GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES

The Guideline for Processing Flexible Endoscopes has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective February 1, 2016. The recommendations in the guideline are intended to be achievable and represent what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative or other invasive procedures may be performed.

Purpose

This document provides guidance to perioperative, endoscopy, and sterile processing personnel for processing all types of reusable flexible endoscopes and accessories. Recommendations are provided for design and construction of the endoscopy suite as well as for controlling and maintaining the environment to support processing activities. Guidance is provided for maintaining records of processing for traceability and for quality assurance measures related to processing flexible endoscopes and accessories.

Patients have a right to undergo endoscopic procedures in a safe, clean environment where personnel adhere to consistent, evidence-based practices for processing every flexible endoscope every time care is provided. It is essential that the risk of patient-to-patient transmission of infection via flexible endoscopes be minimized as much as is reasonably possible.

Infections related to endoscopy procedures may be caused by endogenous microorganisms that colonize the mucosal surfaces of the gastrointestinal or respiratory tract and gain access to the bloodstream or other sterile tissues as a consequence of the procedure.[1] Endogenous infections include infections such as cholangitis that may occur after endoscopic procedures of the biliary tract or pneumonia that may occur after endoscopic procedures of the respiratory tract.[1]

Infections related to endoscopy procedures may also be caused by exogenous microorganisms that are transmitted from previous patients or from the inanimate environment by contaminated endoscopes or accessories.[1] The US Food and Drug Administration (FDA) has identified two recurrent themes as contributing to persistent bronchoscope contamination and transmission of exogenous infection:

- a failure to meticulously follow the manufacturer's written instructions for processing and
- the continued use of bronchoscopes despite issues with integrity, maintenance, and mechanical problems.[2]

If flexible endoscopes are not correctly processed, exposure to body fluids and tissue remnants from previous patients may result in the transmission of pathogens to large numbers of subsequent patients.[3] In a systematic search of the literature to clarify the epidemiology of *Klebsiella* species in endoscopy-associated outbreaks, Gastmeier and Vonberg[4] found that insufficient processing was the main reason for subsequent pathogen transmission. The authors concluded that strict adherence to guidelines for processing flexible endoscopes in combination with alertness to the potential for pathogen transmission after endoscopy procedures was required, and that additional studies were needed to determine the true risk of pathogen transmission via flexible endoscopes.

Because of the many different types of flexible endoscopes and the differences in flexible endoscope construction, not all steps discussed in this guideline (eg, leak testing) will apply to all endoscopes; however, some steps (eg, manual cleaning) will apply to all flexible endoscopes. The European Society of Gastrointestinal Endoscopy (ESGE) has proposed a classification of endoscope families[5] based on similar characteristics, including the number, construction, and purpose of the different endoscope channels and their clinical applications.

- Group 1 endoscopes are typically intended for use in the gastrointestinal tract. This group includes endoscopes that have air/water channels, have an instrument/suction channel, and may have an additional instrument or waterjet channel. Examples of Group 1 endoscopes are gastroscopes, colonoscopes, and duodenoscopes with an encapsulated elevator channel.
- Group 2 endoscopes are also intended for use in the gastrointestinal tract. This group includes endoscopes that have air/water channels, have an instrument/suction channel, and may have an additional instrument channel. Group 2 endoscopes also may have an elevator channel and up to two control channels for balloon functions. Examples of Group 2 endoscopes are duodenoscopes with an open elevator channel, echoendoscopes used for endoscopic ultrasound, and enteroscopes.
- Group 3 endoscopes are used in bronchoscopy, otorhinolaryngology applications, gynecology, and urology. This group includes endoscopes with only one channel system for biopsy, irrigation, and suction or endoscopes without any channel. Examples of Group 3 endoscopes are bronchoscopes, cystoscopes, laryngoscopes, and nasendoscopes.

In addition to following the guidance provided in this document, it is critically important for individuals who are responsible for processing Group 1, 2, or 3 flexible