Supplementary material

Supplement Methods 1 Survey for the economic assessment of duodenoscope reprocessing

Scope: Interventional use of the duodenoscope for a patient managed with a reusable medical device with automated washing according to current recommendations [specify storage methods].

Exclusion: treatment by low temperature sterilization with hydrogen peroxide is not included because of the dimensional characteristics of duodenoscopes (length and internal diameter of the lumens of the ducts); for which only treatment by ethylene oxide could be recommended (see FDA). However, this treatment is no longer recommended for hospital sterilization in France.

Explanatory flowchart

Please see Figure 1

AER: Automated Endoscope Reprocessing machine; HC: healthcare. Microbiological control: controls (with consumables and human resources) of the duodenoscope, the water, the endoscope drying cabinet, and the room environment.

References used:

- The technical guide for the treatment of endoscopes from the DGOS
- Instruction No. DGOS/PF2/DGS/VSS1/2016/220 of July 4, 2016, on the treatment of flexible heat-sensitive endoscopes with channels within healthcare facilities

General data:

- Name of the establishment:
- Organization of endoscope treatment:
  - o Centralized unit for the establishment: YES – NO
  - o Gastroenterology satellite unit: YES – NO
- Treatment with Automated Endoscope Reprocessing (AER) machine: YES – NO
  - o If YES, number of AER
- Heat-sensitive endoscope drying cabinet (EDC): YES – NO
  - o If YES, number of EDC:
- Number of annual endoscope treatment cycles in the unit:
- Number of annual duodenoscope treatment cycles:
- Number of duodenoscopes in operation in the center:
- Number of annual duodenoscope uses
  - o Diagnostic purpose:
  - o Interventional purpose (ERCP):

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1. Treatment costs (direct costs):

a. Consumable supply costs:

Stage	Consumable supply used	Quantity	Unit price (including tax)	Total
1. Pre-treatment				
Wiping	Compress/absorbent pad			
Rinsing	Water used (quality to be defines)			
Packaging	« Red » bags (cap/envelope)			
Personal protective equipment	Single use gloves			
	Glasses			
2. Preliminary stage automated washing				
Immersion	Detergent			
	Water			
Channel irrigation	Syringe			
	Water used			
Sheath wiping	Compress/ absorbent pad			
Swabbing	Single use swabs			
Extremity brushing	Brushes			
Personal protective equipment	Single use gloves			
	Glasses			
	Single use apron			
3. Automated washing				
First rinsing	Water (volume consumed)			
Disinfection	Disinfectant			
Second rinsing	Bacteriologically controlled water (volume consumed)			
Automatization	Electricity consumed			
Drying				
Personal protective equipment	Single use gloves			
	FFP2 mask			
	Glasses			
4. Packaging	« Green » bag (cap/envelope)			
	Nonwoven drape			
Personal protective equipment	Single use gloves			
5. Storage				

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b. Cost of mobilized human resources:

Stage	Who/qualification	Time spent	Weighted cost
1. Pre-treatment			
2. Preliminary stage automated washing			
3. Automated washing			
4. Drying-Packaging			
5. Storage			
6. Provision			
7. Controls before use			

2. Indirect and associated costs

a. For the microbiological control of duodenoscopes

Consumable cost	Consumable used	Quantity	Unit price (including tax)	Total
1. In-situ control	Collection vial			
	Sterile swab			
	Disinfecting alcohol			
	Sterile gloves			
2. Laboratory control	B code from the biological procedures' classification			
	?			

Cost of mobilized human resources	Who/qualification	Time spent	Weighted cost
Collection			
Transport			
Analysis			
Decision			

b. For the microbiological control of the treatment unit environment

Consumable cost	Consumable used	Quantity	Unit price (including tax)	Total
1. In-situ control	Collection vial			
	Sterile swab			
	Disinfecting alcohol			
	Sterile gloves			
3. Laboratory control	?			
	?			

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Cost of mobilized human resources	**Who/qualification**	**Time spent**	**Weighted cost**
Collection			
Transport			
Analysis			
Decision			

c. For the microbiological control of associated equipment

These costs will be weighted by:

- ✓ On the one hand, according to the number of controls carried out (for duodenoscopes it is recommended to perform a quarterly control at least, and, if necessary, at each maintenance return)
- ✓ on the other hand, according to the duodenoscope occupancy ratio of the automated washing equipment and cabinets

Consumable cost	**Consumable used**	**Quantity**	**Unit price (including tax)**	**Total**
Automated washing	*DGOS Guide for automated washing, 2003*			
1. In-situ control of automated washing	Collection vial			
	Sterile swab			
	Disinfecting alcohol			
	Sterile gloves			
2. Laboratory control	IVDR (in-vitro diagnostic medical devices)			
	Other consumables			
Cost of mobilized human resources	**Who/qualification**	**Time spent**		**Weighted cost**
Collection				
Transport				
Analysis				
Decision				
Enceinte	*ARLIN Pays de Loire Guide 2015/ Reco SF2H-SFED 2011*			
1. In-situ control	Agar plate/culture media			
	Collection vial			
	Sterile swab			
	Disinfecting alcohol			
	Sterile gloves			
2. Laboratory control	IVDR			
	Other consumables			
Cost of mobilized human resources	**Who/qualification**	**Time spent**		**Weighted cost**
Collection				

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Transport			
Analysis			
Decision			

d. Purchase and maintenance costs

For duodenoscopes: the costs are to be calculated on the annual basis of the number of uses per endoscope in relation to its average life span
For automated washing equipment and cabinets: the costs are to be weighted by the percentage of use dedicated to duodenoscopes.

1. Duodenoscope				
Purchase cost	Endoscope			
	Accessories			
	Warranty			
Training costs	Biomedical staff			
	Users			
Maintenance costs	Other consumables			
	Replacement parts			
	Service			
	Troubleshooting assistance			
Average life span of the medical device				
2. Automated washing	*Quality control of automated washing Université de Technologie de Compiègne 2006 guidelines* *http://www.utc.fr/master-qualite/public/publications/qualite_et_biomedical/UTC/dess_tbh/03-04/projets/chaussende_loheal/main%20Clateau%20CH%20Comp.htm*			
Purchase cost	Endoscope			
	Accessories			
	Warranty			
Training costs	Biomedical staff			
	Users			
Qualification costs				
Annual requalification costs				
Maintenance costs	Consumables			
	Replacement parts			
	Service			
Average life span of the medical device				

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3. EDC	*High Council of Public Health Recommendations, 2013*			
Purchase cost	Endoscope			
	Accessories			
	Warranty			
Training costs	Biomedical staff			
	Users			
Qualification costs				
Annual requalification costs				
Maintenance costs	Consumables			
	Replacement parts			
	Service			
Average life span of the medical device				

e. QMS implementation costs

Referential: GREPHH

The costs to be estimated are

- the drafting and revision of specific procedures related to the treatment of duodenoscopes,
- practice audits.
  - o Basic audit
  - o Maintenance audit
  - o EDC audit

- And recordings based on the tools « traca-test »

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Supplement Table 1 Items considered for the cost of an endoscopic retrograde cholangiopancreatographies, in the survey-based and the theoretical approaches

Item	Survey-based approach	Theoretical approach
Duodenoscope (purchase, maintenance)	Evaluated	Evaluated
Automatic endoscope reprocessor (purchase, maintenance)	Not evaluated	Evaluated
Endoscope Drying Cabinet (purchase, maintenance)	Not evaluated	Evaluated
Microbiological controls	Evaluated	Evaluated
Reprocessing (consumables, human resources)	Evaluated	Evaluated
Overheads	Evaluated	Evaluated
Post-procedural treatment due to duodenoscope-related infections	Not evaluated	Not evaluated
ERCP-related infections	Not evaluated	Not evaluated
Disposal (biohazard)	Not evaluated	Not evaluated
Downtime due to breakdown or maintenance	Not evaluated	Not evaluated
Storage	Evaluated	Evaluated

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Supplement Table 2 Consumables and operation time for duodenoscope reprocessing considered for the modeling cost assessment

Step	Description	Consumables	Time (minutes)
Preliminary treatment	Wiping	Hand towels	around 5
	Aspiration insufflation		
Leak test	Connection inflation	Water	
	Immersion		
		Non sterile disposable gloves	
	Deflation		
1st cleaning	Tray with detergent	Water – Non sterile disposable gloves	≥ 10
		Detergent	
	Swabbing	Swabs	
	Brushing	Brush	
1st rinse	Irrigation rinse	Standard care water	around 3
		Syringe	
		Or tubing to disinfect	
2nd cleaning	Immersion	Tray (for disinfection)	≥ 5
		Water	
Disinfection	Immersion	Disinfectant	3
		Water	
		Tray to be treated after use	around 2
Final rinse	Soaking blowing	Sterile disposable gloves	around 3
		Biologically controlled water	
		Sterile tray or disposable sheet	
		Tray to be treated after each use	around 2
Drying	Blow	Sterile disposable gloves	around 3

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Supplement Table 3 Number of microbiological controls considered for the modeling cost assessment

Device	Number of microbiological controls (per year)
Duodenoscope	6
Water	5
EDC	4
Room environment	4

EDC: Endoscope Drying Cabinet

Supplement Table 4 Costs of purchase and maintenance considered for the modeling cost assessment

Device	Purchase cost	Product life cycle	Purchase cost (per year)	Maintenance cost (per year)
Duodenoscope	€30,000	4 years	€7,500	€6,000
AER	€30,000	6 years	€5,000	€6,000
EDC	€26,000	8 years	€3,250	€1,700

AER: Automated Endoscope Reprocessing machine, EDC: Endoscope Drying Cabinet