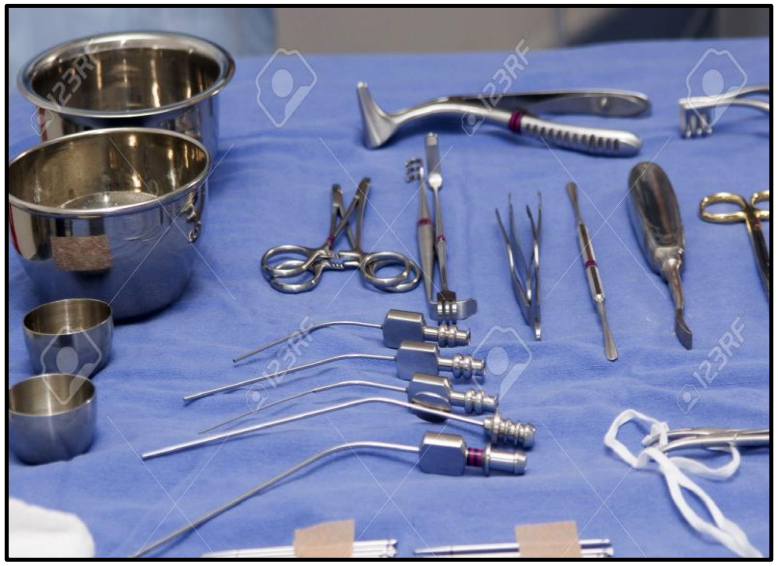
Challenges

Bacterial load:

10^{7-10} CFU/gastrointestinal endoscope. Complexity: elevator channel

Surgical instruments

$<10^{3}$ bacterias



Bacterial load in soiled endoscopes

Author	Type of endoscope	Initial contamination (log 10 CFU/mL)	Decreasing log 10 After cleaning	Average decreasing log
Hanson 1989-1991	Gastro	4.9 b 6.5 b	0-2.2	4.7-4.9
Chu 1998	Gastro	5.71d 9.85 c	4.34 5.11	4.7
Vesley 1999	Gastro Colon	6.7 g 8.5 c	2.0 2.3	4.7 6.2
Alfa 1999	Duodenum Colon	6.84 8.46	4.79 4.27	2.1 4.2
Kovacs 1999	Gastro	7.95 b	3.89	4.1

a- 0 value for bacterias, that represent absolute after cleaning
b- experimentally contaminated endoscopes
c- bioburden in suction channels
d- bioburden on surface of device

Rutala,W.,&Weber,D.J. (2004) Reprocessing endoscopes:United Sates perspective.

Reasons for HAIs outbreaks in endoscopy: no security margins!

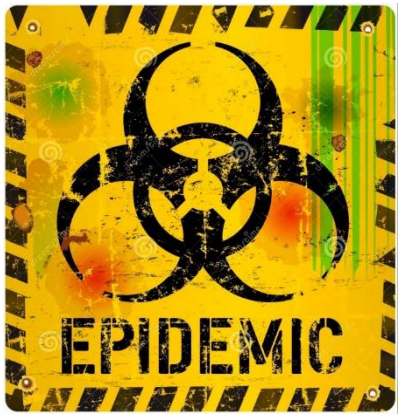
Security margins in reprocessing of endoscopes **is minimum or does not exist** for 3 reasons

- **Bacterial load**
  - GI endoscope contains $10^{7\text{-}10}$ enteral microorganisms
  - Results after cleaning: decreases 2-6 $\log_{10}$
  - HLD decreases 4-6 $\log_{10}$
  - Total results: decrease of 6-12 $\log_{10}$
  - Low security margins (compared to 17 $\log_{10}$ with cleaning and sterilization of surgical instruments)
- **Endoscope complexity**
  - Length, lumens, difficulties in cleaning (hannels, elevator channel)
- **Biofilm**

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

Reprocessing by HLD of duodenoscopes for ERCP

"If safety margin is so small that perfection is required in reprocessing, then the process is extremely relentless to be practical in a hospital"



Carbapenemase producing Enterobacteriaceae and endoscopy

SURVEILLANCE AND OUTBREAK REPORTS

Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009

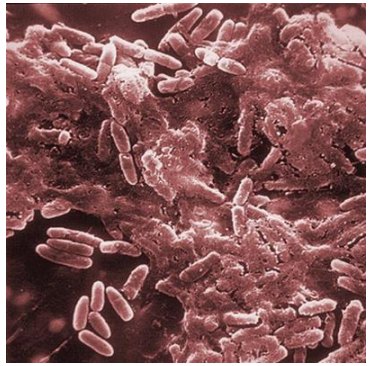
A Carbonne (anne.carbonne@sap.aphp.fr)[1], J M Thiolet[2], S Fournier[3], N Fortineau[4], N Kassis-Chikhani[5], I Boytchev[4], M Aggoune[1], J C Séguier[6], H Sénéchal[7], M P Tavolacci[8], B Coignard[2], P Astagneau[1,9], V Jarlier[3,9,10]

- September 2009 in two hospitals in Paris, France..
- Outbreak of 13 patients with KPC (4 infected and 9 colonized)
- Primary case was a patient from a Greek hospital.
- Of the 13 cases, 7 were secondary cases and associated with a contaminated dudodenoscope used in primary case (attack rate: 41%) and 5 were secondary cases with a patient transferred to another hospital.

SURVEILLANCE AND OUTBREAK REPORTS

Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009

A Carbonne (anne.carbonne@sap.aphp.fr)[1], J M Thiolet[2], S Fournier[3], N Fortineau[4], N Kassis-Chikhani[5], I Boytchev[4], M Aggoune[1], J C Séguier[6], H Sénéchal[7], M P Tavolacci[8], B Coignard[2], P Astagneau[1,9], V Jarlier[3,9,10]



- *K. pneumoniae* grew in cultures from endoscopes
- Attack rate for KPC 41%
- Cleaning and disinfection was done properly (with peracetic acid)
- **Drying process was inadequate**
- *K.pneumoniae* survived sevreal cleaning and disinfection processes

United States Senate
HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE
Patty Murray, Ranking Member

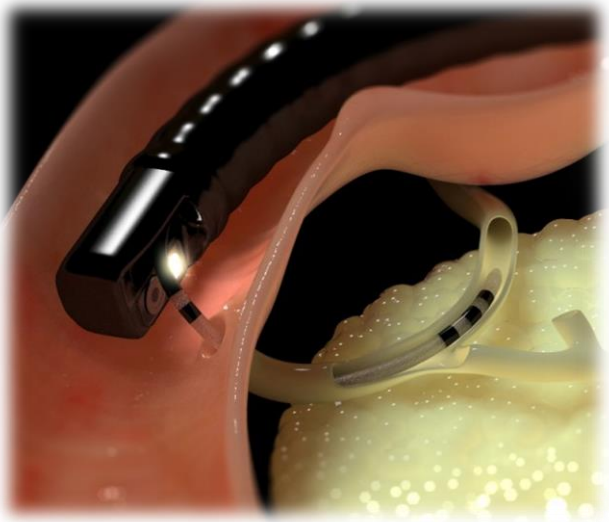
Preventable Tragedies:
Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients

What happened with infections by carbapenemase producing Enterobacteriaceae in endoscopies, in USA?

- September/2013, Hospital and Medical Center Virginia Mason in Seattle, Washington, a group of infected patients were tracked in which a duodenoscope was used to treat pancreas and biliary duct disease.
- Around the same time, personnel from General Advocate Lutheran Hospital, with support from CDC, linked in a similar way an outbreak by superbacterias with duodenoscope used in ERCP.
- **Both hospitals concluded that duodenoscopes for ERCP remained contaminated, even after a thorough cleaning, dissseminating bacterias among patients.**

The growing problema of carbapenemase producing Enterobacteriaceae

- Outbreaks were related to duodenoscopes used in ERCP
- Some **procedures** done in ERCP are: stones extraction from common bile duct, plastic or metalic tubing placement (prosthesis or stents) in common bile duct or páncreas in treating strictures, fistulas or other problems affecting these ducts



Centers for Disease Control and Prevention
MMWR
Weekly / Vol. 62 / Nos. 51 & 52

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

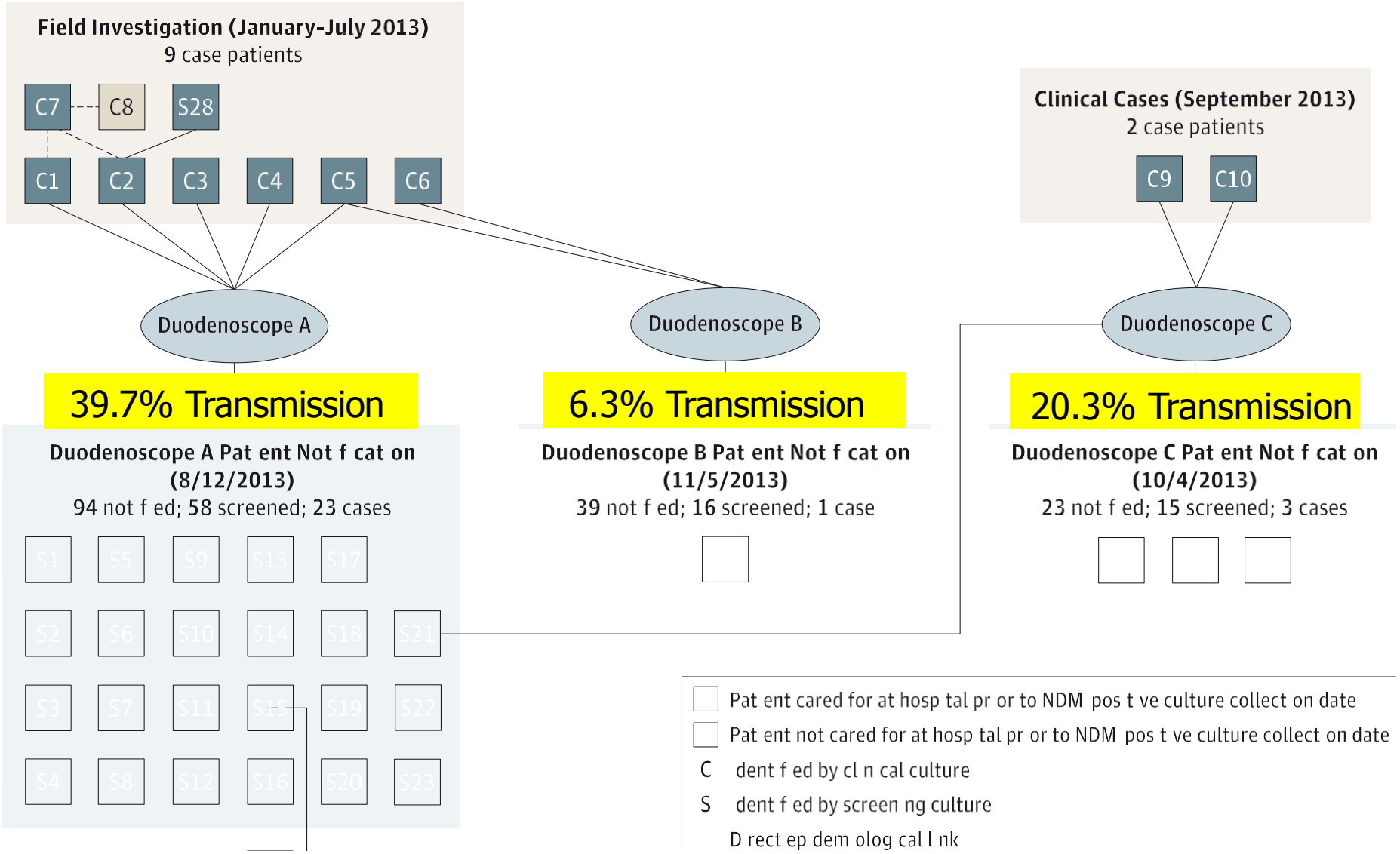
January 3, 2014

- Carbapenemase producing *E. coli*- NDM-1 outbreaks from contaminated duodenoscopes
- University hospital with 650 beds in Chicago, USA
- After manual cleaning and high level disinfection in a automated endoscope reprocessor, positive cultures were obtained from ERCP duodenoscope used in 5 patients.

Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep 2014; 62: 1051 [PMID: 24381080]

Original Investigation

New Delhi Metallo-β-Lactamase–Producing Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopes



Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopes. *JAMA*.2014;312(14):1447–1455. doi:10.1001/jama.2014.12720

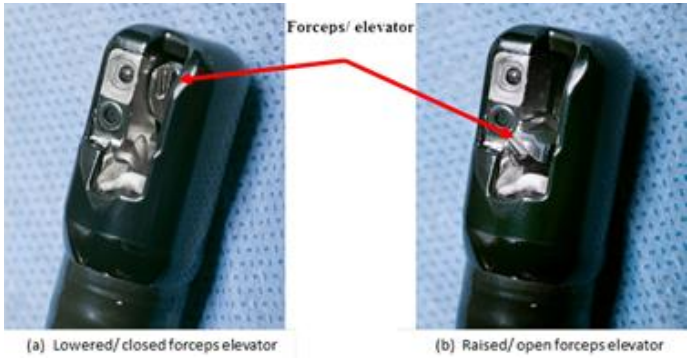
How these outbreaks were known?

Due to the type of microorganisms involved (carbapenemase producing Enterobacteriaceae) this transmission of infections and colonizations arouse an alert.

Retrospective review and direct observation of endoscopes reprocessing did not indentify failures in reprocessing protocol.

What was happening with the duodenoscopes?

Forceps elevator



- Forceps elevator is particularly difficult to clean and requires additional cleaning steps to wht was described up to that moment. **Endoscopes design** were a challenge for cleaning and disinfection.

RESPONSIBILITIES OF EQUIPMENT MANUFACTURERS

RESPONSIBILITIES OF HOSPITALS THAT DON'T REPORT TO THE MINISTRY OF HEALTH

1. Kirschke DL, Jones TF, Craig AS, et al. *Pseudomonas aeruginosa* and *Serratia marcescens* contamination associated with a manufacturing defect in brochoscopes. N Eng J Med 2003;348:214-20.
2. Srinivasan A, Wolfenden LL, Song X, et al. An outbreak of *Pseudomonas aeruginosa* infections associated with flexible bronchoscopes. N Eng J Med 2003;348:221-7.

Improved design of duodenoscopes (FDA approval 20/9/2017)

"Improve security in endoscopes is a priority for FDA, and we encourage manufacturers to pursue innovations that help in reducing risk in patients"

Would duodenoscopes sterilization with ETO be the solution?

1. Published report: In 1/84 duodenoscopes carbapen[illegible]se producing Enterobacteriacea was found af[illegible]of HLD and ETO (Naryzhny I et al Gastrointesti[illegible]259 – 62)

2. If [illegible] of salts ETO fails.. (Alfa et al ICHE 199[illegible]

In spite of these limitations , experts agree that currently the best option is sterilizing these devices!

3. Long aireating periods(18-24 h): increases delay in rotation for its use. Is it feasible in Latinamerica?

Even though sterilization is the option: perform a proper flushing and cleaning of endoscope channels!

Exposure method	Contamination with EPC before HLD with glutaraldehyde	Contamination with EPC after HLD
DAN passive (no perfusion)	$3{,}2 \times 10^8$ $1{,}9 \times 10^9$ $4{,}1 \times 10^8$	$3{,}1 \times 10^8$ $4{,}6 \times 10^8$ $1{,}0 \times 10^8$
DAN active (perfusion in channels with syringe)	3.0×10^8 $9{,}2 \times 10^8$ $8{,}4 \times 10^8$	0 0 0

- Pathogens must be exposed to HLD for inactivation.
- Immersion of endoscopes in HLD or sterilization does not guarantee inactivation of pathogens from channels!
- Only a thorough cleaning (brushing) and immersion of endoscope in HLD and perfusion with siringe in channels eliminates contamination.

Rutala W et al. ICHE. 2016;37:228-231

If we have historical trends of non-compliance , we must teach and get resources to comply with:

1. Don clean gloves to handle reprocessed endoscopes
2. Visual inspection to identify damages in pre cleaning
3. Brush channels several times
4. Do tests to verify cleanliness
5. Clean and disinfect conainers used for transport after its use
6. Use manifying glass and light source for visual inspection
7. Test minimum effective concentration of disinfectant after each use
8. Unload AER promptly aftyer cycle has ended
9. Dry endoscope completely before storage
10. Transport for storage must be done in a clean container
11. For storage use cabinets with filtered air and positive pressure
12. Use biological risk tags in soiled containers
13. Place a tag with information of reprocessing

What conditions are necessary from health personnel for endoscopes reprocessing?

- It is not a task for newly hired personnel. Must be performed by a trained, skilled and certified technician.

- Training must be repeated at least anually and whenever new equipments are included.
- Personnel must show skills (be evaluated)

Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing

Outbreaks of bacterial infection associated with endoscopes are often attributed to improperly reprocessed endoscopes. However, recent reports have identified carbapenem-resistant Enterobacteriaceae (CRE) transmission associated with persistently contaminated duodenoscopes for which no breaches in reprocessing were identified (1).

There is currently very limited information to guide the use of surveillance cultures to assess endoscope reprocessing outside of recognized outbreak settings. Surveillance cultures are not a replacement for appropriate trainin
facilities considerin
staff, infection prev
implementation, ar
The followin

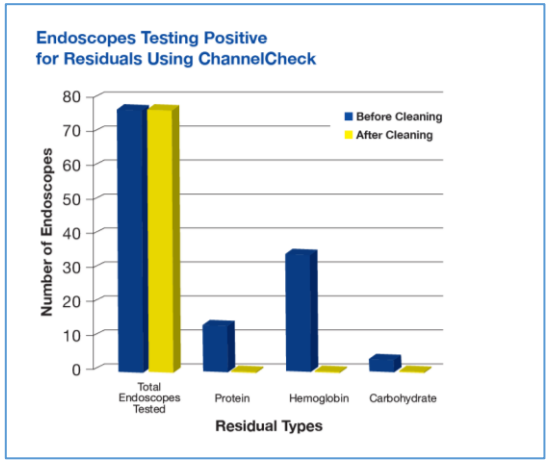
- There are limited reports on surveillance cultures besides outbreaks.
- Surveillance culture DO NOT replace proper training in reprocessing practices.

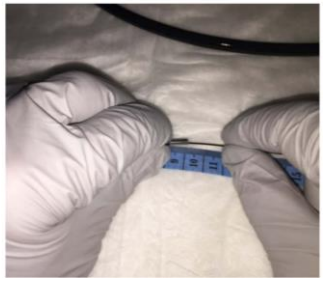
CDC recommendations for culturing duodenoscopes

- During an epidemic outbreak, CDC endorses surveillance culturing to identify contaminated endoscopes and to avoid permanent contamination
- Protocol suggests notifying manufacturers of possible defective devices when bacterias are persistently isolated in cultures.
- Notify patients of posible risks of patient to patient bacterial transmission, related with the procedure, and assess training of personnel in charge of cleaning and disinfecting.

Verify cleanliness before HLD

- Use fast cleaning tests before disinfection or sterilization [AORN, AAMI]
- Visual examination of endoscopeto see if it is soiled [SGNA]. Boroscopes can be used (3.2mm a 0.8mm). Must be done with clean endoscope with an established protocol of boroscope disinfection.





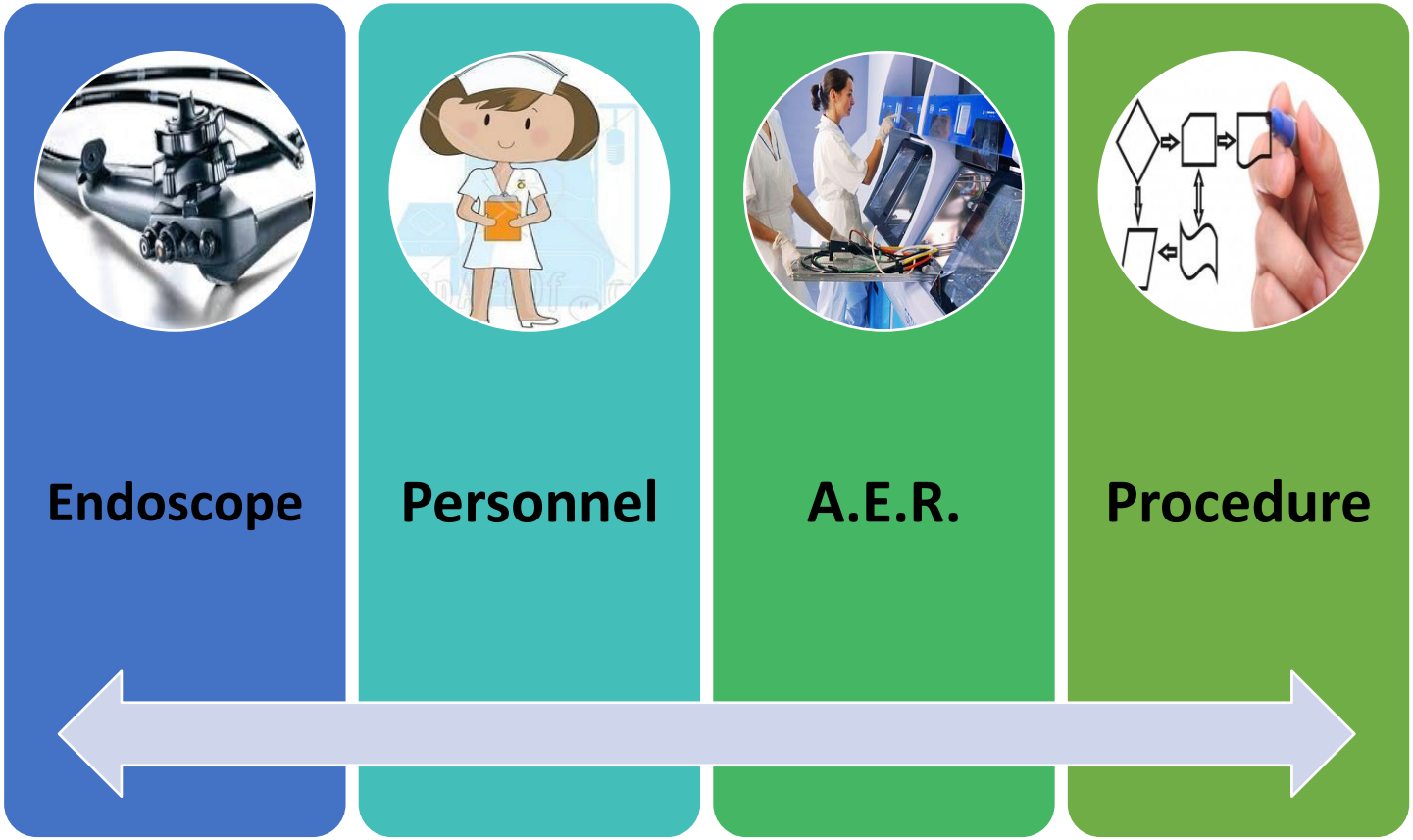
Factors affecting reprocessing

Although studies in outbreaks of EPC, show transmission of multidrug resistant organisms, even with properly done procedures, there are an important number of outbreaks and infections associated to failures in cleaning and disinfection processes

Let us see which are those…..

Reprocessing would be effective if done properly, but several factors alter its efficacy

(Edmiston & Spencer 2014; Dirlam Langlay, Ofstead, Mueller et al, 2014; Petersen et al, 2011; Rutala y Weber, 2015).

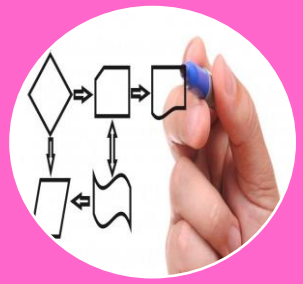


Endoscope

- Endoscopes carry complex designs, that makes thorough cleaning difficult in order to eliminate all organic residuals and microorganisms (Ej. canal de ascenso del duodenoscopio.) *(Edmiston & Spencer, 2014; Rutala y Weber, 2015);*
- A variety of endoscope models require different cleaning procedures, brushes, connectors, etc.
- Hidden damages (i.e., scratches, cracks) capture microorganisms and promote biofilm formation.
- Repeatedly used endoscopes drives to a gradual acummulation of residues, that may favor microbial survival after disinfection.

- ✓ Lack of knowledge of endoscope channels, accesories and specific steps to be followed *(Peterson et al, 2011);*
- ✓ Reduced staff to adequately support workload, work flows and performance; frequent interruptions during reprocessing *(AAMI, 2015);*
- ✓ Inadequate training; limited responsibilities; and pressures for a rapid reuse of endoscopes (high rotation)

Personnel



Process

I

Reprocessing includes certain characteristics that make their efficacy more difficult, including:

- Several steps that have to be followed meticulously;
- Stepds that are liable of human errors (i.e., previous cleaning, manual cleaning);
- Delayed reprocessing; insufficient enzimatic concentration, temperatura and time;

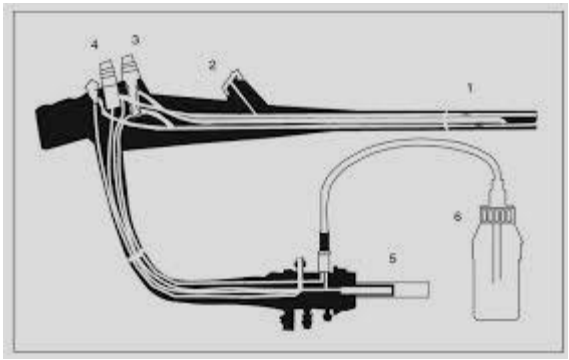
Process II

Reprocessing includes certain characteristics that make their efficacy more difficult, including (continued):

- Inappropiate HLD (i.e., wrong concentration or temperature, reuse life expired, shortened exposition time) (Dirlam Langlay, Ofstead, Mueller et al, 2014);
- Inadequate concentration since endoscope is not dried properly and water excess dilutes HLD;
- Inadequate cleaning before HLD;
- Inadequate drying before storage; and
- Absence of quality control measures to evidence problems or failures in reprocessing.

Frequent errors

- Not cleaning **channels,**
- No adequate evaluation of channels permeability or leaks
- Using insufficient fluid volumes through all channels.
- No proper care of brushes and accesories
- ¡¡¡NOT THOROUGHLY DRYINNG CHANNELS!!!



Guarantee staff skills (training)

Routinely Audit processes (CIH)

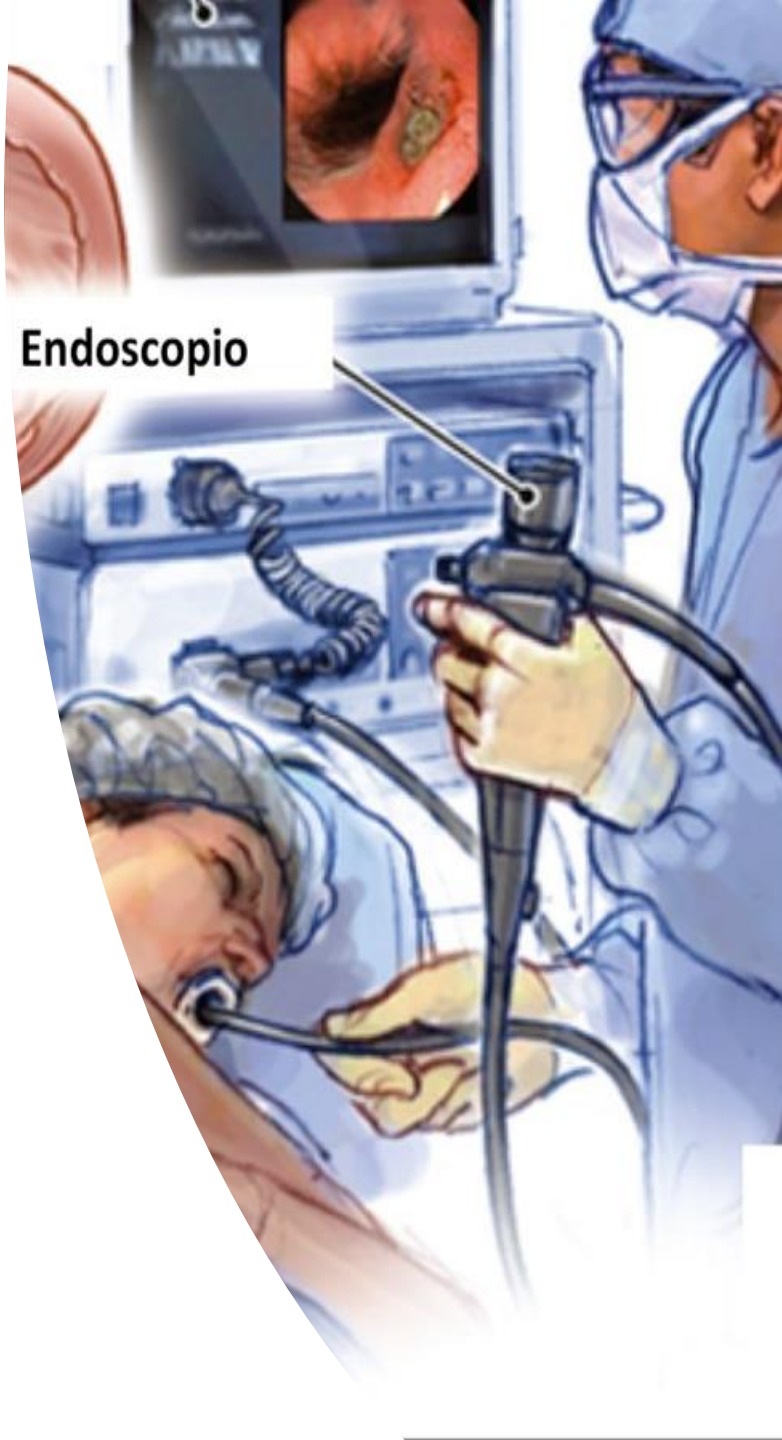
Problems can occur with automated endoscope reprocessors (AER), such as:

- Equipment malfunctioning (i.e washing pumps in AER);
- Using wrong connectors to help irrigate channels during pump washing or with AERs; and
- Not acknowledged problems in wáter supply (i.e. contamination)
- Biofilm

A.E.R.

Concluding:

- Train personnel
- Make sure each step is done correctly
- Perform cleaning tests
- Follow manufacturers' instructions
- Audit and supervise practices
- Define strategies to minimize risks



Special situations…

- Transmission of CJD and vCJD through endoscopes is currently a THEORETICAL RISK. No acses have been documented. (2,3).

1. ASGE Standards of Practice Committee, Banerjee S, Chen B, et al. ASGE STANDARDS OF PRACTICE COMMITTEE, Banerjee S, Shen B, Nelson DB, Lichtenstein DR, Baron TH, Anderson MA, Dominitz JA, Gan SI, Harrison ME, Ikenberry SO, Jagannath SB, Fanelli RD, Lee K, van Guilder T, Stewart LE. Infection control during GI endoscopy. Gastrointest Endosc. 2008 May;67:781-90
2. (46) Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol 2006;12:3953-64.
3. (80) Axon ATR, Beilenhoff U, Bramble MG, et al. Variant *Creutzfeldt-Jakob* disease (vCJD) and gastrointestinal endoscopy. Endoscopy 2001;33:1070-80.

Clostridium difficile.

- Only one report of a possible transmission of *C. difficile* [illegible] nbranous colitis a[illegible]
- Risk [illegible] digestive endosc[illegible]
- Glutara[illegible] acid are capable [illegible] *C. difficile* spores with exposition times of 5 – 20 min. (3-5).

No need to change common practices for endoscope disinfection in *C. difficile*

… but clean and disinfect carefully the settings where a procedure was performed!

1. **Poutanen SM, Simor AE.** 2004. *Clostridium difficile*-associated diarrhea in adults. CMAJ **171**:51–58
2. **Selinger CP, Greer S, Sutton CJ.** 2010. Is gastrointestinal endoscopy a risk factor for *Clostridium difficile* associated diarrhea? Am. J. Infect. Control **38**:581–582.
3. **Hughes CE, Gebhard RL, Peterson LR, Gerding DN.** 1986. Efficacy of routine fiberoptic endoscope cleaning and disinfection for killing *Clostridium difficile.* Gastrointest. Endosc. **32**:7–9.
4. **Rutala WA, Gergen MF, Weber DJ.** 1993. Inactivation of *Clostridium difficile* spores by disinfectants. Infect. Control Hosp. Epidemiol. **14**:36–39.
5. **Wullt M, Odenholt I, Walder M.** 2003. Activity of three disinfectants and acidified nitrite against *Clostridium difficile* spores. Infect. Control Hosp. Epidemiol. **24**:765–768.

CONCLUSIONS

- If a proper processing protocol is accomplished, risk of infection in endoscopy is low (exception made for duodenoscopes).

- Disinfectants must be effective, compatibles and instructions for use must be followed.
- Due to a high number of failures in reprocessing, key aspects are training personnel and assessors, stick to protocols, keep an alert attitude for adverse events and timely communication.

Next Webinar

December 12-2pm EST

"Infection Prevention in Neonatology"

Dr. Roseli Calil

University of Campinas, Brazil