Parc de Salut Barcelona

MAR

Jornadas 2019 de esterilización

30 y 31 de mayo de 2019

La complejidad de los dispositivos médicos: el reto del reprocesamiento

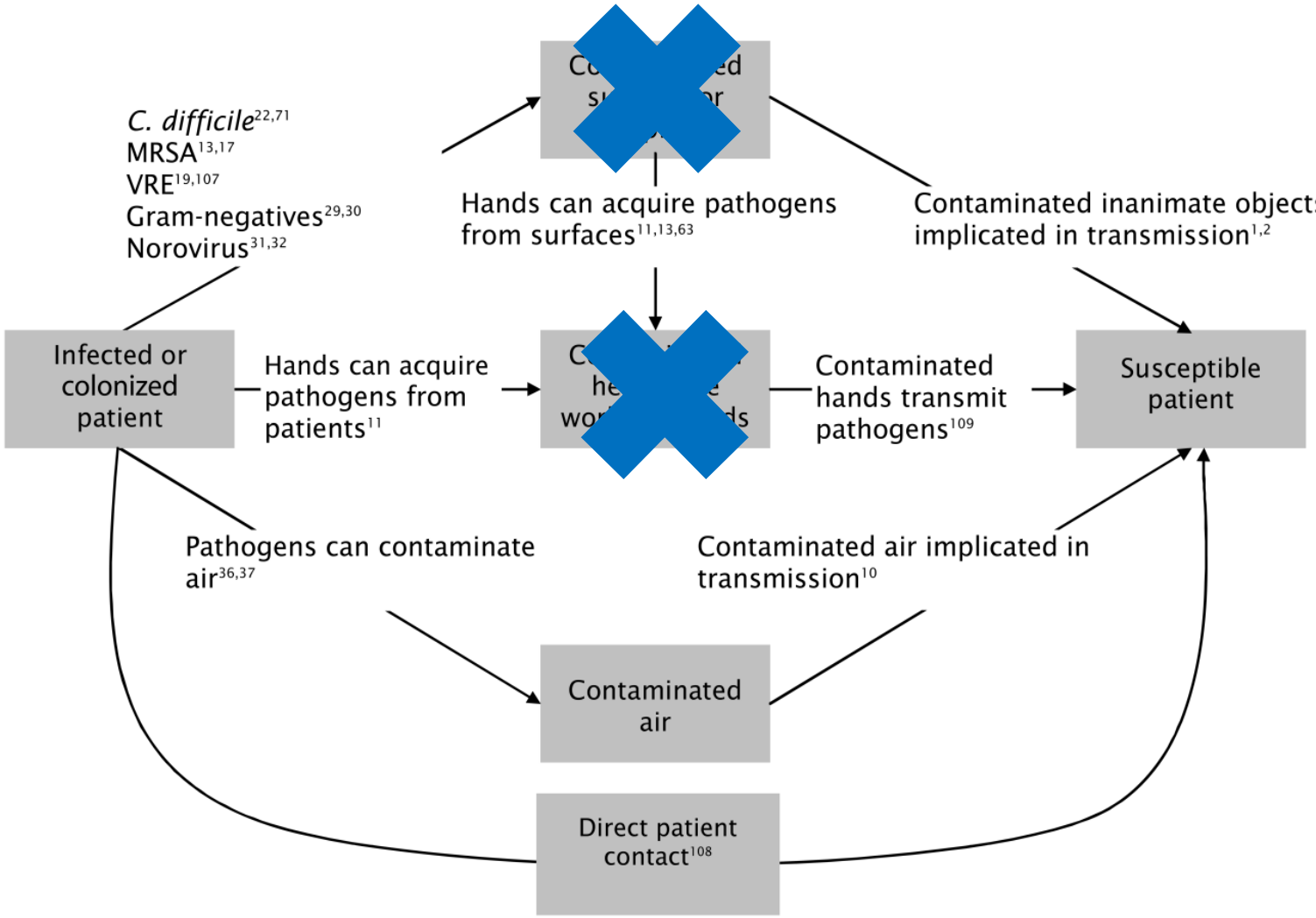
Prevención de la infección en los dispositivos médicos. ¿Cómo debemos hacerlo?

Cristina González Juanes

Control d'Infeccions. Servei d' Epidemiologia i Avaluació. Mayo 2019

¿Cuál es el problema?

¿Dónde podemos actuar?



Infect Control Hosp Epidemiol 2011;32(7) :687-99

¿De qué herramientas disponemos?

Otter *et al. Clin Microbiol*

¿ Qué nos dicen las guidelines?

Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018

5.1 Principles of infection control

RECOMMENDATION

As the carrier status of patients is often unknown, all patients should be treated as potentially infectious.

Clasificaciones a seguir ¿cuáles? Spaulding

▶ **Table 1** Spaulding classification and reprocessing of medical devices.

Spaulding classification	Examples in GI endoscopy	Reprocessing
Noncritical devices	▪ Fingertip for pulse oximetry ▪ Blood pressure cuff ▪ Electrodes for high frequency surgery and ECG ▪ Mouthguard	▪ Manual cleaning and disinfection attaining at least a given level of bactericidal and yeasticidal activity
Semicritical devices	▪ Flexible endoscopes and their endoscope components	▪ Thorough manual cleaning including brushing is mandatory, followed by: Reprocessing, including cleaning, disinfection (attaining at least a given level of minimum bactericidal, fungicidal, mycobactericidal, and virucidal activity), and rinsing ▪ Automated reprocessing in an EWD is strongly recommended ▪ Thorough drying before storage in closed cabinets or storage cabinets with a drying function Competent staff specially trained in endoscope reprocessing (in line with national laws and regulations) are required.
Critical devices	▪ Endoscopic accessories, e. g. biopsy forceps, polypectomy snares, ERCP accessories, etc. ▪ Flexible endoscopes only if medical indication for sterilization is given	For reusable devices, validated and standardized reprocessing, preferably in a CSSD is strongly recommended, including: ▪ Thorough cleaning ▪ Automated reprocessing systems ▪ Sterile packages ▪ Sterilization Proof of structured training for reprocessing medical devices (in line with national laws and regulations)

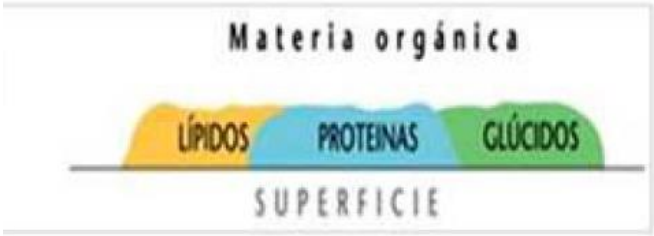
GI, gastrointestinal; ECG, electrocardiogram; EWD, endoscope washer-disinfector; ERCP, endoscopic retrograde cholangiopancreatography; CSSD, central sterilization and supply department.

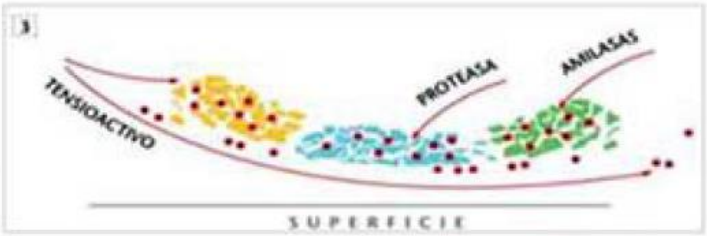
Nuestros objetivos son…

- ✓ Limpieza y desinfección de los endoscopios.
- ✓ Eficacia frente a bacterias MR, virus y esporas.
- ✓ Con productos respetuosos con el medio ambiente.
- ✓ Trazabilidad y seguridad del proceso.

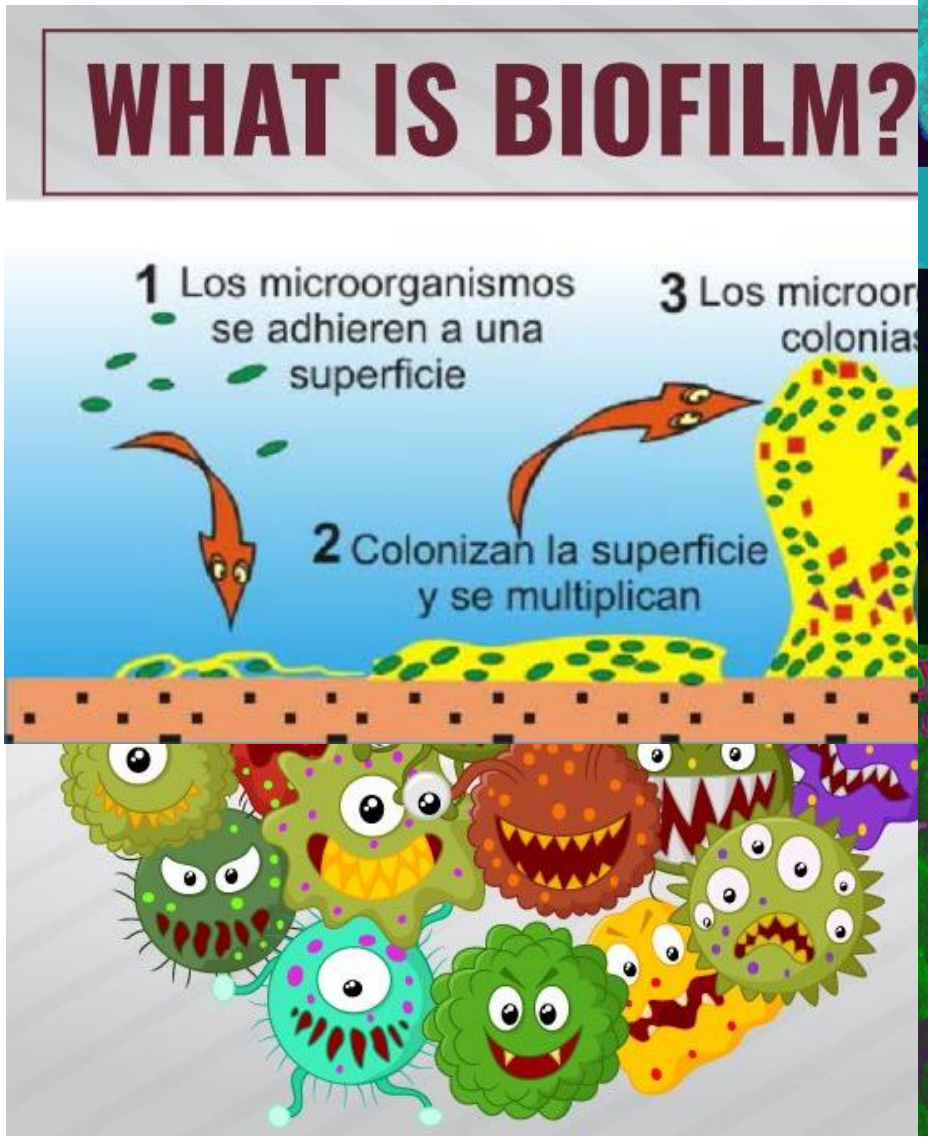
Primero ha

Los detergentes deben ser compatibles con el desinfectante aplicado. Resgistro CE





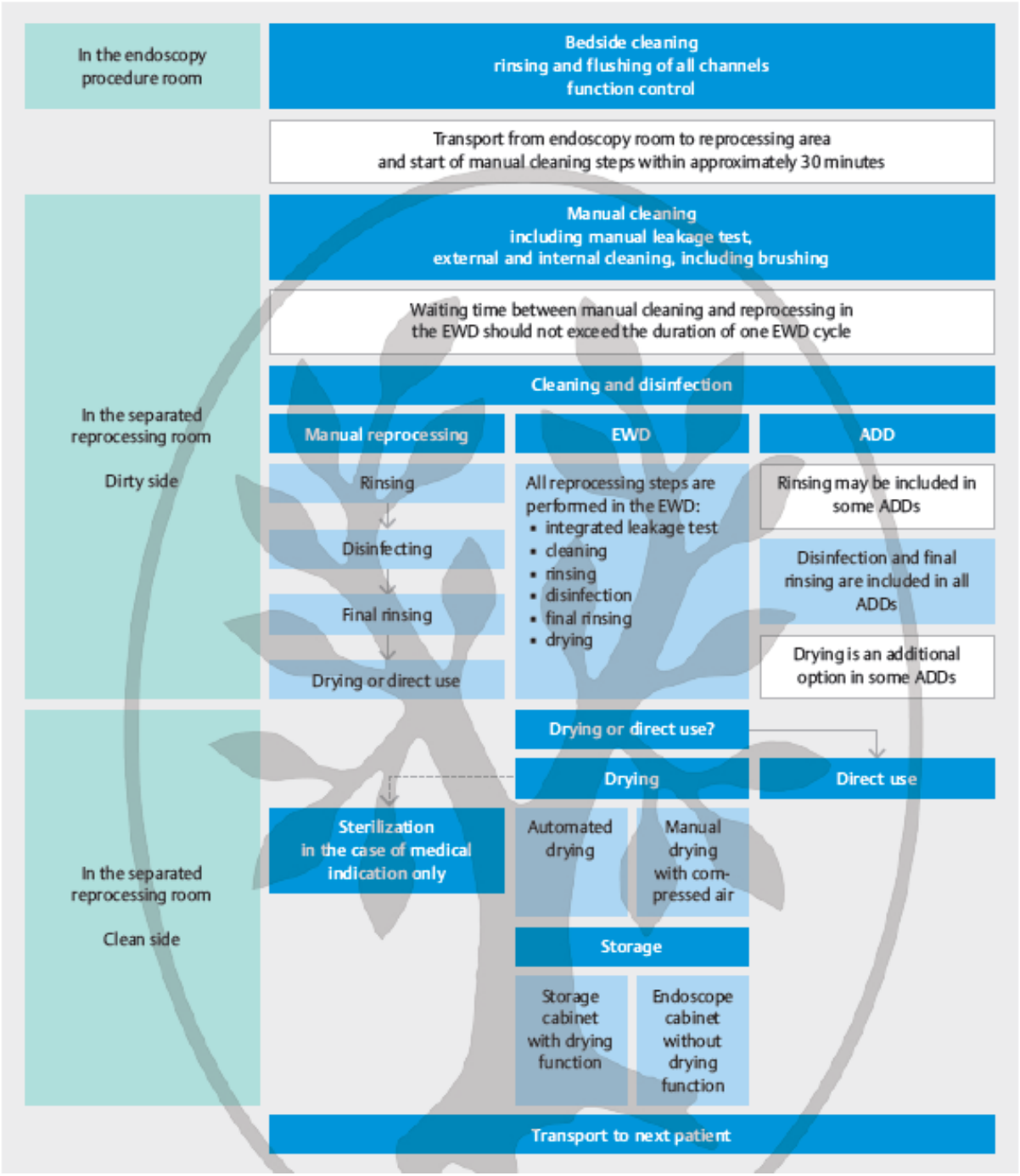
Biofilms


WHAT IS BIOFILM?
1 Los microorganismos se adhieren a una superficie
2 Colonizan la superficie y se multiplican
3 Los microor
colonias

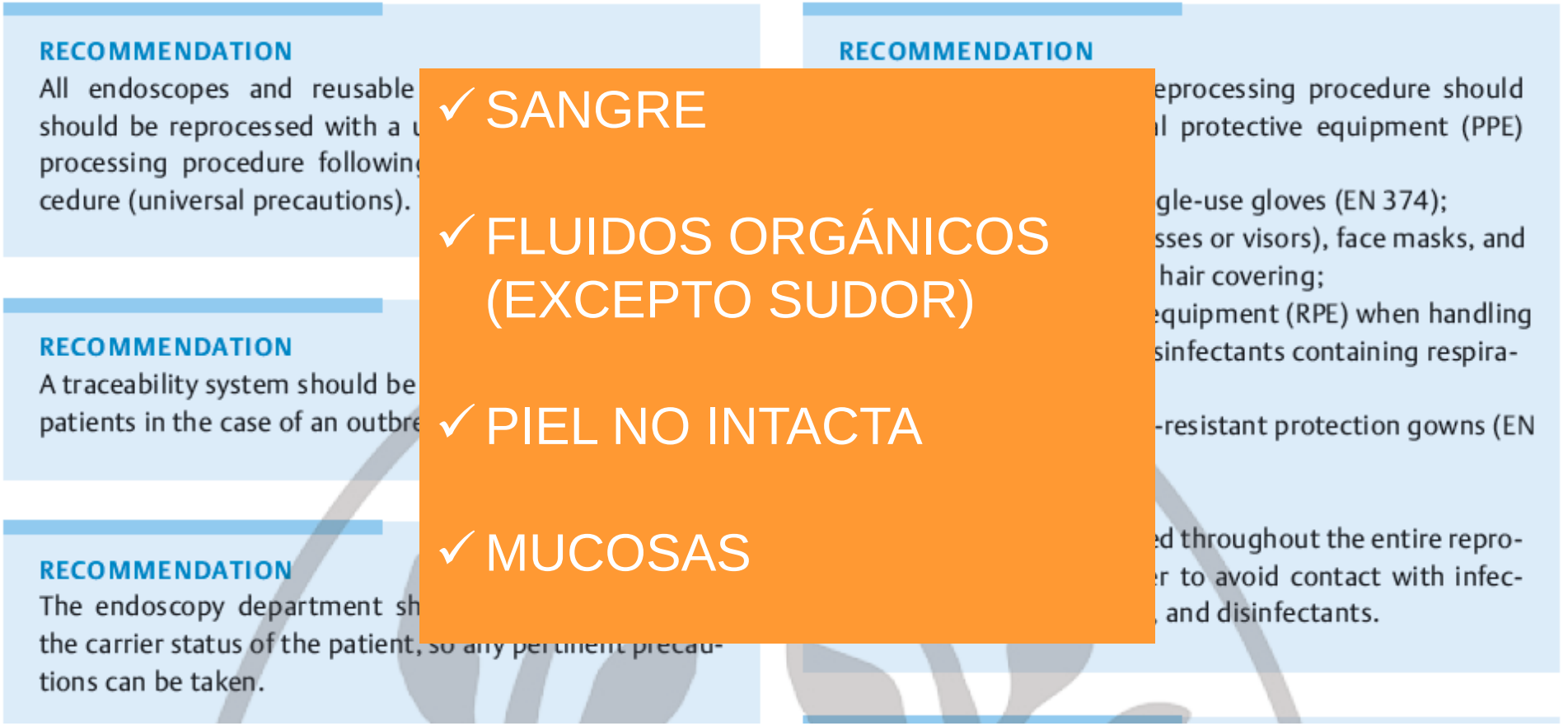

VERÓNICA DONATO
EL MUNDO DE LOS
BIOFILMS

Limpieza y desinfección

LIMPIEZA Y DESINFECCIÓN


In the endoscopy procedure room
Bedside cleaning
rinsing and flushing of all channels
function control
Transport from endoscopy room to reprocessing area
and start of manual cleaning steps within approximately 30 minutes
In the separated reprocessing room
Dirty side
Manual cleaning
including manual leakage test,
external and internal cleaning, including brushing
Waiting time between manual cleaning and reprocessing in the EWD should not exceed the duration of one EWD cycle
Cleaning and disinfection
Manual reprocessing
EWD
ADD
Rinsing
Disinfecting
Final rinsing
Drying or direct use
All reprocessing steps are performed in the EWD:
• integrated leakage test
• cleaning
• rinsing
• disinfection
• final rinsing
• drying
Rinsing may be included in some ADDs
Disinfection and final rinsing are included in all ADDs
Drying is an additional option in some ADDs
In the separated reprocessing room
Clean side
Drying or direct use?
Drying
Direct use
Sterilization
in the case of medical indication only
Automated drying
Manual drying with compressed air
Storage
Storage cabinet with drying function
Endoscope cabinet without drying function
Transport to next patient

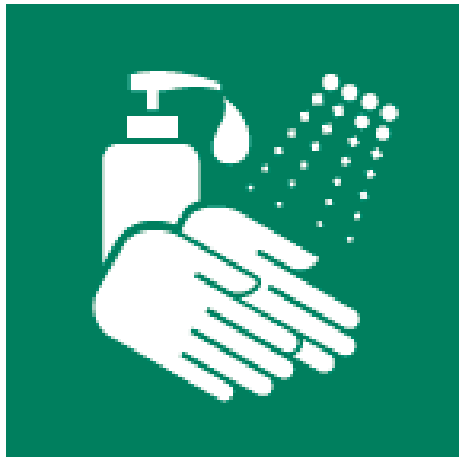
Precauciones universales



- ✓ SANGRE
- ✓ FLUIDOS ORGÁNICOS (EXCEPTO SUDOR)
- ✓ PIEL NO INTACTA
- ✓ MUCOSAS

¡IMPORTANTE!

1



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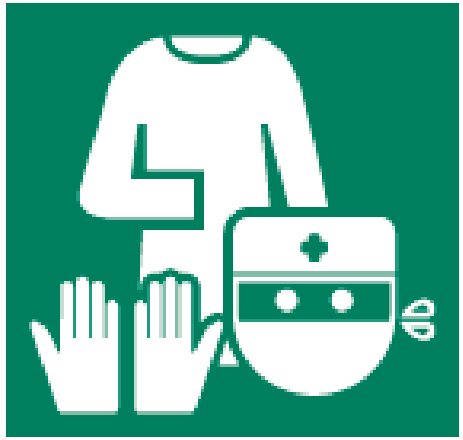

Precautions in the endoscopy unit

A number of essential precautions should be observed in the endoscopy unit in order to minimize infectious risks to both personnel and patients. Hands should be washed before and after each patient interaction, whether or not gloves are worn. The use of soap and water is required when hands are visibly soiled or an employee has an encounter with a patient with a suspected and/or known infectious cause of diarrhea. In all other cases, alcohol-based agents are acceptable.[102,126] In endoscopy units, the prevention of *C difficile* transmission should be considered when endoscopy is performed on patients with diarrhea or known *C difficile* infection. Handwashing with soap and water should be undertaken for mechanical removal of spores from employee hands. Similarly, the

+

Controles microbiológicos…¿cuándo?

10.1 - Controles microbiológicos

En la búsqueda de un sistema de control de calidad, que demuestre la efectividad de las medidas de desinfección y por tanto valide el procesamiento de los endoscopios, se recomienda la realización de controles microbiológicos que cubran cultivos de los endoscopios, de las máquinas desinfectadoras y del agua de uso en endoscopia.

No se ha conseguido evidencia científica referente al método de cultivo microbiológico y la frecuencia en que deben realizarse los controles, para detectar infección y sus causas, aunque de acuerdo a la Norma EN ISO 15883[60] y las instrucciones de los fabricantes de las máquinas desinfectadoras, es seguro que deben seguir una periodicidad (61,64,65).

Por esta razón, cada unidad o servicio deberá regirse por las recomendaciones de su directiva local, aunque nuestra recomendación se adhiere a la de la European Society of Gastroenterology Endoscopy Nurses and Associates (ESGENA), que propone la periodicidad de cultivo de endoscopios, lavadoras y agua, al mismo tiempo, cada 3 meses (66-68).

Cualquier material contaminado, debe ser suspendido de servicio, hasta que se demuestre su resolución mediante resultados microbiologicos favorables.

RECOMMENDATION

Outbreaks should be managed within the multidisciplinary team of endoscopy departments, hospital hygiene experts, microbiologists, manufacturers, and regulatory bodies, if applicable.

Enferm Infecc Microbiol Clin. 2017;xxx(xx):xxx–xxx

Enfermedades Infecciosas y Microbiología Clínica

www.elsevier.es/eimc

Review article

Microbiological monitoring of medical devices after cleaning, disinfection and sterilisation☆

Rosa María Blázquez-Garrido[a,*], Eva Cuchí-Burgos[b], Carmen Martín-Salas[c], Patricia Ruiz-Garbajosa[d]

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[b] Microbiología, Catlab, Viladecavalls, Barcelona, Spain
[c] Servicio de Microbiología, Complejo Hospitalario de Navarra, Pamplona, Navarra, Spain
[d] Servicio de Microbiología, Hospital Universitario Ramón y Cajal, Madrid, Spain

Table 1
Recommendations for microbiological study of endoscopes.

Cut-off point	Microorganisms	Frequency	Guidelines
<10 CFUs per device	Low-risk microbiota (skin and environment) Coagulase-negative *Staphylococcus* Diphtheroids *Micrococcus* spp. *Bacillus* spp.	Not established (except in duodenoscopes: every 60 procedures or monthly)	CDC[9]
Any count	High-risk microbiota *S. aureus Enterococcus* spp. *S. viridans P. aeruginosa* Enterobacteria		
Same cut-off points as ESGENA and GESA	*Enterococcus* spp. Enterobacteria *S. viridans* NF GNB Mycobacteria on bronchoscopes Atypical NF GNB mycobacteria and *Legionella* spp. in water and on washers	Monthly; once circuit is established, may be quarterly	SEIMC 2012[20] UNE EN-ISO 15883[21]
No growth 1–10 CFUs 10–100 CFUs 100–1000 CFUs > 10,000 CFUs	*Enterococcus* spp. Enterobacteria *S. viridans* NF GNB Rapidly growing mycobacteria on bronchoscopes	Monthly Duodenoscopes Bronchial endoscopes Other flexible endoscopes Quarterly Other gastrointestinal endoscopes	GESA 2010[18]
<20 CFUs/channel Indicator microorganisms; any count	Any type of microbiota Indicator microorganisms Enterobacteria *P. aeruginosa S. aureus* Final wash water; Rapidly growing mycobacteria *Legionella* spp.	Quarterly or more often	ESGE-ESGENA 2007[16]
Microorganisms not included Anaerobes Viruses *Helicobacter pylori*		No guidelines mention fungi	

CDC: Centres for Disease Control and Prevention; CFUs: colony-forming units; ESGE-ESGENA: European Society of Gastrointestinal Endoscopy-European Society of Gastroenterology and Endoscopy Nurses and Associates; GESA: Gastroenterological Society of Australia; NF GNB: non-fermenting Gram-negative bacilli; SEIMC: Spanish Association of Infectious Diseases and Clinical Microbiology.

Enferm Infecc Microbiol Clin. 2017;xxx(xx):xxx–xxx

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Table 2
General interpretation of microbiological results.

Microorganisms isolated	Interpretation/action to be taken
Growth of *S. epidermidis* in low counts	Suspected contamination in sampling or sample processing or storage It is recommended that sampling be repeated
Significant counts of microorganisms on several devices Isolation of enteropathogens such as *Salmonella* spp. Isolation of *P. aeruginosa*	Suspected failures in the cleaning/disinfection of devices process It is recommended that the cleaning and disinfection procedure be reviewed and that sampling be repeated
Isolation of *P. aeruginosa* and other non-fermenting GNB	Suspected failures in drying or storage of devices or contamination of wash water. Assess the suitability of placing filters
Repeated growth in significant counts of a microorganism on a single device	Suspected structural problems with the devices It is recommended that the manufacturer review the device and that any leaks be managed

PETICIÓN CULTIVOS LABORATORIO

Laboratori de Referència de Catalunya

SOL·LICITUT ANALÍTICA

Parc de Salut MAR

etiqueta laboratori

IDENTIFICACIÓ DE LA MOSTRA:

DATA:

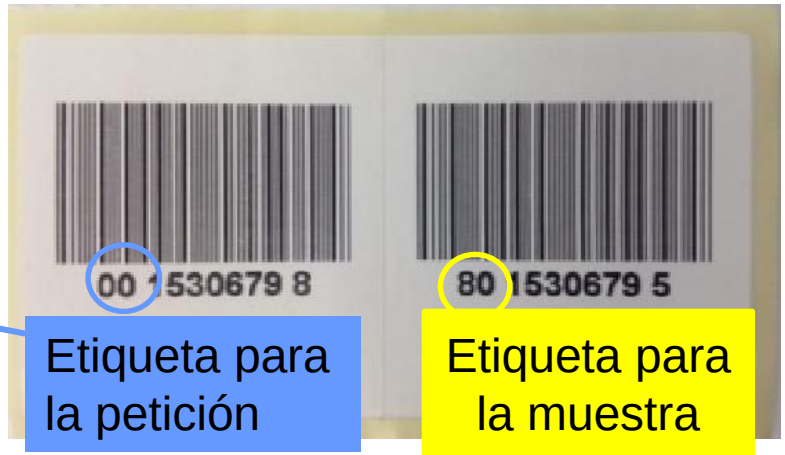
CODI CENTRE: IMA

- ☐ Gastroscop (7750)
- ☐ Colonoscop (7750)
- ☐ Duodenoscop (7750)
- ☐ Enteroscop (7740, 7750)
- ☐ Ecoendoscop (7740, 7750)
- ☐ Broncoscop (7526, 7740, 7750)
- ☐ Cistoscop (7750)
- ☐ Ambientals (7750)
- ☐ Altres: _____

OBSERVACIONS:

7740 Control Micobacteris
7750 Control Microbiològic
7526 Cultiu Legionel·la
7730 Control Micològic

Identificación de la muestra (nº identificación de endoscopio)



Etiqueta para la petición

Etiqueta para la muestra

Marcar tipo utillaje

Condiciones de las salas…

RECOMMENDATION

The room should have:

- Appropriate size and lighting, and ventilation and fume extraction in order to minimize the risks from chemical vapors;
- Appropriate technical equipment and protective measures in order to ensure safe reprocessing following standardized and validated reprocessing procedures;
- Strict spatial or at least operational separation of dirty and clean/storage areas, in order to avoid recontamination of reprocessed endoscopes and endoscopic accessories.

This should be supported by the room architecture and design as well as by the one-way workflow from dirty to clean areas. Ideally, the standards should comply with those of the central sterilization and supply department (CSSD) in the particular country.

RECOMMENDATION

It is the responsibility of the clinical service provider to ensure that adequate facilities for reprocessing are available.

RECOMMENDATION

Independently of the distance between endoscopy rooms and reprocessing area, the workflow should ensure immediate reprocessing of used equipment.

- ✓ Sala ventilada y extracción de vapores.
- ✓ Zona sucia, limpia y de almacenamiento.
- ✓ Agua desmineralizada.
- ✓ Aire comprimido.

✓ ***Personal formado y entrenado***

Trazabilidad y seguridad

7. Documentation and traceability

7.1 Documentation

RECOMMENDATION

The complete reprocessing cycle should be documented:

- Each reprocessing step (including bedside cleaning, manual cleaning, and automated reprocessing in an EWD or ADD) should be recorded manually or electronically, including the names of the persons undertaking each step.
- The process parameters of the EWD and storage cabinets should be documented by printouts or electronically.
- All endoscopes should have a record of their reprocessing showing that they are ready for use on patients.
- The reprocessing record should be documented in the patient's files.

- ✓ Registrar cada paso con persona responsable.
- ✓ Registro de endoscopios listos para su uso.
- ✓ Documentar en la HC del paciente la identificación del endoscopio.
- ✓ Trazabilidad del proceso tanto del lavado como almacenaje.

Trazabilidad y seguridad

ENDOSCOPIAS DIGESTIVAS

Servei de Digestiu

Paciente:
Nº historia: 398599
Edad: 53
Sexo: Mujer
Cama:

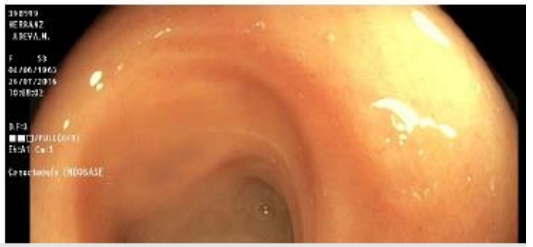
Fecha: 26/07/2016
Nº expl.: DIG247612-118
Procedencia:
Premedicación:
Ubicación:
Nº Serie endoscopio: CF-H180AL2703243 Sala 2

COLONOSCOPIA

Indicación: Cribratge CCR

Preparación: Adequada, Boston 9/9 (CD 3, CT 3, CE 3)

Sedación: 190mg de propofol



Una limpieza cuidadosa...

es inteligente

Limpiar frecuentemente, limpiar bien

(derrota- desalienta a los gérmenes)

Prevenir infecciones... Puede ser extenuante

Pero tener un descanso puede ser mucho peor

GOJO SAGE Sealed Air Diversey Care

Muchass gracias!!