Statement of the European Society of Gastroenterology and Endoscopy Nurses and Associates: European Curriculum for endoscope reprocessing

1. Introduction

Flexible endoscopes are reusable, complex medical devices with numerous lumens and narrow channels. Due to their thermo labile construction and complex design, they require especially trained and competent staff. Appropriate reprocessing of flexible endoscopes and endoscopic accessories are an essential part of patient safety and quality assurance in GI endoscopy.

Since the late 1970s there have been sporadic reports of nosocomial infections linked to endoscopic procedures [1-3]. The majority of documented cases were caused by noncompliance with national and international guidelines (including inadequate reprocessing, drying or storage of endoscopes and endoscopic accessories). Damages, design limitations, contaminated water and EWD were also reported [1-3].

Since the early 2000, infections due to multidrug-resistant organisms (MDROs) have increasingly become a concern in health care. Since 2010, reports of individual cases and outbreaks of MDRO associated with ERCP have been published in the United States of America and Europe (3,4). In addition, there have been cases and series of outbreaks that have only been reported to national regulatory bodies in the respective countries.

The qualification and competencies of the reprocessing staff is a key issue in infection prevention, patient and staff safety.

Therefore, ESGENA developed a European Core Curriculum for reprocessing flexible thermo labile endoscopes.

2. Staff requirements for endoscope reprocessing:

To ensure appropriate and safe endoscope reprocessing, the following staffing requirements should be considered (3--7):

- Dedicated staff: Only specially trained and competent personnel should carry out the reprocessing of endoscopic equipment and this applies both to routine as well as emergency endoscopy.
- Sufficient number of trained and competent staff
- Sufficient time to allow appropriate reprocessing of endoscopes and accessories.
- As the design of endoscopes varies depending on the type of endoscopes and manufacturer, it is essential that staff is familiar with the design and construction of all equipment in order to ensure safe and satisfactory cleaning and disinfection. This also includes loan endoscopes.
- A formal officially recognized training is recommended, followed by competency assessment.
- Regular practice and updated training are essential to maintain competency.
- Initial training, regular updates and regular competency assessment should be documented for endoscopy and reprocessing staff.

- Regular audits should be performed in order to assess compliance with guidelines and to identify any lack of competence or inconsistent attitudes at an early stage.
- If any lack of knowledge or malpractice are identified, immediate actions (e.g. corrections, additional training) should be implemented followed by a re-assessment of competencies.

3. Aims of this European Curriculum

The aims of this Core Curriculum are:

- to improve patient and staff safety in Endoscopy
- to empower nurses and other health care workers working in Endoscopy units and Central Sterilization Service Departments (CSSD)
    - to set standards for the reprocessing of endoscopes and endoscopic devices prior to each individual procedure; whether performed in endoscopy centers, hospitals, private clinics, ambulatory health centers, medical offices and other areas where flexible endoscopes are used;
    - To expand their specific knowledge, skills and competencies necessary for reprocessing of flexible endoscopes and endoscopy related equipment
    - to improve / optimise reprocessing of flexible endoscopes
- To support national nursing societies, official bodies and course organisers
    - to:provide educational opportunities for staff reprocessing flexible endoscopes and endoscopic equipment
    - to promote a recognized qualification for reprocessing flexible endoscopes and endoscopic equipment
    - to advance the professional status of nurses and other health care workers working in Endoscopy units and Central Sterilization Service Departments (CSSD)
- To establish equivalence of training and consequently support free movement within the EU

4. Methodology

The curriculum has been developed by the **ESGENA Education working group**
The curriculum is based on the consensus of nurses

- who have previously been involved in the development of the ESGENA European Core Curriculum for Endoscopy Nurses and the European Job Profile for Endoscopy Nurses
- who have experience in nurse education and the organization of national and local courses for endoscopy nurse education.
- who have been involved in the development of national and international guidelines in hygiene and infection control.

The curriculum is based on

- The ESGENA Job Profile (5)
- The ESGENA Core Curriculum on Endoscopy Nursing (6)
- On the ESGE-ESGENA position statements on Hygiene and infection control (3,4,7)
- national guidelines and curricula for training in endoscope reprocessing (e.g. Germany, NL: UK)

5. Target group

This curriculum is aimed to train health care workers

- working in Endoscopy department and Central Sterilization Service Departments (CSSD)
- involved in the reprocessing of flexible endoscopes and its components

who reprocess flexible endoscopes and their components.

6. Entry Requirements

Staff attending these courses should be nurses or other health care workers who

- Have a formal vocational training in health care that includes basic hygiene and infection control principles, according to national regulations/law
- Be able to speak and write fluently in the national language
- Be able to read, understand and interpret instructions
- Have the right attitude to comply with hygiene and protocol-based approaches to practice
- Have the aptitude and ability to understand and undertake complex technical tasks
- Be able to work independently or as part of a multidisciplinary team
- have a high level of communication and organizational skills, including record keeping

Staff without any formal vocational training within the national health system needs to have additional training in basic hygiene and infection control.

7. The teaching and learning environment

The setting in which courses take place varies from country to country depending on the national health and education systems. The following criteria need to be met (6):

- Theory should be provided at institutes of education or education centres at hospitals
- Theory must be applied to clinical practice in a supervised clinical environment, which must include support from a mentor.
- The educational setting (both the institution and the practical area) must be conducive to learning and encourage critical thinking and discussion.
- The educational setting should follow the principles involved in adult education (e.g., constructivism).

8. Teaching Staff

The teaching staff should be competent in their areas of teaching, both in theory and in practice. Suggested teachers are:

- Endoscopy nurses
- Experts in hygiene and infection control (e.g. Specialist Nurses, Microbiologists, Hygienists, etc)
- Lawyer or legal adviser to cover legal and professional issues
- Other personnel as deemed relevant by the course management team
- Clinical Mentor(s)/Assessor(s) in the student's own department.

9. Course Content

The course consists of 6 different modules. The suggested number of hours results in a 3 days course for nurses from Endoscopy departments and other health care workers who have a formal vocational training in health care

In various European countries vocational training exist for CSSD staff. This course can be included as an Endoscopy specific module in these training concepts.

Module 1: Basics of hygiene, epidemiology and microbiology

Aim of this Module	The aim of this module is to increase the knowledge of • hygiene, infection control and microbiology as well as • prevention strategies for infection transmission
Learning outcome	The students shall have recognize and describe the terms of • hygiene, epidemiology and microbiology • colonization of microorganisms on body surface and different organ systems • routes of transmission of infections • inactivation methods of microorganisms
Content of module	Epidemiological terms • e.g. contamination, colonization, infection, nosocomial infection, infectious disease, incubation period, source of infection, chain of infection, types of transmission, Principles of Microbiology • microorganisms relevant for Endoscopy (their nature, growth, habitat / occurrence, transmission) • endogenous and exogenous routes of infections in Endoscopy • relevance of healthcare acquired infections in endoscopy and national health care systems , including multidrug resistant germs Principles of the decontamination process, with special consideration of: • The complex construction of endoscopic equipment • The methods and agents used
Application	• Competent and correct use of terms relevant to reprocessing of medical devices, hygiene and infection control • Understanding of medical background related to reprocessing of flexible endoscopes • Correct use of health and safety measures and prevention strategies in daily routine
Number of hours	3 hours
Method	Theory

Module 2: Occupational health and safety

Aim of this Module	The aims of this module are • to update the knowledge and skills relevant to health and safety issues in reprocessing medical devices. • to develop strategies for a safe and ergonomic working environment
Learning outcome	The students shall able • to list occupational hazards • to explain and demonstrate how to set up a safe and ergonomic environment in reprocessing of medical devises • to demonstrate appropriate measurers and first aid in emergency situations The students shall be able • to list staff protection measures relevant to endoscopy, including hand hygiene, PPE) • to describe how to manage chemical spillages • to demonstrate aspects of accountability towards self, patient, profession and employer
Content of module	• Potential risks to staff and patients related to endoscope reprocessing • Health and safety concerns regarding reprocessing in endoscopy (chemicals, ergonomics, latex, hazardous substances, etc.) • Hand hygiene • Personnel protection measures in endoscopy • Vaccination • Sharp instruments • Chemical Spillage Management • Waste management in endoscopy
Application	• Use of protection measures for staff, patients and environment • Taking appropriate action to protect patients, self and other members of the team from potential harm
Number of hours	4 hours
Method	Theory and practice

Module 3: Structural requirements for Endoscope Reprocessing units

Aim of this Module	The aim of this module is to familiarize with the structural requirements for endoscope reprocessing, including space, facilities and staff
Learning outcome	The students shall be able to describe • The architectural and technical requirements for endoscope reprocessing areas • The number and qualification of staff necessary to ensure safe reprocessing • Organization and logistics of routine and emergency endoscopy services
Content of module	Separate purpose designed reprocessing rooms with clear separation of dirty and clean areas and equipment, including e.g. • Adequate facilities for manual cleaning • Ventilation/Extraction facilities • Availability of personal protective equipment • Washer-disinfectors • Drying cabinets • Safe storage of chemicals Staff requirements, organisation, logistic and workflow of endoscope reprocessing units in daily routine and for emergency endoscopy service
Application	Competent organisation and correct workflow of endoscope reprocessing
Number of hours	3 hours
Method	Theory

Module 4: Design, construction and use of endoscopes and its components and Accessories

Aim of this Module	The aim of this module is to introduce the construction and principles of • flexible endoscopes and its accessories • washer disinfectors • drying/ storage cabinets
Learning outcome	The student shall be able to describe the construction, function, intended use application, potential malfunction and hazards of : • flexible endoscopes and their accessories • washer disinfectors • drying/ storage cabinets The student shall be able to describe specific measurers for damage prevention
Content of module	Classification of medical devices relevant to Endoscopy • Spaulding classification • Endoscope product families Principles for the design, use, storage and maintenance of • flexible endoscopes (3 endoscope families) • endoscopic accessories • washer disinfectors • drying/ Storage cabinets Material science Damage prevention
Application	Competent use, reprocessing; maintenance and storage of endoscopic equipment
Number of hours	4 hours
Method	Theory + practice

Module 5: Standardised and validated reprocessing of flexible endoscopes and its accessories

Aim of this Module	The aim of this module is to provide specialist knowledge and skills concerning the reprocessing of flexible endoscopes and its accessories
Learning outcome	The student shall be able to demonstrate appropriate reprocessing procedures including cleaning, disinfection, storage, transport and traceability of flexible endoscopes
Content of module	Standardised and validated reprocessing cycle for flexible Endoscopes • Bedside cleaning and functional tests • Transport of contaminated endoscopes and accessories • cleaning methods – manual and automated • Disinfection of endoscopes – manual and automated • Water system and water quality control • Drying and storage of endoscopes and its accessories – manual and automated • Function control and final release ready for use • Occupational health and safety issues • Different formats and systems for documentation and traceability for endoscope reprocessing • Transport and packaging systems for clean endoscopes and accessories ready for use • Opportunities to sterilize flexible endoscopes Characteristics, function and use of • endoscope washer disinfectors • Automate disinfection devices Characteristics, function and use of process chemicals and their composition • Detergents • Disinfectants • Health and safety aspects Potential weaknesses, deficiencies, mistakes • in the overall reprocessing cycle • in the use of endoscope washer disinfectors • in the use of drying / storage cabinets
Application	Competent reprocessing, maintenance and storage of endoscopic equipment
Number of hours	8 hours
Method	Theory + practice

Module 6: Validation and routine testing of standardised reprocessing cycles for flexible endoscopes and its accessories

Aim of this Module	The aim of this module is to provide specialist knowledge and skills concerning validation and routine testing of standardised reprocessing cycles for flexible endoscopes and its accessories
Learning outcome	The student shall able to describe principles of • the validation of reprocessing procedures for flexible endoscopes according to EN ISO 15883 • routine tests including microbiological surveillance The student shall able to describe principles of collecting samples from flexible endoscopes and its accessories for microbiological surveillance and their relevance
Content of module	• validation of reprocessing procedures for flexible endoscopes according to EN ISO 15883 • routine tests including microbiological surveillance • sampling of flexible endoscopes and its accessories for microbiological surveillance
Application	Competent assistance in sampling of flexible endoscopes and their accessories for microbiological surveillance Competent support of validation procedures
Number of hours	2 hours
Method	Theory + practice

10. Assessment of theory and practice

Several methods can be used for the formative and summative assessment of theory and practice (Table 1).

Table 1: Methods available for the assessment of theoretical and practical parts of endoscopy sedation courses

	Assessment of:		Assessment of:	
Assessment Methods	**Groups**	**Individuals**	**Theory (oral or written)**	**Practice**
Standardized cases	X	x	X	x
Direct observation of practice	X	X		X
Oral examination		X	X	
Diary of practice +/- reflective practice/ self-assessment		X	X	X
Practical examination	X	X		X
Quiz	X		X	
Web-based examinations	X	X	X	
Statement of competence from authorized persons		X		X
Written examination (e.g., multiple-choice questionnaire, case study)	X	X	X	

Practical examination of clinical practice is recommended in the form of direct observation of practice, debriefing / analytical reflection with a sign-off of the nominated and approved mentor.

11. Evaluation of courses

At the end of each course students and teachers should evaluate the delivered course with regard to

- Content being relevant to the individual students needs and their place of work
- Quality of the Delivery of the course
- Quality of the Learning environment
- Teacher and Mentor support
- Clinical Service Provider support

12. Accreditation of courses

The course organizers should seek official recognition by national societies and/or official bodies.

13. Implementation of courses

This European curriculum can be a guidance to develop or update a national curriculum:

- If there is no national / local course for sedation management in GI endoscopy available in the country, national teams should be established to plan, implement and monitor courses.
- If courses have already been established, national or local teams should evaluate the existing courses in the light of this European Curriculum.

14. Review Date

2024 - 5 years from publication date

15. Glossary

Assessment

Formative assessment is the assessment *for* learning. Formative assessment is an ongoing process during the whole unit of study to determine a student's knowledge and skills, identifying learning gaps as well as progress during the learning process.

Summative assessment is characterized as assessment *of* learning. It made at the end of the learning process to determine and document the level of understanding the student has achieved. It includes a mark or grade against an expected standard.

Practical hours.

Clinical experience under individual or group supervision with the aim of furthering practical skills.

Theoretical hours.

The study time taken to teach or learn the theory of subjects.

16. References

1. Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol 2006;12:3953–64
2. Kovaleva J, Peters FTM, van der Mei HC, Degener JE. Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy. Clin. Microbiol. Rev. 2013, 26(2): 231-254
3. Beilenhoff U, Blum R, Bierung H, et al. 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. Endoscopy 2018; 50: 1205–1234
4. Beilenhoff U, Biering H, Blum R, et al. Prevention of multidrug-resistant infections from contaminated duodenoscopes: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA). Endoscopy **2017**; 49: 1098-1106
5. U. Beilenhoff et al. ESGENA Statement: European Job Profile for Endoscopy Nurses. Endoscopy 2004;36:1025–30.
6. European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA). ESGENA Core Curriculum for Endoscopy Nursing. 2008. www.esgena.org
7. Beilenhoff U, Biering H, Blum R, et al. ESGE-ESGENA technical specification for process validation and routine testing of endoscope reprocessing in washer-disinfectors according to EN ISO 15883, parts 1, 4, and ISO/TS 15883-5. Endoscopy **2017**; 49:1262-1275

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