HIGH-LEVEL DISINFECTIC COMPARED TO STERILIZATION IN INFECTION CONTROL ASSOCIATED WITH REPROCESSING LAPAROSCOPES AND ARTHROSCOPES

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Un Compromiso con la Excelencia

Disclaimer

All opinions expressed during this participation in the **XXIII World Congress of Sterilization** event are personal and do not necessarily represent the opinion of **ASP**.

PROBLEM STATEMENT

Infections associated in health care *(HAI)* are the **most frequent adverse event** during patient care[1], **any institution or country** cannot have solved the problem[2].

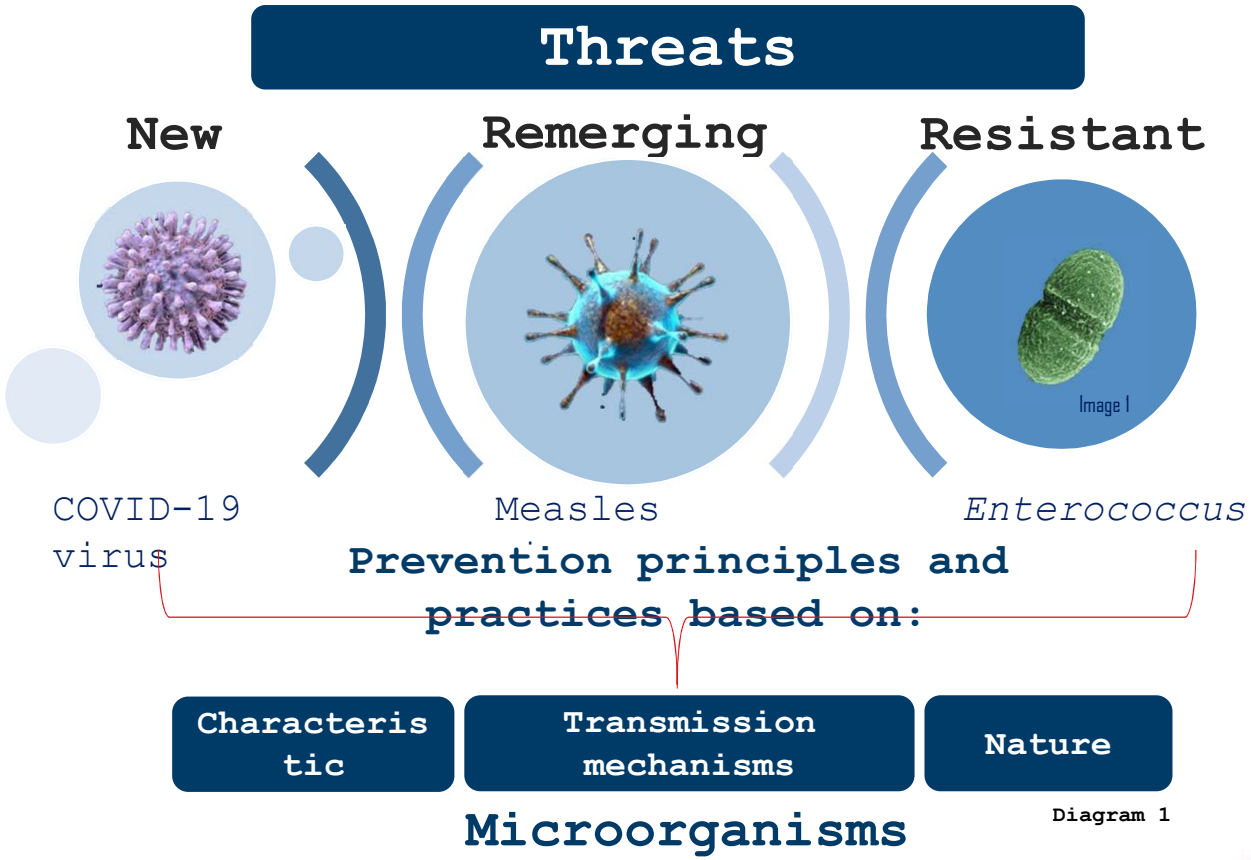


Diagram 1

WHO. WORLD HEALTH ORGANIZATION. (2021, 4 8). *Clean care is safer care* . Global burden of healthcare-associated infections: https://www.who.int/gpsc/country_work/burden_hcai/es/
Image 1. United States Department of Agriculture. (2009). *Image Enterococcus faecalis* . [Image]. Retrieved from https://en.wikipedia.org/wiki/Enterococcus_faecalis#/media/File:Enterococcus_faecalis20023-300.jpg

PROBLEM STATEMENT

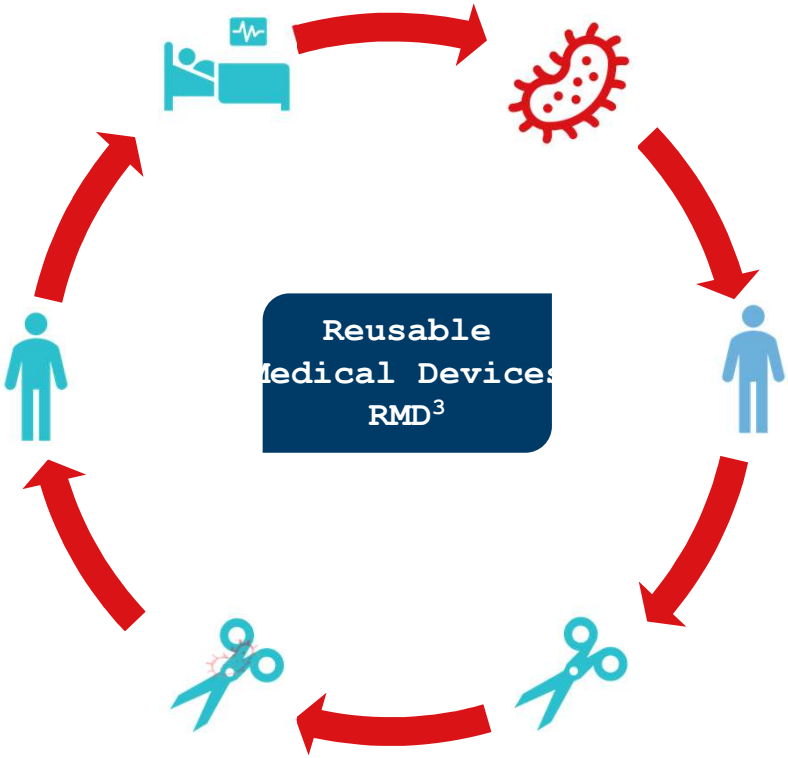
Healthcare Associated Infections *HAI*

5.4 million
Surgical interventions [1]

100 patients

1 SSI patient*

* Surgical Site Infection

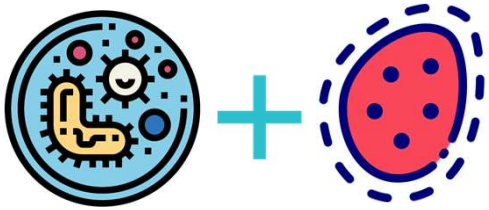


Chain of Infection from the perspective of the Reprocessing Department

[1] IAHCSMM. The Central Service Technical Manual. 8th ed . 2016.
[2] IAHCSMM. Central Services Technical Manual. 7th ed . Illinois; 2013. 522 p.
[3] WFHSS. Reusable medical device [Internet]. WFHSS World Federation for Hospital Sterilization Sciences. 2020 [cited 2021 Jul 28]. Available at: https://wfhss-guidelines.com/reusable-medical-device/
[4] Malagón C, Álvarez C. Hospital Infections. 3rd ed . Colombia; 2010. 859 p.

PROBLEM STATEMENT

Laparoscopes and arthroscopes



Ability of high-level disinfection to eliminate a majority of the microorganisms

Disinfection

Sterilization

Ability of sterilization to eliminate every microorganisms

Rutala W, Weber D. Guideline for disinfection and sterilization in healthcare facilities, 2008 [Internet]. 2019. Available at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

JUSTIFICATION

Scientific

- Controversy [1]
- Regulatory gap[2]

Economic

- HAI
- DM damage

Personal health

- Morbidity

Society

- Public health

[1] Rutala W, Weber D. Guideline for disinfection and sterilization in healthcare facilities, 2008 [Internet]. 2019. Available at : https://www.cdc.gov/infectioncontrol/guidelines/disinfection/
[2] Ministry of Health and Social Protection - Republic of Colombia. Resolution 2183 of 2004 [Internet]. 2004 [cited 2021 Jul 5]. Available at: https://www.minsalud.gov.co/Normatividad_Nuevo/RESOLUCI%C3%93N%202183%20DE%202004.pdf

HYPOTHESIS

- H_0: The effectiveness of the disinfection process for laparoscopes and arthroscopes is equivalent to the effectiveness of the sterilization process

- H_a: The effectiveness of the disinfection process for laparoscopes and arthroscopes is different from the effectiveness of the sterilization process

RESEARCH QUESTION

¿What is the **effectiveness** of high-level disinfection **compared** to sterilization in controlling infections associated with the reprocessing of laparoscopes and arthroscopes in patients having minimally invasive surgery?

P Primary studies of minimally invasive surgical procedures by laparoscopy or arthroscopy.

I High level disinfection.

C Sterilization.

O Healthcare Associated Infections.

HEALTHCARE ASSOCIATED INFECTIONS

USA (2006 to 2008)[1]

- SSI rate of 1.9%
- 9.7 days of additional hospital stay
- Increase in costs per admission of USD 20,842
- **Most common pathogens:** *Staphylococcus aureus* , Coagulase negative *staphylococci* , *Escherichia coli* , *Enterococcus faecalis* , *Pseudomonas aeruginosa* , *Enterobacter spp* . and *Klebsiella spp* .

Europe (2004)[1]

- HAIs affect 11% of patients undergoing a surgical procedure
- ISO costs: €1.47 to 19.1 billion
- Increase of approximately 6.5 days in hospital stay.
- **France:** Significant increase in the risk of mortality from 4 to 15 times.

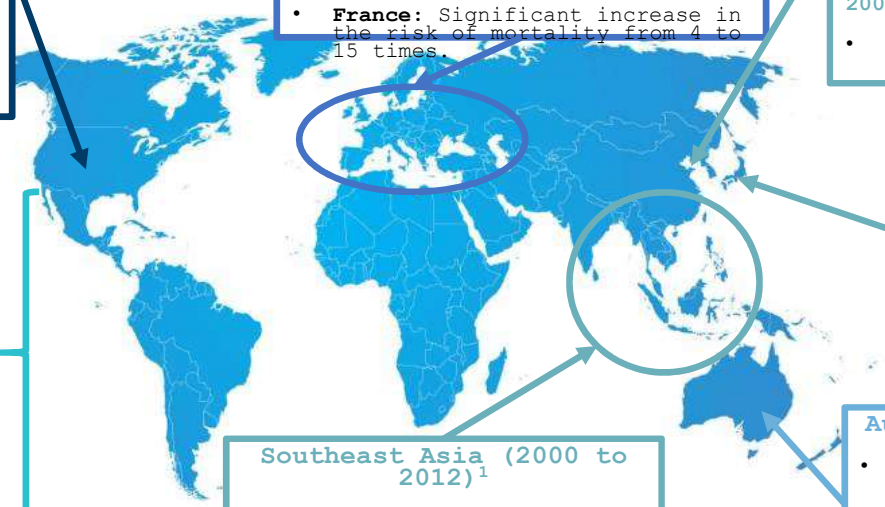
Republic of Korea[1]

2000

- ISOs constituted 17.2% of all reported HAIs.
- 1,730 was estimated for each episode of surgical site infection.

2008 to 2012

- Infection rate of 3.12% for gastrectomy, 2.05% for hip arthroplasty and 1.90% for knee arthroplasty.



Latin America (2013)

- **Uruguay:** incidence rate of surgical site infections of 3.2% for appendectomy , 2.5% for surgery cardiac arrest, 6.2% for cholecystectomy and 15.4% for colon surgery [1].
- **Chile:** Rate for ISO of 1.89% for hip arthroplasty and in cholecystectomy performed via laparotomy it was 4.12% times higher than laparoscopic cholecystectomy[1].
- **Colombia :**
  - National proportion of hospital infections of 1.25[2]
  - common pathogens : *Staphylococcus aureus* , *Pseudomonas aeruginosa* , *Klebsiella pneumoniae and E. coli* .

Japan (2013, n=417 hospitals)[1]

- Average additional hospital stay of 20.7 days.
- Average spending on health greater than USD 8,791.

Southeast Asia (2000 to 2012)[1]

- Cumulative incidence of HAI of 7.8%.
- **Singapore (2008):** ISO incidence of 8.3% for general, neurological and orthopedic surgery .

Australia (2002 to 2013)[1]

- 5,023 Surgical site infections in 183,625 procedures (n=81 hospitals).
- **Most common pathogens:** *Staphylococcus aureus* and *Escherichia coli* .

[1] World Health Organization. Global guidelines for the prevention of surgical site infection [Internet]. 2018. Available at : https://www.who.int/gpsc/global-guidelines-web.pdf?ua=
[2] Ministry of Health and Social Protection - Republic of Colombia. Program for the prevention, surveillance and control of infections associated with health care-IAAS and antimicrobial resistance [Internet]. 2018. Available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/PP/PAI/programa-iaas-ram.pdf?ID=16565
[3] Ministry of Health and Social Protection - Republic of Colombia. Detect, prevent and reduce infections associated with health care [Internet]. 2015. Available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/CA/Detectar-Infecciones.pdf

MEDICAL DEVICE REPROCESSING

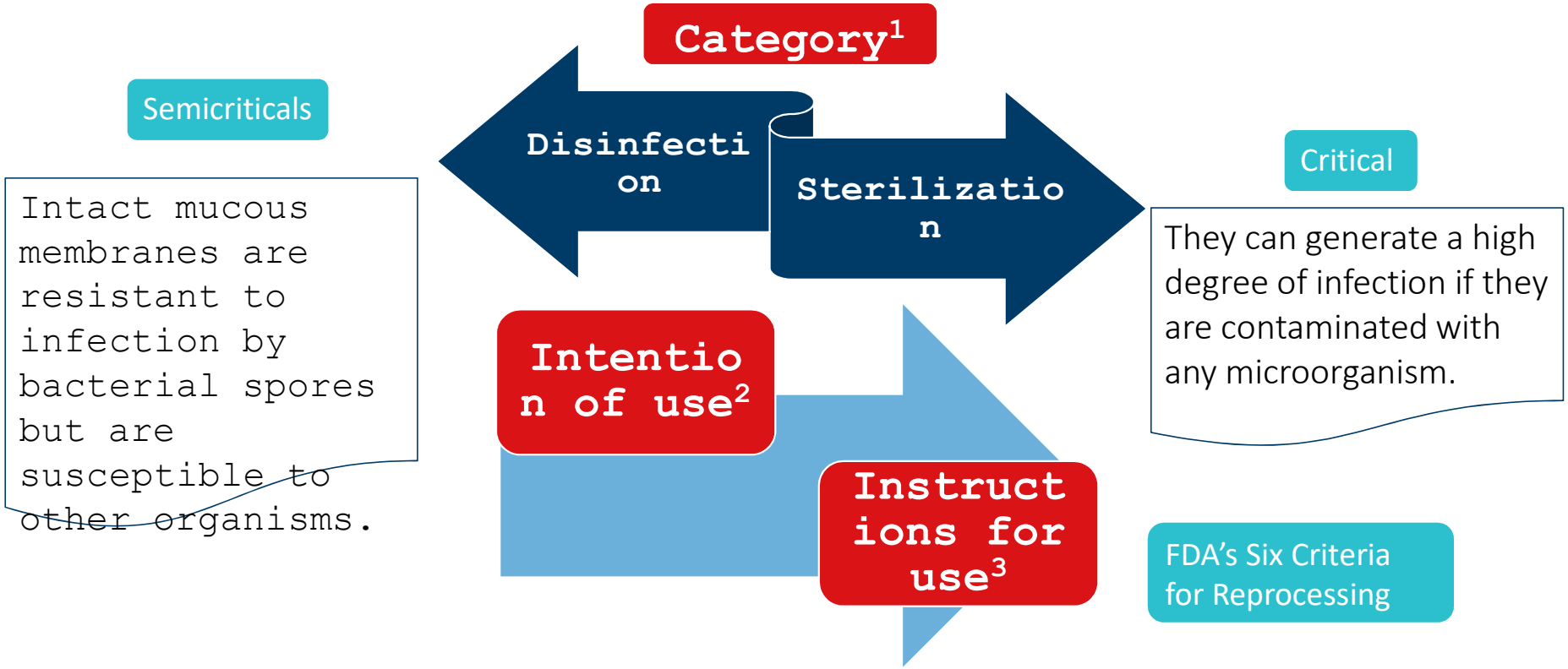


Diagrama 5. Rodríguez, S. 2022. ASP. Adaptada de [1] Rutala W, Weber D. Guía para la desinfección y esterilización en centros sanitarios, 2008 [Internet]. 2019. Disponible en: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/, [2] FDA. Reprocesamiento de dispositivos médicos en entornos sanitarios: Métodos de validación y etiquetado - Guía para la industria y el personal de la Administración de Alimentos y Medicamentos [Internet]. 2011. Disponible en: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling and [3] Organización Internacional de Normalización. ISO 17664-2:2021 Procesamiento de productos sanitarios - Información que debe proporcionar el fabricante de productos sanitarios para el procesamiento de productos sanitarios - Parte 2:

GENERAL OBJECTIVE

¿What is being done?	¿What must be done?
High level disinfection is applied to laparoscopes and arthroscopes.	**Laparoscopes and arthroscopes must be sterilized.**

To **determine** the effectiveness of high-level disinfection and sterilization of laparoscopes and arthroscopes used in minimally invasive surgery, **identifying** their relationship with the **development** of infections associated with the use of these medical

SPECIFIC OBJECTIVES

- Describe the **characteristics of the population** (primary items), laparoscopy and arthroscopy equipment, and high-level disinfection and sterilization methods.
- **Identify the risk** of infection associated with the use of reprocessed laparoscopes and arthroscopes through high-level disinfection and sterilization in primary studies.
- Determine the **factors related** to the presence of health care-associated infections in the reprocessing of laparoscopes and arthroscopes that are used in minimally invasive surgery.
- Identify the **microorganisms isolated** from laparoscopes and arthroscopes when related to infections associated with their use.
- Establish the **costs generated** for health systems and patients as a consequence of

APPROACH TYPE OF STUDY

A study with a quantitative approach was intended, with a deductive and logical approach to the event to summarize the results of primary studies and establish common aspects between different sources of scientific evidence following a rigorous method.

Integrative or Synthesis study:

Systematic review of the literature that was developed based on the methodology established in the *Cochrane Handbook for systematic Reviews of Interventions version 6.2.*

INCLUSION CRITERIA

Participant type

- Primary studies of minimally invasive surgical procedures by laparoscopy or arthroscopy.

Intervention type

- Disinfection:
  - **High level disinfection.**
  - Sterilization with sterilizing chemical liquids.

Comparator type

- Sterilization:
  - **High temperature sterilization.**
  - Low temperature sterilization.

Outcome

- HAI
  - Clinical
  - Administrative and legal

✓ Randomized clinical trial

✓ Observational studies such as case reports, case reports or series, prevalence studies, cases and controls, cohort studies, and systematic reviews; published and unpublished , with full text, since

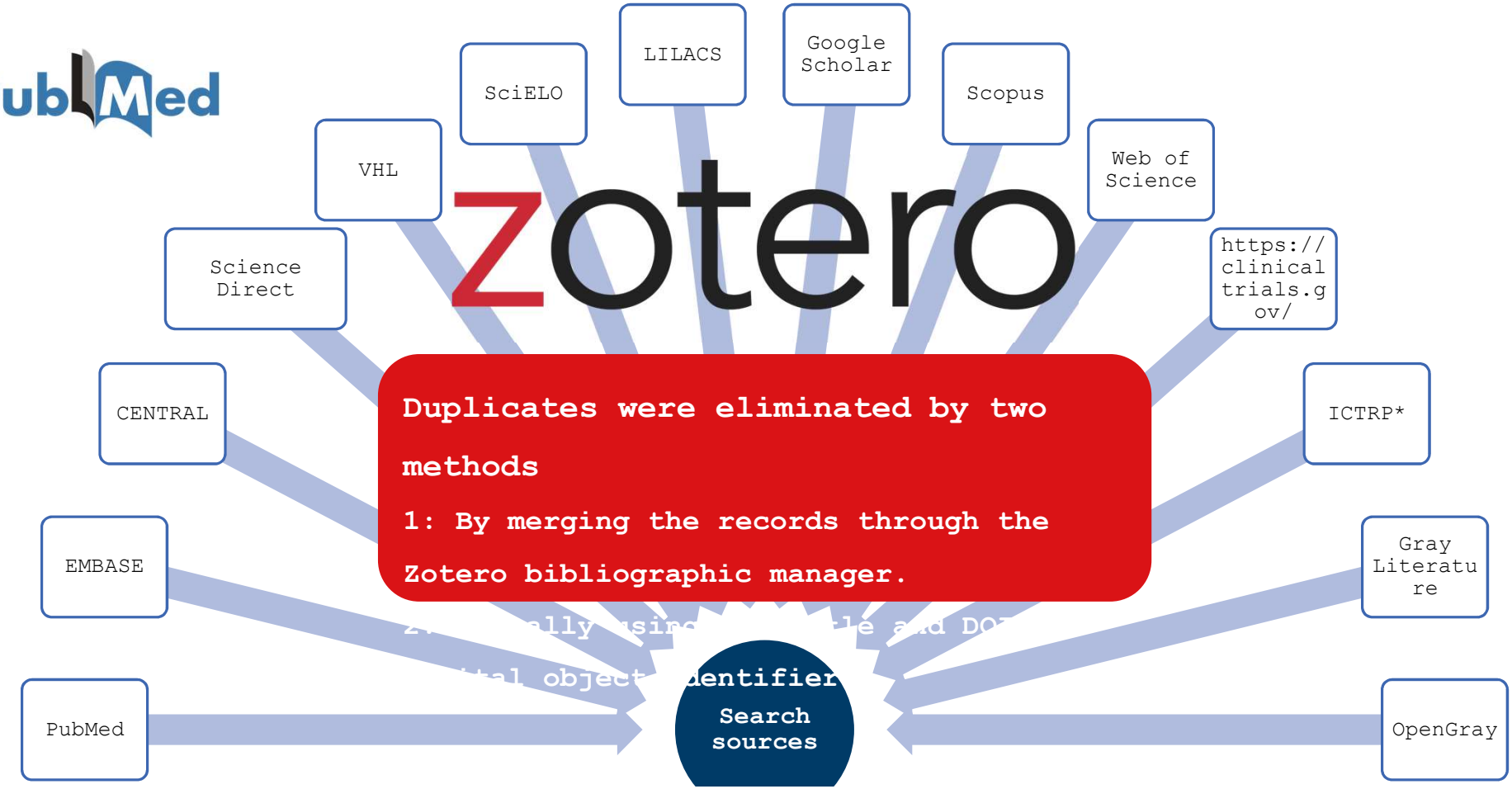
SEARCH AND SELECTION OF STUDIES

Search equations

- Standardized terms: DeSC , MeSH , EMTREE
- Free

PICO	Términos MeSH	Términos EMTREE	Términos DeCS	Términos libres
P	Laparoscopes Laparoscopy Arthroscopes Arthroscopy	Laparoscope Laparoscopy Arthroscope Arthroscopy	Laparoscopia quirúrgica Laparoscopios Laparoscopía Artroscopios Artroscopía	Minimally Invasive Surgical Procedures Laparoscopes Laparoscopy Laparoscopies Arthroscopes Arthroscopy Arthroscopies
I	Disinfection	Disinfection	Desinfección	Reprocessing Reprocessing of medical devices High level disinfection
C	Sterilization	Instrument sterilization	Esterilización Centro de material y esterilización	Sterilization
O	Infections Cross Infection Surgical Wound Infection Disease Outbreaks Disease Transmission, Infectious	Infection Cross Infection Surgical infection Disease transmission	Infecciones Infección hospitalaria Infección de la Herida Quirúrgica Brotes de Enfermedades Transmisión de Enfermedad Infecciosa	Infection Health care associated infection Surgical site infection Disease Outbreaks Disease transmission

SEARCH AND SELECTION OF STUDIES



Duplicates were eliminated by two methods

1: By merging the records through the Zotero bibliographic manager.

2: Manually using title and DOI digital object identifier

SEARCH AND SELECTION OF STUDIES

Screening template

No.	Base de datos	Datos del estudios				Tipo de estudio	Sujetos de estudio
		Título del artículo	DOI	Año de publicación	Abstract		

Criterios de inclusión									
Participantes		Intervención	Desenlace		Desenlaces				
Procedimiento		Método de Reprocesamiento			Primario: Infección asociada a la atención en salud	Secundarios			
Laparoscopia	Artroscopia	Desinfección de alto nivel	Esterilización	Reprocesamiento		Discapacidad a largo plazo	Morbilidad	Mortalidad	Costos para los sistemas de salud

Texto completo	Juicio de selección	Justificación	Comentarios adicionales

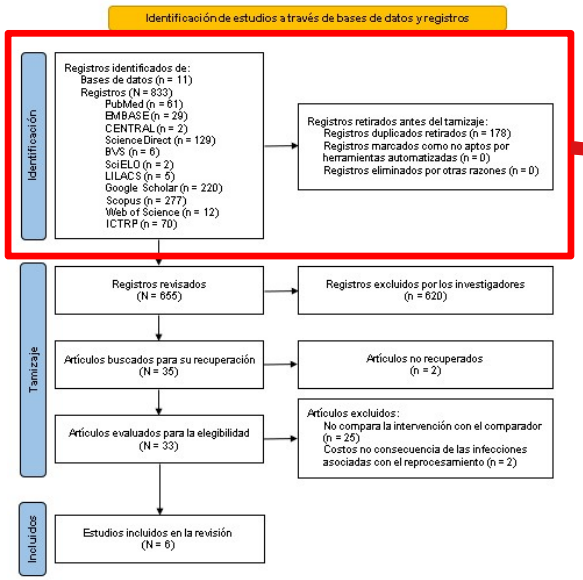
No included: 0
In doubt: 1
Included: 2

SEARCH AND SELECTION OF STUDIES

According to **resolution 8.430 of October 4, 1993, of the Colombian Ministry of Health**, which "establishes the scientific, technical and administrative standards for health research", article 11, literal a, it is **considered a research without risk** given that no intervention or intentional modification of the biological, physiological, psychological or social variables of the individuals participating in the study is performed.

CES University was petitioned for the endorsement of the **research and innovation committee and the ethics committee** to carry out the study. The protocol was **submitted and approved** by

SEARCH AND SELECTION OF STUDIES



Identified

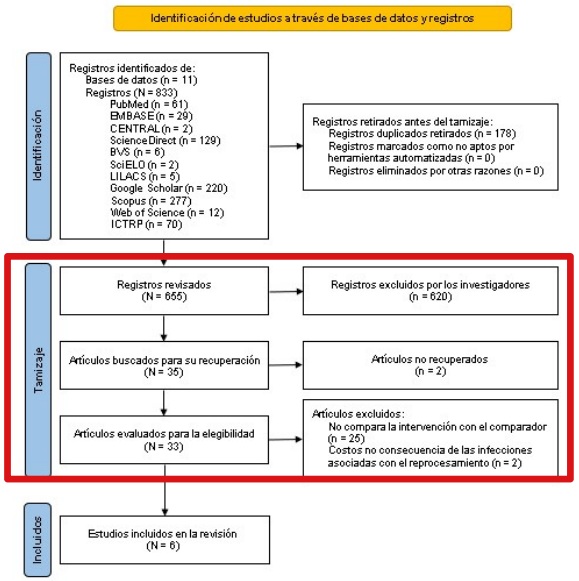
Registros identificados de:
Bases de datos (n = 11)
Registros (N = 833)
PubMed (n = 61)
EMBASE (n = 29)
CENTRAL (n = 2)
ScienceDirect (n = 129)
BVS (n = 6)
SciELO (n = 2)
LILACS (n = 5)
Google Scholar (n = 220)
Scopus (n = 277)
Web of Science (n = 12)
ICTRP (n = 70)

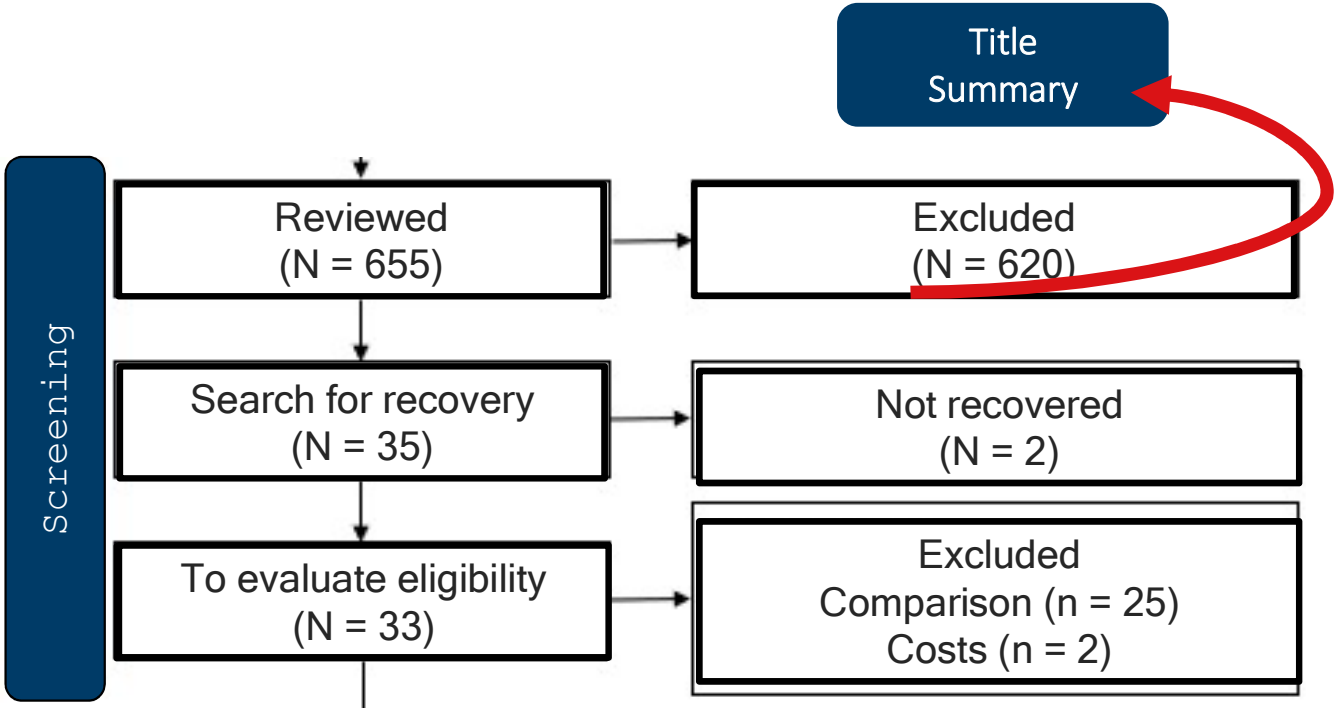
833 Registers

Records withdrawn before screening
Duplicates (n = 178)
Unfit (n = 0)
Others (n = 0)

178 Duplicates

SEARCH AND SELECTION OF STUDIES





Documents that did not correspond to clinical studies, such as guidelines, books, letters to the editor and expert consensus.
Failure to make an explicit comparison between high-level disinfection and sterilization.

SEARCH RESULTS

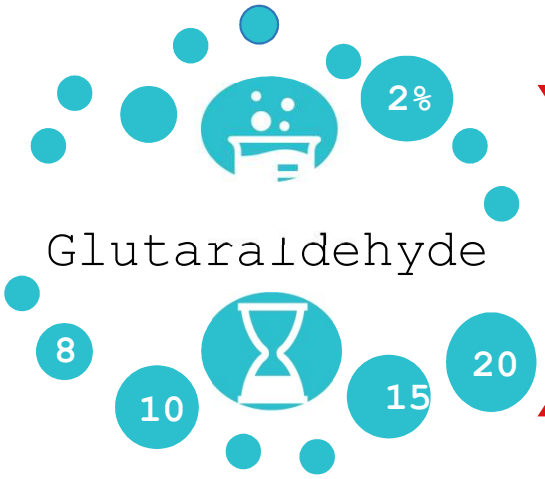
INCLUDED

Studies included in the review (N=6)

Author (Year) Desing Country	
Huezo (1983) EE.UU.	Analytical study of databases
Stearns (1983) EE.UU.	Review of the literature
Rutala (1991) EE.UU.	Cross-sectional - Review of the literature
Ayliffe (1992) UK	Review of the literature
Muscarella (1996) EE.UU.	Review of the literature
Ulualp (2000) Turquía	Quasi-experimental

CHARACTERISTICS OF INCLUDED STUDIES

Reprocessing Method



Disinfection

Huezo *et al* . (1983)
Stearns *et al.* (1983)
Ayliffe *et al.* (1992)

Ethylene oxide

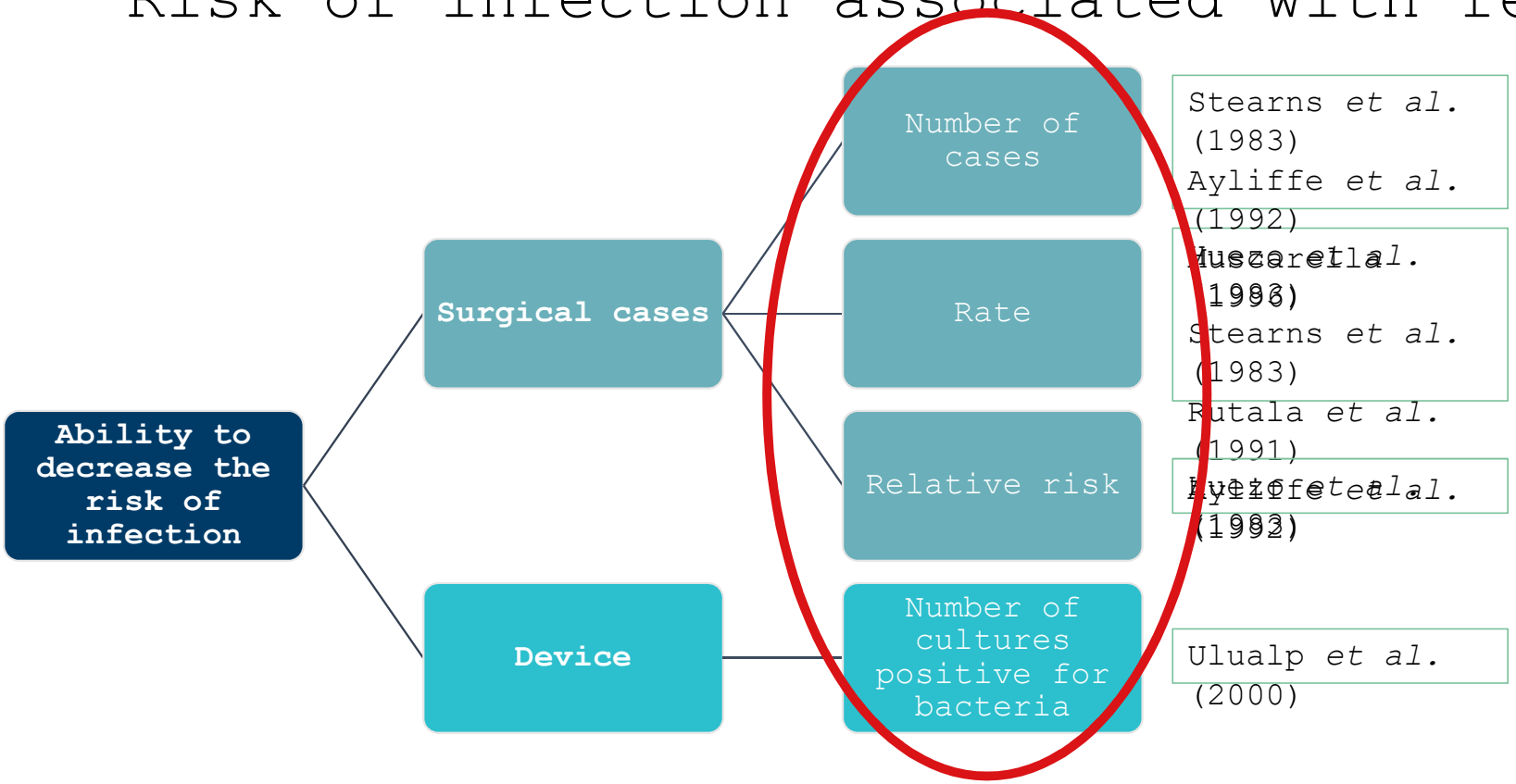
Steam

Sterilization

Stearns *et al.* (1983)
Huezo *et al* . (1983)
Stearns *et al.* (1983)
Rutala *et al* (1991)
Ayliffe *et al.*

CHARACTERISTICS OF INCLUDED STUDIES

Risk of infection associated with reproces



CHARACTERISTICS OF INCLUDED STUDIES

Factors associated with the risk of infection

Surgical procedures

- Stearns *et al.* (1983)
  - arthrotomy
  - Wound Type
  - Hour
  - shave
  - Post operative time
- *Huezo et al* . (1983)
  - surgical time
  - ports

Patient

- Huezo *et al* . (1983)
  - Age
  - Race
  - Marital status
  - Possibility of PID*
- Stearns *et al.* (1983)
  - steroid therapy
  - malnutrition
  - Diabetes
  - Obesity

* Pelvic inflammatory disease

Enviroment

- Ayliffe *et al.* (1992)
  - Air pollution

Processing

- Muscarella (1996)
  - Improper cleaning of the medical device
  - Improper use of high level disinfectant
  - Improper storage of equipment

Device

- Ulualp *et al* . (2000)
  - Hidden areas
  - Keys
  - Valves

Economic

- Huezo *et al* . (1983)
- Economic reasons
- Practicality

CHARACTERISTICS OF INCLUDED STUDIES

	Related microorganisms
Stearns *et al.* (1983)	• ***Clostridium perfringens*** • ***Aspergillus*** • ***Staphylococcus Aureus***
Rutala *et al.* (1991) Ayliffe *et al.*(1992)	• ***Staphylococcus Aureus*** • **Anaerobic**
Ulualp *et al*. (2000)	• ***B. stearothermophilus*** • ***Aspergillus*** • ***S. aureus*** • **Hepatitis B virus**

CHARACTERISTICS OF INCLUDED STUDIES

No randomized clinical trials or studies with rigorous methodology were found that met the inclusion criteria.

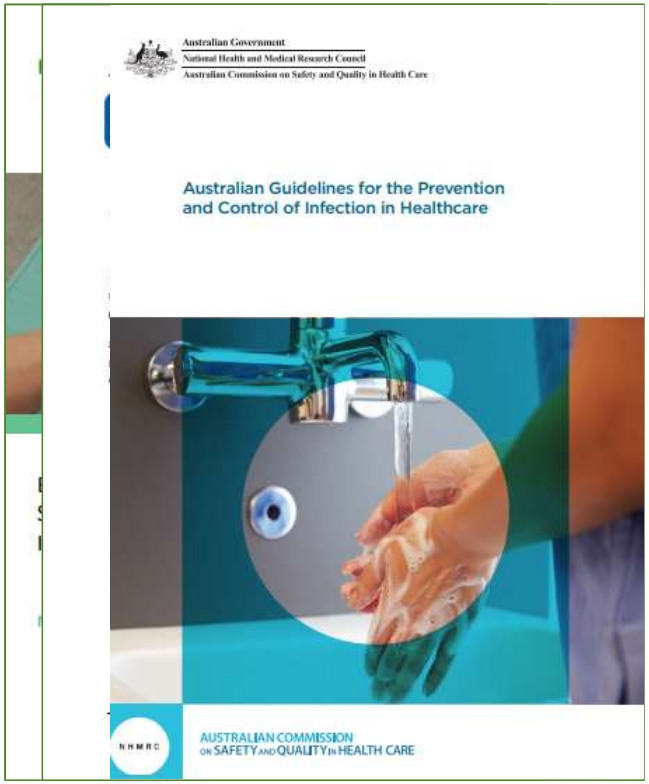
It was not possible to make a statistical synthesis by means of a meta-analysis.

Ulualp et al. (2000)
Reuse

Critical medical devices → **Sterilize** → **Wide margin of safety**

Thermosensitive high turnover expensive → **Disinfect** → **Intrinsic resistance to glutaraldehyde Mycobacteria**

Huezo *et al*. (1983)
Stearns *et al.* (1983)
Rutala *et al* (1991)
Ayliffe *et al.* (1992)
Ulualp *et al.* (2000)



Standard disinfection and sterilization procedures have demonstrated **efficacy and effectiveness** in reprocessing reusable medical devices even when they are contaminated with multidrug-resistant microorganisms such as *Mycobacterium tuberculosis*.

It is recognized that this efficacy and effectiveness is affected only when the devices are potentially contaminated with prions, infectious agents that cause diseases such as Creutzfeldt-Jakob.

Rutala *et al*. (2015) mentions that several researchers have reported the in vitro efficacy of glutaraldehyde solutions at 2% or more; however, he lists a series of microorganisms with which relative resistance is reported: *M. chelonae* , *Mycobacterium avium-intracellulare* , *Mycobacterium xenopi* , *Methylobacterium* , *esophilicum* , *Trichosporon* , ascospores of fungi for example, *Microascus cinereus* , *Chaetomium lobosum and Cryptosporidium* .

Rutala W, Weber D. Guideline for disinfection and sterilization in healthcare facilities, 2008 [Internet]. 2019. Available at : https://www.cdc.gov/infectioncontrol/guidelines/disinfection/
Ling M, Ching P, Widitaputra A, Stewart A, Sirijindadirat N, Thu L. APSIC guidelines for disinfection and sterilization of instruments in health care facilities. Antimicrobial Resist Infect Control. 2018;7(1):25.
World Health Organization. Decontamination and Reprocessing of Medical Devices for Health-care Facilities [Internet]. 2016. Available at: https://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1&isAllowed=y

Tosh *et al.* (2011)	10,48%	Artroscopia	*Pseudomona aeruginosa*	Flash	Restos de tejido, no Flash
Ramesh *et al.* (2003) India	8 casos	Ginecológicos	*Mycobacterium tuberculosis (3)*	Glutaraldehído 20 min	Revaluar
Jain *et al.* (2005) Reino Unido	Un caso	Colecistectomía	No reporta	Vapor	Desensablar Desaprobado Glutaraldehído
Rajini *et al.* (2005)	Un caso	Ginecológica	*Mycobacterium chelonae*	Glutaraldehído 30 min	Desinfectante agua
Villar *et al.* (2015) Brasil	3000	Laparoscopio	*Mycobacterium abscessus*	Glutaraldehído 30 a 60 min	ANVISA 2009 prohíbe

Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, et al. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009. Infect Control Hosp Epidemiol. 2011;32(12):1179-86.
Ramesh H, Prakash K, Lekha V, Jacob G, Venugopal A, Venugopal B. Port-site tuberculosis after laparoscopy. Surg Endosc. 2003;17(6):930.
Jain S, Stoker D, Vathianathan R. Port-site tuberculosis following laparoscopic cholecystectomy: a case report and review of literature. Indian J Surg. 2005;67(4):205-6.
Rajini M, Prasad S, Reddy R, Bhat R, Vimala K. Postoperative infection of laparoscopic surgery wound due to Mycobacterium chelonae. Indian J Med Microbiol. 2007;25(2):163.
Villar GB, de Mello Freitas FT, Ramos JP, Campos CED, de Souza Caldas PC, Bordalo FS, et al. Risk factors for Mycobacterium abscessus subsp. bolletii infection after laparoscopic surgery during an outbreak in Brazil. Infect Control Hosp Epidemiol. 2015;36(1):81-6.

Critics = Sterilize

American National Standard

ANSI/AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities

AAMI

Critics = Sterilize

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

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LIMITATIONS

- Only articles available in **English, French, Portuguese and Spanish** were included .
- The included studies **lack a rigorous methodology**, **only one** reported **effect measurement.**
- The most recent study included is from **2000**.
- Some of the non-systematic reviews do not list the complete information from **their primary studies.**
- Conflict of interest is **declared** by one of the researchers.

This review was registered with Cochrane on September 6, 2021 under registration number COCHRANEPHAHS-2021-00048. It is not possible to continue with the process as the issue is not adjusted to its current scope, given that they are channeling their limited resources to the priority issues in the processes that are already advanced.

It is evident that **rigorous methodological studies** are needed.

It is important that **governments** encourage this type of research.

The decision to sterilize or high-level disinfect laparoscopes and arthroscopes has been related **more to factors** other than their **intended use as a critical medical device**.

It is necessary to adhere to the **manufacturer's recommendations** to avoid premature deterioration of medical devices and to follow the cleaning, decontamination, disinfection and sterilization protocols of the institutions.

Outbreaks or pseudo -outbreaks related to the use of laparoscopes and arthroscopes have **increased**; however, the **short postoperative follow-up** of these surgical procedures makes it difficult to determine their origin.

The fact that some laparoscopes and arthroscopes are **temperature sensitive** does **not justify** using only high-level disinfection as an alternative to reprocessing.

Thank you…
Gracias…

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