



中國醫藥大學附設醫院
China Medical University Hospital

內視鏡再處理國際規範現況 與展望

中國醫藥大學附設醫院

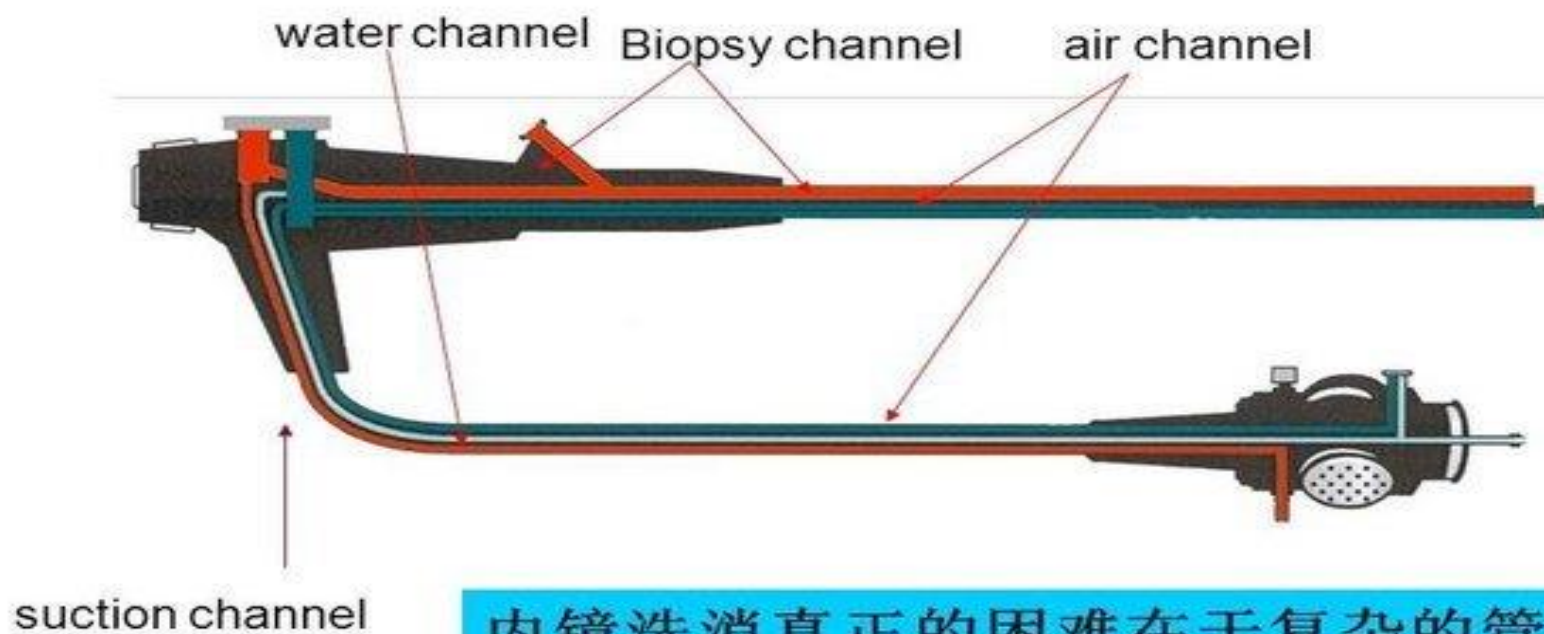
感染管制小組 李桂珠



前言

- 消化道內視鏡是現代醫學中用以預防、診斷或和治療許多消化系統疾病不可或缺的重要工具。
- 消化道內視鏡有著複雜的構造，且重複的使用在不同的病患身上。因此，消化道內視鏡每次使用前的清洗、消毒處理，關係著每一個受查病患的安全。
- 以適當、正確的方式清洗、消毒和滅菌是非常重要的，否則進而造成感染。

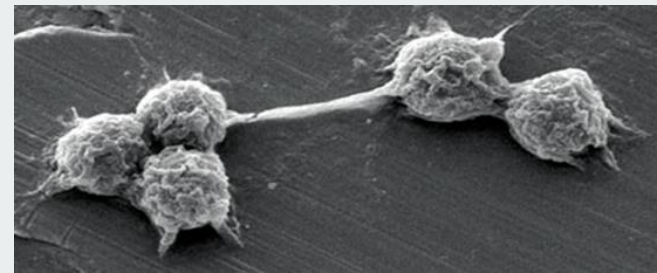
内镜的管道结构



内镜洗消真正的困难在于复杂的管道

內視鏡感染議題

- 內視鏡相關的感染是近幾年的熱門話題。以往只針對病人是否受到**病毒**的感染，但現今因為各種**抗藥性細菌**的出現也使得醫界重新思考內視鏡所導致的相關細菌感染。
- 越來越多的文獻顯示內視鏡的清潔乾淨與否和後續的消毒成效有相關。
- 即便經過適當的再處理的內視鏡可能還是感染之虞。



內視鏡感染議題



University of Pittsburgh

Schools of the Health Sciences Media Relations

"Patient safety is our top priority," said senior author Carlene Muto, M.D. **Hospital**. "We are confident that the change from disinfection to sterilization and we are glad to share our findings with hospitals nationwide."

After tracking and monitoring an uptick in antibiotic-resistant infection **Retrograde Cholangiopancreatography** (ERCP) procedure with flexible scopes which are equipped with an "elevator channel" used to deflect access while examining a patient's gastrointestinal tract. The elevator channel is most commonly used in ERCP scopes.

UPMC took the scopes out of service, notified the manufacturer and began to replace between each use. When it was ultimately determined that the normal practice of gas sterilization using ethylene oxide to ensure proper disinfection of the



NEWS SPORTS LIFE MONEY TECH TRAVEL OPINION 60° CROSSWORDS YOUR TAKE

Deadly bacteria outbreak inflames di

Peter Eisler, 11:25 p.m. EDT March 18, 2015



(Photo: Melissa Brower, AP)

f 772 t 201 in 79 c 36

The contaminated medical scopes linked since 2013 to a series of deadly superbug outbreaks in at least eight hospitals across the country all had been cleaned and disinfected using high-tech appliances cleared by the government to kill the bacteria behind such infections.


The outbreaks in Los Angeles, Seattle, Chicago and other cities infected scores of patients with antibiotic-resistant bacteria, mostly a strain called CRE that has nightmarish mortality rates of 40% or more. And in each case, the hospital relied on an automated endoscope reprocessor, or AER, to disinfect the scopes between uses.

2013年起美國有8家醫院一連串爆發的致死性**超級細菌感染**與污染的內視鏡有相關，即便已使用政府**核可有效的清潔劑**和**消毒劑**



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2015 Top 10 Patient Safety



TOP 8 內視鏡及外科器械再處理不當

ECRI Institute's Top 10 Patient Safety Concerns for 2015

- 1 Alarm hazards: inadequate alarm configuration policies and practices*
- 2 Data integrity: incorrect or missing data in EHRs and other health IT systems
- 3 Managing patient violence
- 4 Mix-up of IV lines leading to misadministration of drugs and solutions*
- 5 Care coordination events related to medication reconciliation
- 6 Failure to conduct independent double checks independently*
- 7 Opioid-related events
- 8 Inadequate reprocessing of endoscopes and surgical instruments
- 9 Inadequate patient handoffs related to patient transport*
- 10 Medication errors related to pounds and kilograms*

MS15138

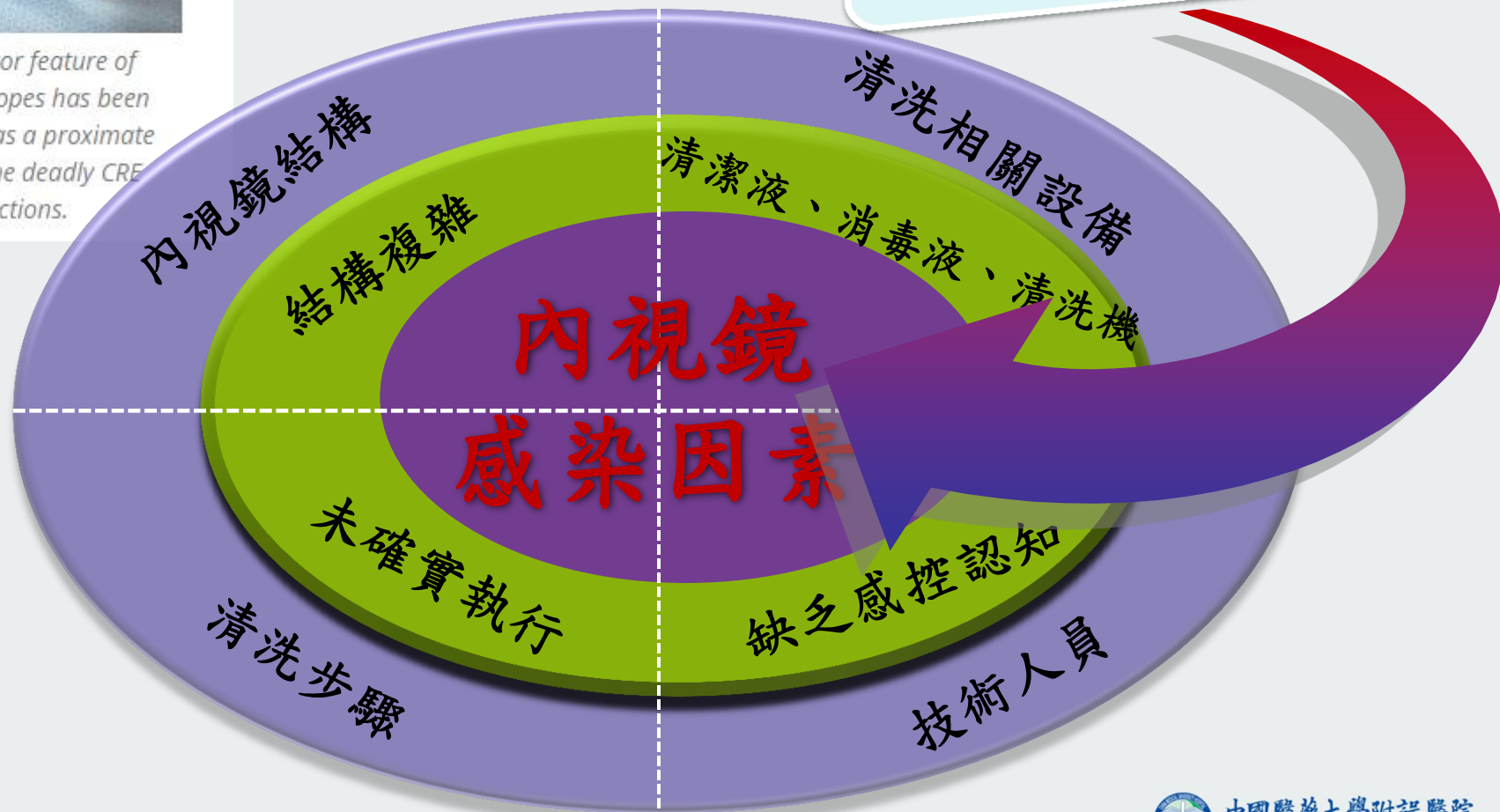
ECRI(2015) . Top 10 Patient Safety Concerns for Healthcare

導致內視鏡感染的相關因素



The elevator feature of duodenoscopes has been implicated as a proximate cause of the deadly CRE infections.

2015 SGNA分析





ASIA PACIFIC SOCIETY OF
INFECTION CONTROL

THE APSIC GUIDELINES
FOR DISINFECTION AND STERILISATION OF INSTRUMENTS IN HEALTH
CARE FACILITIES

Revised Jan 2017



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Reprocessing Endoscope Equipment/Device



Reprocessing Endoscope Equipment/Devices

- **Critical Endoscope:**

- such as joint and **sterile cavities**. ex arthroscope and laparoscope

- **Semic-critical Endoscop:**

- Fiberoptic or video endoscop . ex larygoscope 、 nasopharyngeal endoscope 、 transesophageal probes 、 colonoscopes 、 gastroscopes 、 **duodenoscope** 、 sigmoidoscopes and enteroscope

- Since flexible **Bronchoscopes** and **cytoscope** are entering a sterile cavity ,it is highly recommended that should be sterilized.

Education and Training

- a) **Staff** assigned to reprocess endoscope must receive device-specific reprocessing instructions **to ensure proper cleaning and high-level disinfection or sterilisation.**
- b) Competency testing of personnel reprocessing endoscopes shall be performed **at initiation of employment and at least annually and**
- c) **Temporary personnel** shall not be allowed to reprocess endoscopes until **Competency** has been established.

人員認知

觀察行為◆ %完成步驟的比率◆ (n=69)

➤在乾淨水中完成測漏測試	77
➤完整的拆卸內視鏡	100
➤刷洗所有內視鏡的管腔和零件	43
➤內視鏡完整浸泡在清潔劑中	99
➤零件完整浸泡在清潔劑中	99
➤以清潔劑刷洗內視鏡	99
➤以水沖洗內視鏡	96
➤打入空氣	84
➤放入AER且完成高層次消毒的自動循環	100
➤以酒精沖洗內視鏡	86
➤使加壓空氣以乾燥內視鏡	45
➤再懸吊乾燥前擦拭外表	90

*只有1.4%時間的人工清洗且後續自動高層次消毒是完全符合指引要求的 vs. 75.4% 使用自動清洗和消毒

*45%的時間裡有多個步驟沒執行。

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton
Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors
and Automation. 2010 Gastroenterology Nursing. Vol 33, No. 4, pp.

304-311

Cleaning Procedures

Bedside Clean:**Immediately** following completion of the endoscopy procedure

a)**Flush** and **wipe** the endoscope at point-of-use;

b)Use a Freshly prepared **enzjmatic** Cleaning solution;and

c)Place the endoscope and accessories in a covered,leak proof container with **a biohazard** label and transport to the designated Cleaning area.



前置清潔(Pre cleaning)

- 當內視鏡從病人體內取出後，應立即使用沾有酵素清潔劑的紗布擦拭**內視鏡外部**，並**打氣打水10-15秒讓管腔黏液先排出**，在**抽吸酵素清潔劑**至回流液體呈現清澈為止

Cleaning Procedures

Cleaning:The following steps must be included in the **Cleaning procedure**:

d)Follow the **manufacture's recommendation for Cleaning and Cleaning Products**;

e)Perform leak testing after each use;prior to Cleaning:

i. Verify the potency and integrity of endoscope sheath through **leak testing**,performed prior to,and during,immersion of the endoscop;

漏水測試(Leak testing)

- 確認防水蓋內是否潮濕，如有潮濕應以紗布擦拭後確認是否有無破損及需更換
- 確認防水蓋與電接部是否完全閉合
- 連接測試機(或使用內視鏡自動清洗機)

如有持續性氣泡冒出，代表內視鏡有破損情形，
應立即聯繫內視鏡廠商

Cleaning Procedures

- ii. Perform the **leak test** according to the **manufacturer's instructions**;
- iii. An endoscope that fails the **dry leak test** should not undergo the immersion leak test;
- iv. Soak and manually clean all immersible endoscope components with water and a recommended **cleaning agent** prior to automated or further manual disinfection or sterilization;

Cleaning Procedures

- v. **Disconnect** and **disassemble** endoscope components(e.g.,air/water and suction valves)as far as possible and completely immerse the endoscope and components **in enzymatic cleaner**;
- vi. **Flush** and **brush all channels** and **lumens** of the endoscope while submerged to remove debris and minimize aerosols;
- vii. Ensure that brushes used for Cleaning lumens are of an **appropriate size**,inspected before and after use,and discarded or **Cleaned,high-level disinfectioned** and **dried** following use;

Cleaning Procedures

- viii. Consider **irrigation adaptors** or **manifolds** that may be recommended by the manufacturer to facilitate Cleaning;
- ix. Thoroughly rinse endoscope and all components with **clean filtered water** prior to **disinfection/sterilization** and remove excess rinse water;
- x. Identify damaged endoscopes immediately recover from service;
- xi. Discard enzymatic cleaner after each use;
- xii. **Discard disposable cleaning items** or thoroughly clean and **high-level disinfect/sterilise non-disposable items** between uses.

Special cleaning for doudenoscope

The doudenoscope is complex endoscopic instrument for **ERCP** that features a **specific channel**, with allows the manipulation of a guide wire at the terminal end of this channel .This separate channel is the elevator channel that is complex in design and crevices that are **difficult to access with a cleaning** brush. Outbreaks related to doudenoscope involving CRE and other MDRO have been reported.



Special cleaning for doudenoscope

Meticulously cleaning doudenoscope prior to HLD should reduce the risk of transmitting pathogens but may entirely eliminate it. Thus, it is **important to follow manufacture's instruction to clean** the elevator parts and using appropriate connectors and brushes are also critical to achieve thorough cleaning.

Regular review of staff in the endoscopy unit in the competency of cleaning the doudenoscope is important.

十二指腸鏡

先端可分離式



先端不可分離式



十二指腸鏡 清潔、消毒滅菌標準程序

(一) 取出十二指腸鏡
↓
(二) 前置清潔
↓
(三) 手工清潔-A (先端可分離式) -B (先端不可分離式)
↓
(四) 漏水測試
↓
(五) 高層次消毒
↓
(六) 漂清及乾燥
↓
(七) 存放
十二指腸鏡輔助器械滅菌

Disinfection and Sterilisation

- a) Choose a disinfectant that is **compatible** with the endoscopes
- b) Monitor the efficacy of the disinfectant before each use with test strip available from the product manufacturer;
- c) **Maintain a written log of monitoring test results;**
- d) **Do not use** disinfectant past their expiry date;
- e) Carefully follow the **manufacturer's direction** regarding the ambient temperature and duration of **contact for the** disinfectant (e.g. 2% glutaraldehyde for 20 minutes at 20 °C);

Disinfection and Sterilisation

- f) Completely immerse the endoscopes and endoscope components **in the high-level disinfectant /sterilant** and ensure all channels are perfused;and
- g) Following disinfectant **,rinse the** endoscope and flush the channels with **filtered or sterile water.**

高層次消毒後沖洗

(Rinse after high level disinfection)

- 使用足夠無菌水或過濾水（濾心0.2 μm ）徹底沖洗器械（如2加崙）
- 內腔使用大量水沖洗(>100毫升)，並至少進行3次沖洗，每次至少1分鐘

注意：確實沖洗器械以免殘留溶劑造成病人危害

Special Disinfection and Sterilisation process for doudenscope

To minimize the immediate risk, it is recommended to adhere current endoscope reprocessing guideline with **any one of** the methods for reprocessing doudenscopes (priority ranked)

- a) **Ethylene oxide sterilization** with peroidic microbiologic surveillance.
- b) **HLD done twice** with **peroidic microbiologic surveillance**.
- c) **HLD** with scope quarantine until **negative culture**.

Special Disinfection and Sterilisation process for doudenscope

- d) **Liquid chemical sterilizing** system using **peracetic acid**(rinsed with extensively treats potable water)with peroidic microbiologic surverillance.
- e) Other FDA-cleared low-temperature sterilizing technology(provides material compatibility and sterilizing validation testing perfomed using the sterilizer and endoscope) after HLD,with peroidic microbiologic surverillance .
- f) HLD with peroidic microbiologic surverillance .

Follow US CDC interim protocol,it is recommented to test each doudenscope either **once a month** or **after 60 ERCP** procedured

Biopsy Forceps and Brushes

- Because of **difficulty cleaning** biopsy forceps/brushes, it is strongly recommended that **disposable** items be used.
- Reusable biopsy forceps and brushes that break the mucosal barrier **must be sterilised** after each use.
- Reusable biopsy forceps/brushes must be meticulously cleaned prior to sterilisation using **ultrasonic cleaning**

Drying and Storgage of Endoscope

Steps in final drying of **semi-critical engoscope** include;

- a) Initial flushing of all channels with medical or filtered **air**;
- b) Flushing all channels with **70% isopropy alcohol(IPA)** to aid in the drying process, and
- c) Second flushing of channels with instrument grade air or drying in **a HEAP-filteted drying cabinet.**

Storage procedure must include:

- a) Remove **caps, valves** and other detachable components during Storage and reassemble just before use; close to endoscope in a manner that
- b) Storage semi-critical endoscopes by hanging vertically in dedicated close, ventilated cabinet outside of the **decontamination** area and **procedure room**,
- c) **HEPA-filtered** channel purge drying cabinet should be used for Storage

Storage procedure must include:

- d) Storage endoscopes to **coil, touch the sides, floor** or bottom of the cabinet while handing, or be store in their cases;
- f) Ensure that endoscopes storage cabinet are **constructed of non-porous material that can be cleaned**
- g) **Clean and disinfect** endoscopes storage cabinet at **least weekly** with an approved **lower-level disinfect ant.**

2016 SGNA 內視鏡 清潔、消毒標準作業流程

- 前置清潔(Pre cleaning)
- 漏水測試(Leak testing)
- 手工清潔(Manual cleaning)
- 清潔後沖洗(Rinse after cleaning)
- 檢視(Visual inspection)
- 高層次消毒(High-level disinfection/manual or automated)
- 高層次消毒後沖洗(Rinse after high level disinfection)
- 乾燥(Drying/alcohol and forced air)
- 儲存(Storage)

為何要增加『檢視(Visual inspection)』步驟??

- 類似手術時『暫停 (Time-out)』的步驟，可於高層次消毒前做再次的確認，**確保器械清潔程度，也可避免器械因高層次消毒受損的情形**



Recommendations

1. Individuals responsible for reprocessing endoscopes shall be **specially trained** and shall meet the facility's written endoscope processing competency requirements, including ongoing **education and training** and **annual competency testing** (IA)
2. Each health care setting in which endoscopic procedures are performed shall have written, detailed procedures for the cleaning and handling of endoscopes. (IIA)
3. **Critical endoscopes** shall be **sterilized** prior to use. (IA)

Recommendations

4. Semi-critical endoscopes require a minimum of **high-level disinfection** prior to use. (IA)
5. Adequate ventilation is required to remove toxic vapours generated by, or emitted from, cleaning or disinfection agent. (IA)
6. Endoscope cleaning shall commence Immediately following completion of the clinical procedure. (IA)

Recommendations

7. Patency and integrity of the endoscope sheath shall be verified through **leak testing**, performed after each use. (IA)
8. Endoscopic equipment/devices shall be **rinsed** and **excess water** removed prior to disinfection or sterilization. (IIA)
9. Endoscopic accessories (e.g., biopsy forceps and brushes) that enter sterile (IA)

Recommendations

10. Final **drying** of semi critical endoscopes shall be facilitated by flushing all channels with filtered air, followed by **70% isopropyl alcohol**, followed by forced air purging of the channels. (IA)
11. Semi critical endoscopes shall be stored in a dedicated, **closed, ventilated cabinet** outside of the reprocessing area and procedure room. (IIA)
12. The **water bottle** and its **connecting tube**, used for cleaning the endoscope lens and irrigation during ERCP(endoscopic retrograde cholangiopancreatography) procedure, shall be cleaned and sterilized following manufacturers instructions. (IIIA)

Recommendations

13. A preventive maintenance program for automated endoscope reprocessor (AER) shall be **implemented** and **documented**. (IIIA)

14. Healthcare settings shall have policies in place providing a **permanent record** of endoscope use and reprocessing, as well as a system to track endoscopes and clients/patients/residents that includes recording the endoscope **number in the client/patient/resident** record. (IIIA)

Recommendations

15. Enhancement in methods for **reprocessing duodenoscopes** should be **followed and documented**. (IIA)

16. **Regular surveillance for bacterial** contamination of duodenoscopes after reprocessing using a special culture method and test is recommended. (IIA)

從意識上、操作上， 樹立醫療安全理念

提升感控意識

- 加強感控理念，提高感控各項操作順從性

醫院主管重視

- 合理投入清洗消毒的人力資源和清洗消毒設備

提供專業知識與操作技能

- 提供從業人員素質與專業知識面

加強監管

- 避免內視鏡清洗消毒流程省略與錯誤



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謝謝聆聽
敬請指教

