Endoscopy Center Designand Practice

Considerations for effective processes and good infection control practices



Hong Kong Hospital Authority Advanced Course for Infection Control Nurses - November 2017

Learning Objectives



 Describe key considerations in design and process to establish a new endoscopy center

2. Understand key infection control requirements

3. Review characteristics of robust quality control program

4. Review metrics for staffing, procedures and processes

5. Identify controversial issues

Janet Prust - Disclosure

Employee of 3M Health Care Infection Prevention Division

Association for Advancement of Medical Instrumentation (AAMI) Positions held:

AAMI Board of Directors – Director representing industry since 2015 Member:

AAMI Finance committee

Sterilization Standards Committee

WG 61: Chemical sterilants hospital practices – co-chair

WG 84: Endoscope reprocessing

WG 40: Steam sterilization hospital practices

WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13

WG 93: Cleaning of reusable devices

Sterilization of endoscopes stakeholders group

Task group – HVAC conditions in OR



What is the type of reusable medical device responsible for more exogenous patient infections than any other?

Answer: Flexible endoscopes

ECRI Top 10 Patient Health Technology Hazard since 2013.



Image source: Google images

Key Requirements for Endoscopy Center Success



- Trained, qualified, caring endoscopists, nursing staff and assistive personnel
- 2. Properly functioning and maintained equipment and medical devices
- 3. Adequately designed and equipped space
 - Patient preparation, procedures and recovery
 - Endoscope reprocessing
 - Administrative functions
- 4. Welcoming, calm environment
- 5. Robust quality assurance and continuous quality improvement program
- 6. Trained personnel and equipment
 - Ability to perform cardiopulmonary resuscitation or other emergency intervention

Endoscopy Center Establishment Process - Initial

Business Case

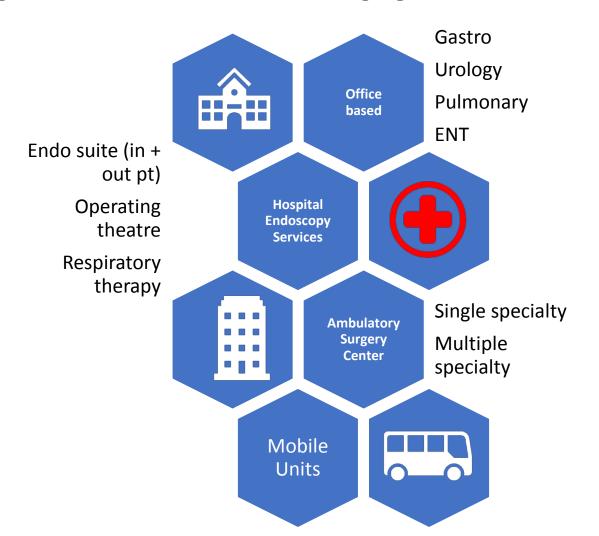
Facility needs and requirements

Design and costing

Regulatory and certifications

Staffing, equipment, policy

Types of Endoscopy Facilities



- All types of facilities require high level of quality procedures and support functions
- Comfortable and private patient environment
- Compliant with all regulations
- Provide a safety environment for patients and staff.

Regulations

Government

National and local (most interested in infection control aspects)

Licensing and credentialing requirements

Physicians, nursing, facility + staffing

Certification requirements for reimbursement

- Private insurers
- 3rd Party certification bodies, e.g. JCI

Practice guidelines and standards

Other

- Trade laws
- Employment and employee safety laws
- Privacy laws
- Building codes, e.g. HVAC, fire protection, earthquake protection, etc.



- Regulatory requirement
 assessment is completed as part
 of business plan and through out
 development, construction and
 implementation.
- Regulations and auditing bodies may vary based on location

Certifications - Types and Focus Areas

Patient-related functions

- Patient rights
- Organization ethics
- Assessment of patients
- Care of patients
- Education of patients and family
- Continuity of care

Organization functions

- Standards for organization improvement
- Leadership
- Management of the environment of care
- Human resources
- Information technology
- Surveillance, prevention, and control of infection.

Designing the Facility

The endoscopy unit should have enough space to accommodate people, activities, and growth. Procedure room space will depend on the planned activity, with more complex cases generally taking place in larger rooms to accommodate more equipment, supplies, storage, and staff.

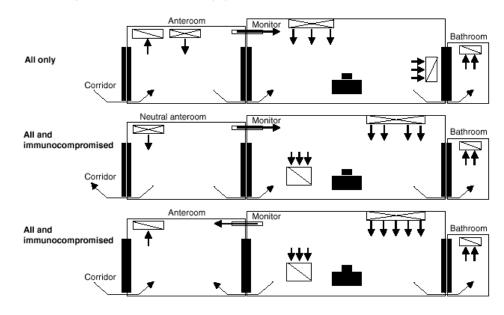
- Facility reception and waiting area
- Preparation/recovery areas
- Procedure rooms endoscopy area
 - 1:1 to preparation room
- Restrooms
- Support area
 - Separate soiled, clean, storage areas for endoscopes (aka utility areas)
 - Separate environmental cleaning storage area and EVS staff central area
 - Other supplies (e.g. medications, single use, linens, office etc.)
 - Food preparation/storage
- Staff and administration area (e.g. lockers/restrooms and lounge/lunch room)
- Education and training area/ conference room



Designing the Facility - continued

- Utility requirements
 - HVAC
 - Electricity
 - Water
 - Data and communications
- Life and Safety systems
 - Sprinklers and fire alarms
- Waste management
 - Medical waste
 - General waste
 - Recyclable waste
 - Soiled linen

FIGURE 2. Example of airborne infection isolation (All) room with anteroom and neutral anteroom



Source: Used with permission from Andrew J. Streifel, M.P.H., University of Minnesota.

Note: Top diagram indicates airflow patterns when patient with only airborne infectious disease occupies room. Middle and bottom diagrams indicate recommended airflow patterns when room is occupied by immunocompromised patient with airborne infectious disease. Stacked black boxes represent patient beds. Long open boxes with cross-hatches represent supply air. Open boxes with single, diagonal slashes represent air exhaust registers. Arrows indicate directions of airflow.

- *All isolation room with anteroom engineering features include
- pressure differential of 2.5 Pa (0.01-in. water gauge);
- airflow differential >125 cfm supply versus exhaust;
- · sealed room with approximately 0.5-sq. ft. leakage;
- · clean to dirty airflow;
- · monitoring;
- ≥12 air exchanges/hr (ACH) new or renovation, 6 ACH existing; and
- · anteroom airflow patterns

Source: Guidelines for environmental infection control CDC 2003)

Exercise: Calculate # of Procedure Rooms

Volume calculator for Endoscopy Unit

| ected me | Annual # procedures | 1500 |
|----------------------------------|-----------------------------|------|
| | Annual operation days | 230 |
| Capacity /room | Work hours | 6 |
| | Average procedure time | 30 |
| | Aveage room turnaround time | 20 |
| Number of Procedure Rooms Needed | | 3.8 |

Typical Procedure times:

Upper GI: 15 min

Colonoscopy: 30 min

ERCP: 45 min

EUS: 45 min

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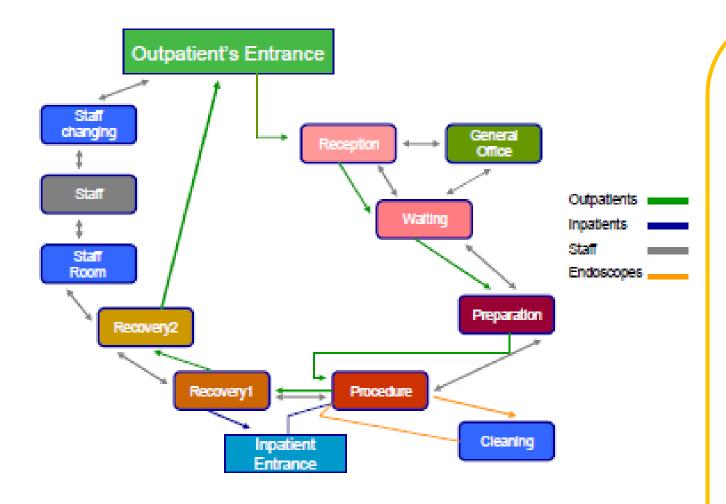
Information Management Systems

Consideration: Access, procedures and storage + security



- Patient identification bar code
- Electronic medical records/ EHR
- Scheduling and billing
- Compliance records
- Reprocessing records
- Medication security (e.g. bar code and tracking)
- Surveillance records

Patient and Staff Flow - Hospital Endoscopy Unit



Note: Diagram overview of flow. Additional areas recommended.

Unidirectional flow contributes to both efficiency, productivity and safety

- Separate entrance for OP vs.
 IP
- Staff areas separate and not accessible by patient of family
- Separate prep and recovery areas
- Security
- Clear signage

Facility Design Examples

Create a pleasant environment

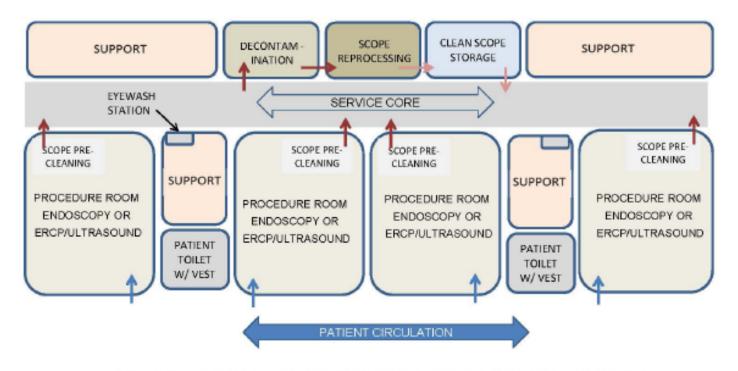
- Consider "patient/ public" area and "service/staff" area in design and flow
- Parallel corridors
- Consider finishes aesthetic look and feel but durable surfaces that help inhibit microbial growth/easily and effectively cleaned
- Minimize "institutional" image
- Aesthetic lighting, e.g. wall sconce instead of overhead light in recovery area
- Sound proofing to create quiet environment in private areas and away from service noise
- Ergonomic design for staff



Source: Guidelines for designing a digestive disease endoscopy unit: Report of WEO (5)

Example – Parallel Corridor Design

Facilitate controlled areas



ENDOSCOPY SUITE DETAILED FLOW WITH TWO OR MORE PROCEDURE ROOMS

Preparation Area

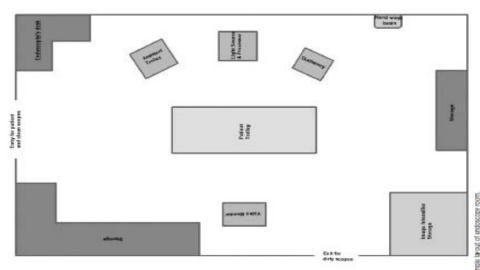
- Adjacent to main waiting area
- Privacy with lockers to change and store street clothes
- Accommodate wheel chairs
- Adjacent to private restrooms
- Separate private waiting area if patients not taken directly into procedures room



Patient Procedure Room

- Accommodate trolleys
- Minimum size of 6 x 5 m
 Larger space for ERCP procedures
- Adequate space for interventional procedures
- Adequate space for anesthesia services
- Adequate supplies for procedure plus
- Should not open to public area or high traffic corridor
- Adjacent to recovery area
- Separate entrances for clean and soiled equipment movement
- Positive pressure ventilation
- Medical gas systems
- Direct access to the reprocessing area
- Space and supplies for endoscope pre-cleaning activities.
 - May be in adjacent area or alcove



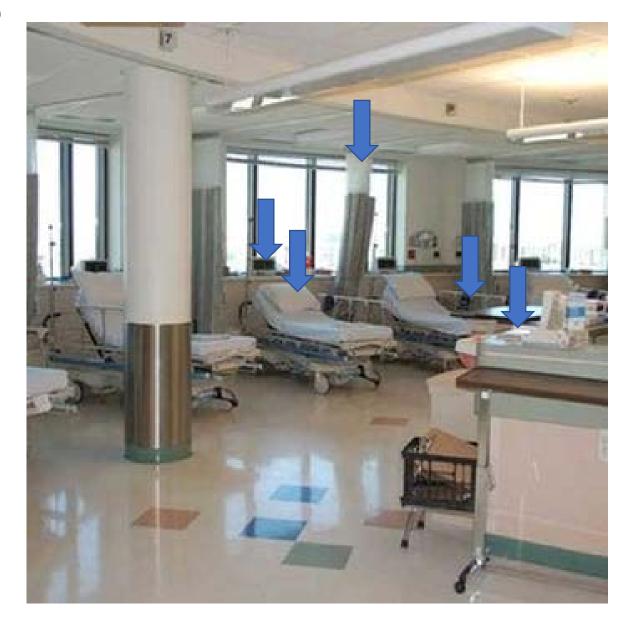


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Recovery Area – 1st Stage

<u>Immediate post procedure</u>

- Accommodate trolley and chair for escort
- Curtained / privacy with each area curtained
- Clear and easy visualization by staff
- Service outlets, oxygen and medical vacuum
- A patient/staff call system
- Pulse oximetry monitoring



Recovery Area – 2nd Stage

Patient + family area

- Open design with staff station central and readily visible
- Seating for family
- Light snacks and refreshments available
- Light music / pleasant background sound



General Considerations Reprocessing Area

Design

- 1. Work flow
- 2. Patient volume (current and anticipated)
- 3. Number and types of endoscopes/equipment
- 4. Quantity and type(s) of processing equipment

- Scopes/equipment storage requirements
- Supply/chemical storage requirements
- 7. Traffic flow
- 8. Required utilities (e.g., medical-grade air, water quality, ventilation)



Endoscope Reprocessing Area

Separation of contaminated from clean and storage areas

Dirty Area

- Adequate space for transport and storage of soiled endoscopes
- Physically separated from Clean area
 - Pass through to clean area
- Negative pressure air flow
- PPE supplies
- Cleaning supplies and storage
- Minimum double, preferable triple sink
- Counter space and equipment for leak testing
- Inspection area and equipment
- Cleaning verification equipment
- Disinfectant concentration testing supplies
- Separate hand wash sink
- Separate emergency eye wash sink
- Pass through AER

Clean Area

- Positive pressure HVAC system
- Drying equipment
 Medical grade air and accessories
- Adjacent to the storage area



Staffing and Staff Considerations

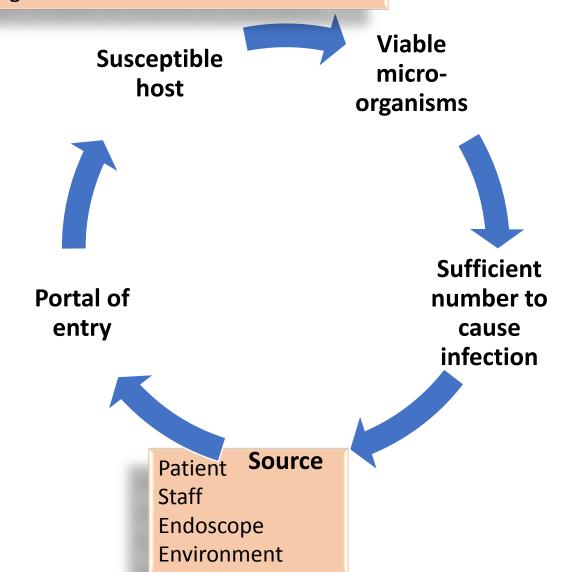
Endoscopy staff can facilitate or prevent patient to patient transmission



- Adequate staffing to manage procedure volume
- Clear designation of roles and responsibilities including IP or liason
- Meet required credentials and/or certifications
- Contentious
- Caring
- Diligent
- Good team member
- Proactive training and issues

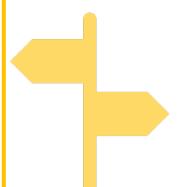
Endoscopy Chain of Infection

Endoscopy unit presents challenges related to source of infections



Measures to Disrupt the Chain of Infection

- 1. Effective cleaning, disinfection, and sterilization of medical equipment; Single use devices should NOT be reprocessed
- 2. Correct use of PPE
- 3. Good staff personal hygiene
- 4. Adequate engineering controls (e.g., ventilation, room design, non-contaminated water supply)
- 5. Effective cleaning and disinfection of environmental surfaces
- 6. Adequate administrative control and support
- 7. Training and continuing education
- 8. Adequate written standardized operating procedures
- 9. Documentation



Culture of Safety

Quality Assurance is dependent on promoting a culture of patient and staff safety



- Quality assurance is dependent on promoting a culture of patient safety
- All members of the GI team are engaged in infection prevention measures
- Supervisors and other leader model this culture
- Staff are empowered
- Staff understand their role
- Benchmarking and quality metrics are defined
- Frequent training occurs and competencies assessed
- Process are audited
- Results are tracked and communicated to staff

Endoscopy Infection Control Program Components



- 1. Culture of safety
- 2. Effective hand hygiene program
- 3. PPE and attire program
- 4. Endoscope and equipment reprocessing
- 5. Medication administration
- 6. Communication devices in GI lab
- 7. Robust Quality Control and Risk Management program
- 8. Post discharge surveillance
- 9. Response to failures

Clean, concise written policy and procedures are required to establish IC program expectations.

Infection Prevention Policy Implementation and Maintenance



- Must be available and accessible to staff at all times.
- Must be reviewed annually and updated according to institutional policy.
- IPs, supervisors and facility leaders must remain current on new guidelines or instructions, regulatory agencies, professional organizations, or manufacturers.

Hand Hygiene

Apply standard precautions in procedure room:

- Before patient contact
- Before clean/aseptic procedures
- After body fluids exposure risks (even if gloves are worn)
- After touching a patient
- After touching a patient's surroundings

- Strategic placement of hand hygiene equipment, increases compliance by personnel.
 - Sinks
 - Soap dispensers
 - Paper towel dispensers
- Alcohol-based foam dispensers should be conveniently located to permit good hand hygiene practices.

Personal Hygiene and Occupational Policy

Policies and procedures on hand hygiene should be developed and communicated to employees to include:

- Approval by infection prevention personnel or the designated employee health personnel.
- Fingernails should be kept short and clean and should not extend beyond the fingertips.
- Artificial nails, including gels, extensions or tips, acrylic overlays, or other enhancements should not be worn
- Develop specific policy regarding the use of nail polish, including clear nail polish;
 - the issue remains unresolved and requires further study.

- All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering.
- Jewelry and wristwatches should not be worn in the processing area.

Staff should be offered vaccinations

Rationale: Careful attention to hand hygiene can minimize the potential for acquiring or transmitting disease. Artificial nails can promote the growth of fungus under the nails. Careful attention to hand hygiene can minimize the potential for acquiring or transmitting

Source: ANSI/AAMI ST91:2015.

Performance Indicators for Measuring Hand Hygiene Compliance



- Periodically monitor and record adherence of hand hygiene by direct observation.
- Monitor the volume of alcohol-based hand rub used in a dispenser.
- Monitor adherence to policies related to wearing of artificial nails and the length of nails

Personal Protective Equipment (PPE)

Specialized clothing or equipment that does not permit blood or other potentially infectious material to pass through clothing or into skin, eyes, or mouth when worn by an employee as protection against hazard or spread of infection



Required PPE

- Gloves to protect hands
- Gowns to protect skin and/or clothing including long sleeves
- Masks to protect mouth/nose;
- Respirators to protect respiratory tract from airborne infectious agents;
- Goggles/eye shields to protect eyes
- Face shield to protect face, mouth, nose, and eyes
- Head and shoe covers to protect

Effective use of PPE includes proper removal and disposal of contaminated PPE to prevent exposure to infection among both the GI staff and others. Staff must demonstrate competency in donning and removing the PPEs.

Source: ASGE 2008, FDA 2015, OSHA 2012

Attire – Reprocessing Area



Required Attire

- Staff should change into clean uniforms that are provided by and donned at the facility
- Change attire daily or more often as needed (i.e., when wet, grossly soiled, etc.)
- Reusable uniforms should be laundered by a health care-accredited laundry
- Shoes should be clean, have non-skid soles, and be sturdy enough to prevent injury if an item drops on the foot
- Liquid-resistant shoe covers should be worn if there is potential for contamination
- Use of cover apparel when leaving area to travel to other areas of the health care facility
- Change into street clothes when they leave the health care facility or going between buildings

Bloodborne Pathogen Policy

Develop and implement an "exposure control plan" describing employee protection measures to include the following actions:



- Standard precautions
- Proper use of protective clothing and equipment;
- Provision of training;
- Offer of Hepatitis B vaccination
- Implementation of controls such as safer medical devices (e.g., needleless system, sharps containers).

Bloodborne pathogens are infectious microorganisms that can cause disease in humans. These pathogens include Hepatitis B, Hepatitis C, and HIV. Health care workers are at risk for exposure to bloodborne pathogens (OSHA, 2012).

Special Considerations

Known infectious/isolation patients presenting with *Clostridium difficile*, tuberculosis, Vancomycin-Resistant *enterococci* (VRE), carbapenem-resistant *enterobacteriaceae* (CRE), and other infections:

- Require specific IP procedures, e.g. meticulous handwashing using soap and water (not alcohol-based hand sanitizers)
- Rigorous / enhanced cleaning of the environment with an EPA-registered hospital disinfectant
 of all surfaces fallow care of patients with known pathogens
- Restrict room access following procedures with suspected or known airborne transmitted illness (e.g. tuberculosis) (AORN, 2015).
- Personnel should be proactive, familiar with facility policies and guidelines
- IP to establish possible scenarios and procedures
- Patient parasitic or vermin infestations (e.g. head lice, scabies, or bed bugs.) require special precautions to prevent spread of infestations
- Be aware of community outbreaks

Source: SGNA 2017

Environmental Decontamination

Recommendations:

- Develop written policies and procedure for routine and non-routine cleaning and/or disinfection of the environment.
- Staff must were PPE
- Management is responsible for ensuring proper procedures are followed.
- Blood and other potentially infectious materials should be promptly cleaned up.
- Contaminated items should be discarded in compliance federal regulations.
- Policy to include processes for handling specimens, contaminated wastes, and linen
- Disinfecting non-critical patient care surfaces should be done between each patient and when visibly soiled with a EPA registered hospital disinfectant.
- When available, use disposable equipment on patients with contact precautions.

Communications Devices in the GI Setting

- Cell phones, tablets, other personal communication and/or hand-held electronic devices equipment and their accessories
- Clean/disinfect with a low-level disinfectant according to the manufacturer's instructions before and after being brought into the endoscopy setting.
- Wash before and after each use in the GI setting.

Source: SGNA 2017, ASGE2008.

Environmental Cleaning – Reprocessing Area

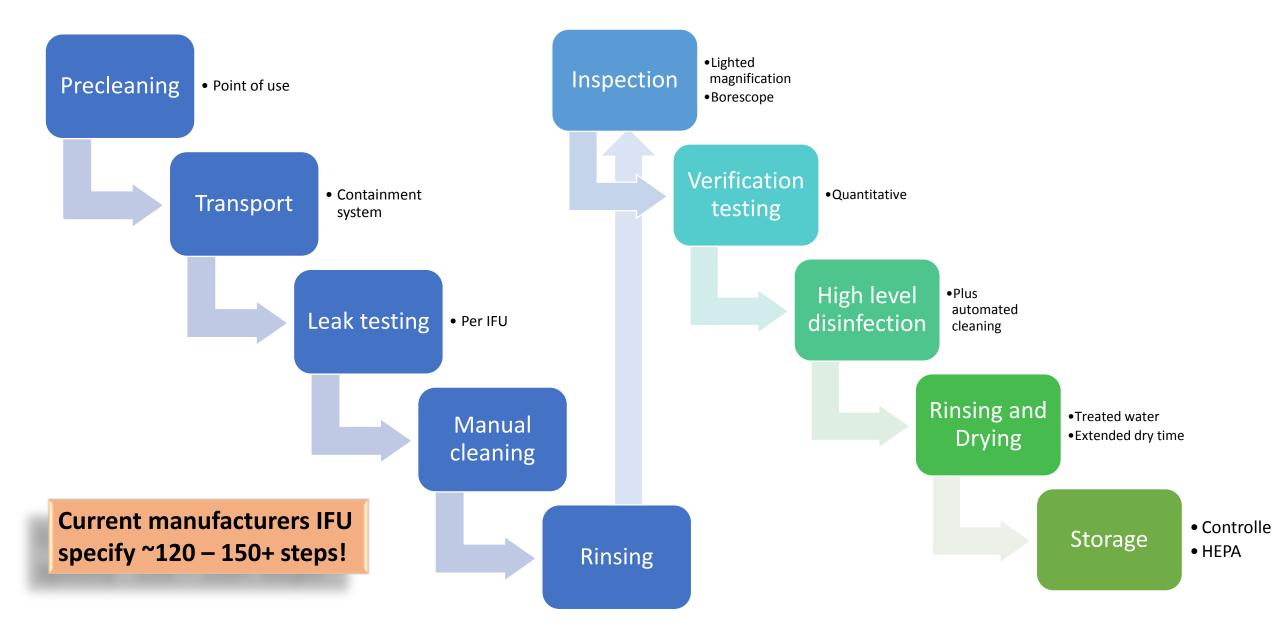
Environmental cleaning and disinfection procedures in areas used for any aspect of patient care, decontamination, preparation, or sterilization should ensure a high level of cleanliness at all times.

- Floors and horizontal work surfaces should be cleaned at least daily
- Walls, storage shelves, endoscope storage cabinets, and air intake and return ducts, should be cleaned
 on a regularly scheduled basis and more often if needed
- Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired.
- Light fixtures or covers should be cleaned regularly (weekly or monthly)
- Avoid contaminating patient-ready devices copes or compromising the integrity of packaging during cleaning.
- Observe sequence of cleaning to avoid transferring contaminants from "dirty" to "clean" areas and surfaces.
- Provide separate storage areas for environmental cleaning supplies for the decontamination and clean areas.
- Establish written policy and procedures
- Have available and follow current IFU for all products used

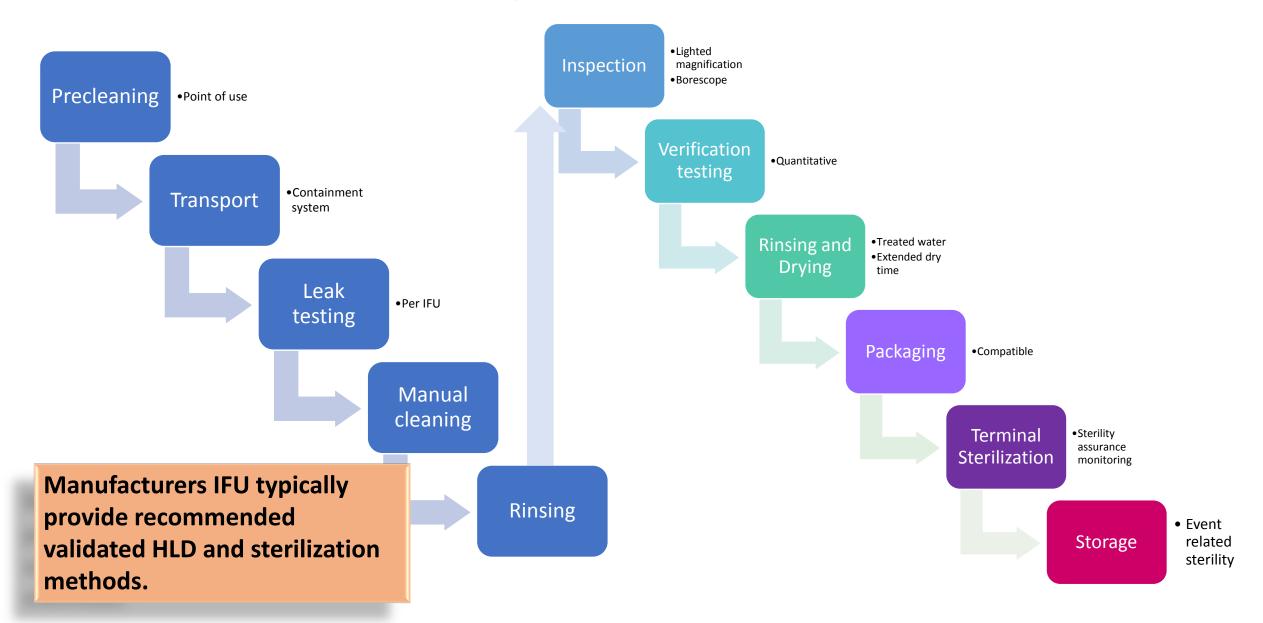


Source: ANSI/AAMI ST91:2015.

Endoscope Processing Steps – High Level Disinfection



Endoscope Processing Steps – Terminal Sterilization



Microbial Surveillance of Endoscopes



Guideline recommendations

- ESGE/ ESGENA- Minimum every three months
- ASGE/ Multisociety: Consider monthly for duodenoscopes
- GoSA: Varies based on scope type; monthly for high risk. Included monthly testing of AER and Water
- APSIC: Periodic surveillance
- Periodic surveillance of duodenoscopes recommended by US CDC 2015, 2017
 - Controversial
 - Lack of validated method and requires environmental culture
 - Frequency
 - Questions on validity
 - Method does not detect all pathogens
 - CDC Recommendation is 1x/mo or after 60 procedure
- AORN 2016 and SGNA 2017
 - Recommend to conduct a risk assessment
 - May be considered in event of an outbreak
 - Can be used as a method for assessing quality of reprocessing or defects in endoscopes
- AAMI 2015: No guidance; 2018 TBD

Length of Storage Time for HLD endoscopes







General storage recommendations

- Clean, dust free environment and free of microbial contamination; made of material that can be disinfected
- Should not be stored in procedure room
- Wet endoscopes should be reprocessed before use
- Liquid chemical sterilant systems are JIT reprocess before use

Varying evidence recommendations presented in 10+ studies

Guideline recommendations

- SGNA: 7 days; storage cabinet
- AORN: Perform risk assessment; suggest drying cabinet
- ASGE: references SGNA and reprocess before use for therapeutic procedure
- ESGE/ ESGENA: HEPA filtered, humidity controlled drying cabinet
- AAMI: Perform risk assessment
- Australia: Drying cabinet
- APSIC: HEPA filtered drying cabinet
- APIC: Cystoscope maximum 5 days; other types no recommendation

Medication Administration



Safe injection practices

- No reuse of syringes or needles
- Single use drug vials
- Sterile gloves
- Appropriate site prep
- Needlestick prevention practice
- Documentation
- Standard precautions

Appropriate PPE

- Face shield and masks
 - Protection from splashes and aerosols

Training and Competency Assessment

Infection prevention education and adherence is critical

All personnel (physicians, nurses, assistive personnel must complete a comprehensive orientation and training program:

- Core components
- Standard precautions
- Personal protective equipment
- Patient privacy
- Quality system requirements

Reprocessing:

- Training on reprocessing reusable medical equipment
- Only performed by trained, qualified staff
- Temporary staff only allowed after competency
- Vendor-provided training should be conducted by manufacturer Clinical Educators.
 - Sales reps should provide documented competency
 - Training must be completed on each type and brand of endoscope

Quality Assurance Measures



Elements:

- Supervision
- Training and annual competency review
- Assuring the availability of appropriate equipment and supplies
- Procedures for reporting lapses and infections

Reprocessing:

- Quality Assurance of Endoscope Reprocessing
- IP in reprocessing is crucial to patient safety
- Numerous infections/outbreaks tied to contaminated endoscopes

Quality Assurance and Quality Control

Documentation must be generated and maintained:

- Each procedure date and time
- Patient's name and medical record number or identifier
- Endoscopist's name
- Endoscope model and serial number or other identifier
- Start and end time of pre-cleaning
- AER or Sterilizer model, serial number, load or other identifier
- Names of staff reprocessed the endoscope

Other documentation essential for infection control:

- Information and audit results of reprocessing activities
 - Should be shared with reprocessing staff
- Equipment performance and maintenance records
- MEC test results of high-level disinfectants



Risk Management / Assessment

Perform risk assessment to ensure that:

- All essential steps of reprocessing are met and maintained
- Precleaning occurs at the point of use and transported safely to the reprocessing area
- Staff competencies are verified
- Sufficient staffing when routine and/or emergency procedures are performed

- Manufacturer's IFUs are readily available and followed
- Necessary reprocessing equipment/ supplies are available
- Physical space is adequate for reprocessing
- HVAC parameters are monitored and controlled
- Storage of endoscopes is appropriate
- Documentation providing complete traceability is maintained

Post Discharge Surveillance



- Not commonly performed
- Implemented when know breach or outbreak
- Not mentioned in current guidelines
- No good prospective studies
- Patient screening focuses on bloodborne pathogens when exposed to contaminated devices
- Patient screening focused on specific organisms in outbreak situations

Response to Failure in Infection Prevention

Facilities should have written protocols or policies to address patient exposure to potential infections including roles and responsibilities to report



- All infections related to endoscopic procedures should be reported to :
 - Infection prevention;
 - appropriate health agencies as required;
 - FDA if US manufactured equipment
 - the manufacturer of the equipment, reprocessing supply item ,or accessory in question (Rutala et al.,
- Breaches with serious potential infection risks should be reported to facility leadership
- Affected individuals are notified
- Investigation should trace the source of infection to the specific patient(s)
- Deficiencies are corrected
- Process improvements monitored to ensure maintained

Reference Videos

https://www.youtube.com/watch?v=3FbOSSsu58U

FDA - March 2010

https://www.youtube.com/watch?v=FCiVReLvSU8

AAMI Dec 2016

https://www.youtube.com/watch?v=14ceHIS- Hs

The Johns Hopkins Hospital Endoscope Suite 2012

https://www.youtube.com/watch?v=7KWsBdZMEnA

Olympus Reprocessing Instructions Oct 2015

https://www.youtube.com/watch?v=1RicPF9e65E NHS Endo Service - UK

Summary

- 1. Designing and endoscopy center is a complex process with many design considerations
- 2. Risk of infection in endoscopy centers is an important consideration in design and implementation
- 3. Infection control policy should be established and maintained
- 4. Reprocessing of endoscopes is a complicated process and close adherence to on-going training, monitoring and auditing should be conducted.
- 5. Quality assurance metrics and a quality control program can help mitigate risk

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- 16. O'Horo, J. C., Farrell, A., Sohail, M. R., et al. (2016). Carbapenem-resistant Enterobacteriaceae and endoscopy: An evolving threat. Am J Infect Control 44, 9: 1032-6.

Thank you for your time and attention!