



Investigating Reasons of Positive Surveillance Rate of the Flexible Endoscope in the Operation Room

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Abstract

Flexible endoscopes are semi critical medical devices since they encounter mucous membranes during the diagnostic and therapeutic procedures. Due to the sophisticated design of flexible endoscopes with long and narrow lumens, they are difficult to clean and disinfect. This difficulty would be an infection source for patients underwent flexible endoscopes related procedures. This investigation proceeded to understand the reasons induced positive surveillance rate in a medical center in Taiwan. Reasons include three aspects

1. Personnel aspects include incorrectness of manual cleaning process, Insufficient cleaning process education and training and without special-assigned staff in charge of flexible cleaning duty.
2. Environmental issues include improper storage space, and the endoscope storage cabinet has no temperature and humidity detection and cleaning and disinfection.
3. Operational elements involve lacking washing machine; staffs misinterpreted OPA concentration test, OPA test strip validity period was incorrectly marked, Flexible endoscopes and storage boxes did not precede terminal disinfection procedure regularly.

Since the advanced technology of flexible endoscopes is on the cutting age, the potential infection resources should be resolved for nosocomial infection control and patient safety reasons. Creating a holistic program to reduce the positive surveillance rate on every single potential reason would be the next achievement efforts toward patient safety and nosocomial infection control.

Introduction

The number of inspection procedures performed by endoscopes increasing year by year as innovative endoscopic technology. New challenges in infection prevention of proper post-treatment, disinfection, and accessories is a key to the patient safety of endoscopes procedures are raising [1]. Literature indicates that reprocessing endoscopes according to the manufacturer's reprocessing guidelines results in a low risk of transmitting microbes to patients, but any deviation during reprocessing can lead to microbial survival and increased infection risk [2-4].

Flexible endoscopes are semi-critical medical devices since they encounter mucous membranes during the diagnostic and therapeutic procedures. Due to the sophisticated design of flexible endoscopes with long and narrow lumens, they are difficult to clean and disinfect. Plus high-level disinfection reprocessing method destroying microorganisms except for spores, contaminated flexible endoscopes are the most frequently among medical devices [5]. For most reported shows multi-antibiotics resistant microorganisms found, most of the outbreaks are missed.

The reprocessing quality of flexible endoscopes plays the crucial role in infection control since most of the breakouts of flexible endoscopes related to breaches in the reprocessing process. Major reprocessing of flexible endoscopes includes cleaning, high-level disinfection, rinsing and drying then storage [6].

Status Analysis

In November 2014, the one of medical center hospitals in Taiwan established the "Ultrasonic and Endoscope Management Team" to integrate cross-team continuous monitoring quality indicators to create a patient-centered and safe environment to enhance service quality.

The positive rate of the flexible endoscope from September to November 2017 was 14% of the

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operation room. The manager did not establish a safety standard reprocessing process of the flexible endoscopes. This investigation aimed to find out the positive rate of flexible endoscopes in the operation room and based on the investigation to set up the reprocessing and storage guidelines of flexible endoscopes in the operation room in the further quality improvement program. Through rigorous and correct safety management to reduce the bacterial positive surveillance rate of flexible endoscopes to achieve the hospital philosophy of "improve medical quality, and fulfill social responsibility."

Characteristics and workforce configuration of the operation room

From January to September 2017, there were 27 operating rooms in 14 specialties. The total number of operations performed was 28,896 and the monthly average procedures number was 3210. There is 126 nursing staff in the operating room, with under 2 years working experience staffs are 59 (46.8%), 3-5 years working experience staffs are 31 (24.6%), over five years working experience staffs are 36 (28.6%), and an average working experience was six years.

Reprocessing process of flexible endoscope

"Ultrasonic and Endoscopy Management Team" was established in November, 2014. After the establishment of the endoscope management team, the disinfection line of the flexible endoscope cleaning process and internal inspection of each component are regularly audited year every year. The audition includes microbial tests.

Endoscope microbial inspection process

The flexible endoscopes are disinfected by high-level disinfection solution and storage in an open space. The less than ten colonies of environmental bacteria are allowed after sterilized by the guidelines.

Results

There are seven flexible endoscopes in total, three choledochoscopes for general surgery, 2 for ureteroscopy and two bronchoscopes. Each department's self-manage flexible endoscope. The storage space of the flexible endoscope of general surgery and urology are at room temperature and the thoracic surgery storage in a cabinet. At the beginning of the manual cleaning process, soaking in the enzyme cleaner for 1 minute, then brush the inner channels under flowing water, draining the air supply/water supply ports of internal channels. Then immersing into Cidex-OPA for 12 minutes.

The infection control center performs flexible endoscopy microbiological surveillance quarterly. The choledochoscopy grown bacteria both on September 29, 2017, and November 3, 2017, the choledochoscopy grew bacteria too. The positive rate of flexible endoscopy in the operating room was 14%.

Five management team members from Infection Control Center inspected flexible endoscopes in the operation room from November 06 to November 10, 2017. The inspection included cleaning and disinfection process and found that the manual cleaning process of the operating room was incorrect (25%), without cleaning machine for flexible endoscopes (25%), improper storage (17.5%), OPA concentration test correctness (17.5%), OPA test strip expiration date Marked (10%), without proper cleaning space (2.5%), fixed cleaning staff (2.5%). In-depth investigations revealed that the flexible endoscopes were not well disinfected at the end, and the endoscope storage cabinets did not monitor temperature and humidity.

As above, we found through the checklist that the main reasons for the positive rate of flexible endoscopes were:

1. Personnel Aspect: The manual cleaning process was incorrect, insufficient, and there was no fixed cleaning staff.
2. Environmental Aspect: improper storage space without temperature and humidity monitoring of flexible endoscopes
3. The operating aspects: hand washing, OPA concentration test, and expiration date were errors. During the period from November 21st to November 30th, 2017, the project team will further understand the exact cause of the long-term positive rate of the flexible endoscopes in the operating room and observe and interview personnel.

The results details are as follows:

Personnel aspects

The manual cleaning process is incorrect: After the observing investigation found that the nursing staff did not wipe the outer sheath twice with enzyme gauze. Moreover, aspirated the enzyme solution to irrigate the inner channels and remove the mucus and blood in the lumen of the endoscope. There was no disinfection step after cleaning the flexible endoscopes and didn't inject 95% alcohol into the lumen, and the outside of the flexible endoscopes was wiped dry.

Insufficient cleaning process education and training: The senior nursing staffs taught new ones how to clean the flexible endoscopes. There was no formal education and training program and didn't understand the purpose and importance of each step. The senior nursing staff said that they taught their new staffs based on their own experience without attending any formal education and training course.

There is no special-assigned in charge of flexible cleaning duty

Through interviews, all nursing staff could clean flexible endoscopes. There is no special-assigned in charge of flexible cleaning duty. Moreover, they cleaned flexible endoscopes based on their experience.

Environmental aspects

Improper storage space: Every single department managed their flexible endoscopes on their own. Through investigation, the flexible endoscopes of general surgery and urology were cleaned and stored directly in the storage cabinet. The storage cabinet contained foam and stored at room temperature.

The endoscope storage cabinet has no temperature and humidity detection and cleaning and disinfection

Through observation, the storage cabinet was in room temperature and humidity without disinfection. During the interview, the nursing staff did not know whether the storage cabinet was clean or not where the endoscope was preserved.

Operational aspects

Lack of washing machine: Due to financial problems and the low using frequency of flexible endoscopes in the operating room, the nursing staff should clean manually instead.

Staffs misinterpreted OPA concentration test: Through the check and interview, it is unclear that the nursing staff preceded the Cidex-OPA concentration test. They didn't know that the Cidex-OPA concentration test paper should be immersed in the Cidex-OPA

solution for 1 second and then interpret color change after the test paper is taken out from the solution for 90 seconds.

OPA test strip validity period is incorrectly marked: Through the check and interview, the employee didn't know about the OPA test strip expired validity period is 90 days.

Flexible endoscopes and storage boxes didn't precede terminal disinfection procedure regularly: After the flexible endoscope was used, it is manually cleaned and dried then placed in the storage cabinet. Until the next patient, it should be disinfected with Cidex-OPA. During the interview, the nursing staff didn't know the importance of terminal disinfection of the flexible endoscopes and storage cabinet.

Conclusion

According to the analysis of the current situation and on-the-spot inspection, the specific factors according to the current situation, and the cause of the positive rate of bacterial culture in flexible endoscopes were as follow

Personnel aspects

1. The manual cleaning process was incorrect,
2. The education and training of the cleaning process were insufficient.
3. There cleaning personnel were unprofessional

Environmental aspects

1. The way the endoscope is stored is incorrect
2. The endoscope storage was without cleaning and disinfection temperature and humidity monitoring.

Operational process

1. No washing machine,
2. OPA concentration test error,
3. OPA test paper expiration date is incorrect,
4. Endoscope and storage box has no terminal disinfection.

There is no reason to compromise the endoscope reprocessing procedure, cross-contaminated would be an issue in clinical practice. This investigation found personnel, environmental and operational reasons induced bacterial growth in flexible endoscopes. We hope to manage a program to solve this problem in the future. A bacterial free is vital for patient underwent flexible endoscopes diagnostic or therapeutic procedures [7-9].

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