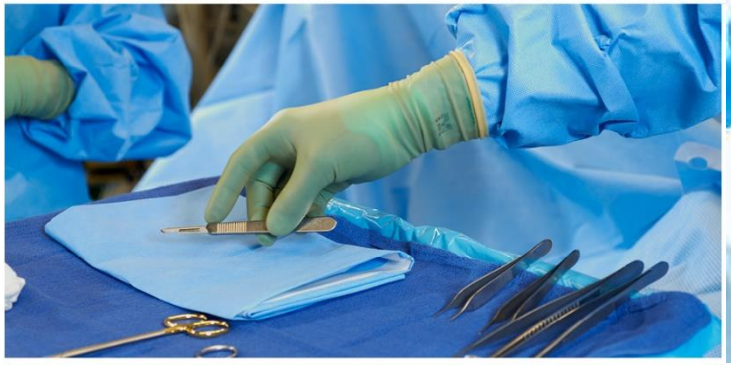


Standard Implementation in COVID-19 Pandemic for Perioperative Management

Maliwan Gritiyutanont

November 13, 2021

Disclosure

- No conflict of interest.
- I do not endorse or sell any commercial products. Any photos or examples of commercial products are included strictly for educational purposes.
- Always consult manufacturers for instruction for use (IFU).
- The content of this sharing based on current evidence-based practices as of **November 5, 2021**

Building Blocks

- Strategies to reduce the risk of infection and enhance safety
- AORN guidelines and updated guidelines in the era of COVID-19 (evidenced-based)
  - ✓ Environmental cleaning
  - ✓ Surgical smoke (air quality)
  - ✓ Reprocessing of surgical instruments

The content of this sharing based on current evidence-based practices as of **November 5, 2021**

1 Strategies to reduce the risk of infection and enhance safety

ประเด็นคำถามในช่วงสถานการณ์ COVID-19

- แนวทางการปฏิบัติในการล้าง การทำลายเชื้อและการทำให้ปราศจากเชื้อเครื่องมือที่ใช้กับผู้ป่วยที่ได้รับการวินิจฉัยหรือสงสัยว่ามีการติดเชื้อ COVID-19 ต่างจากเดิมหรือไม่
- เครื่องมือที่ซับซ้อนและมีจำนวนจำกัด ควรบริหารจัดการอย่างไรให้สามารถใช้งานได้อย่างปลอดภัย เพียงพอ และทันต่อความต้องการ
- แนวทางการปฏิบัติในการบริหารจัดการสิ่งแวดล้อมในห้องผ่าตัด
- แนวทางการปฏิบัติสำหรับการผ่าตัดผู้ป่วยติดเชื้อ COVID-19 ในต่างประเทศ มีอะไรที่แตกต่างหรือควรนำมาปรับใช้ในการผ่าตัดในประเทศไทยหรือไม่
- อุปกรณ์ป้องกันอันตรายส่วนบุคคล PPE และเรื่อง decontamination หน้ากาก N95 Respirator (ขาดแคลน)
- อื่น ๆ อีกมากมาย

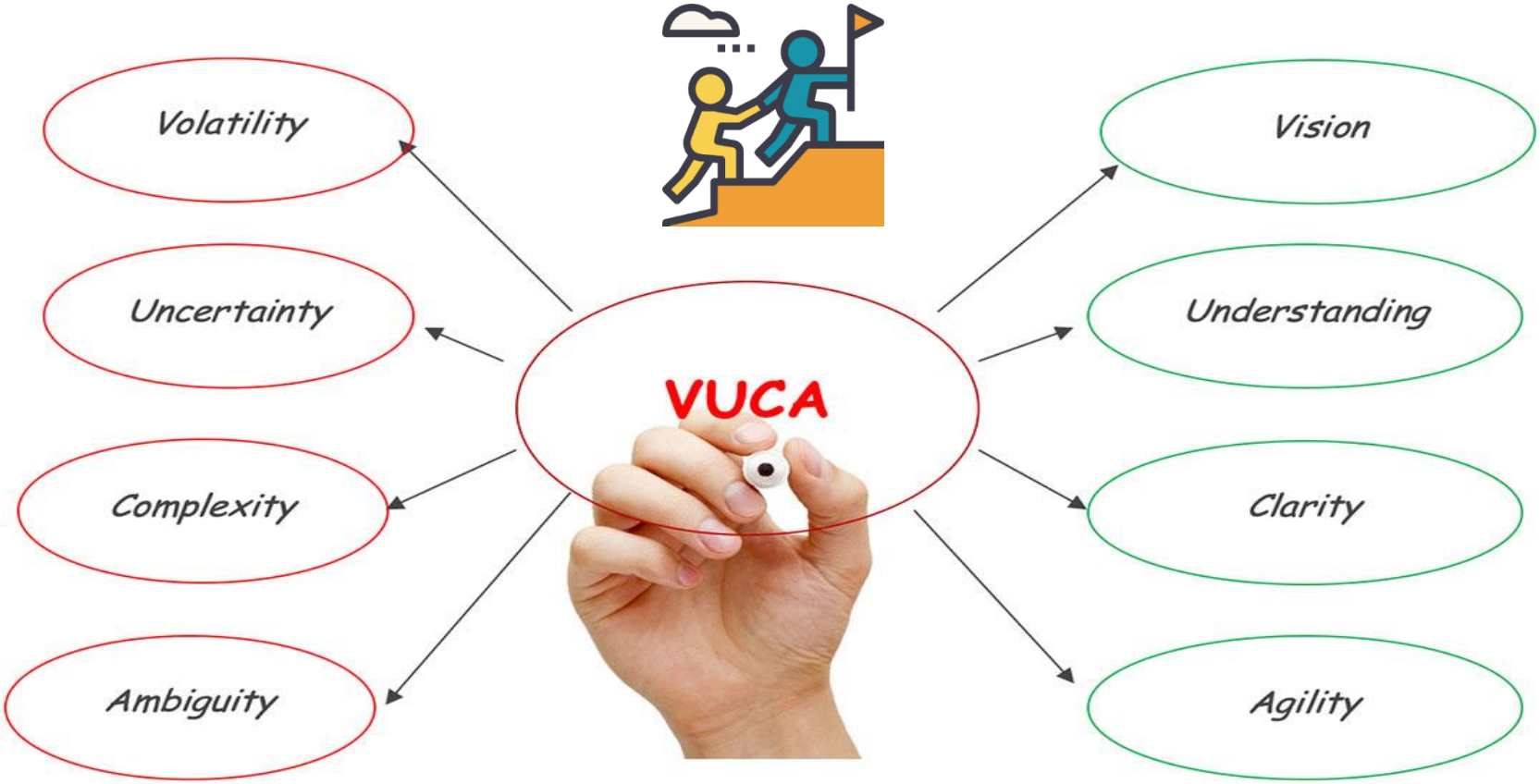
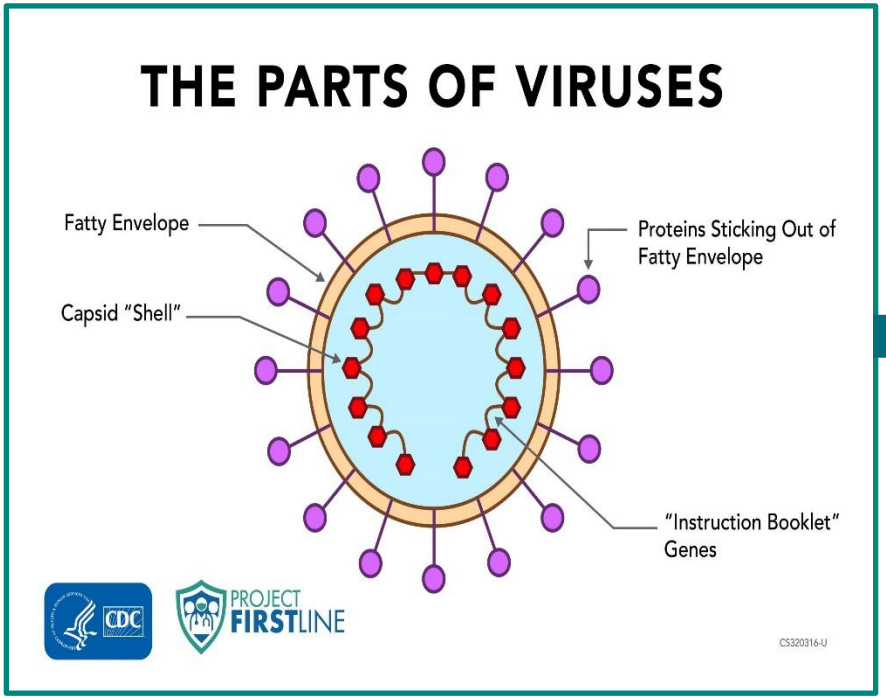
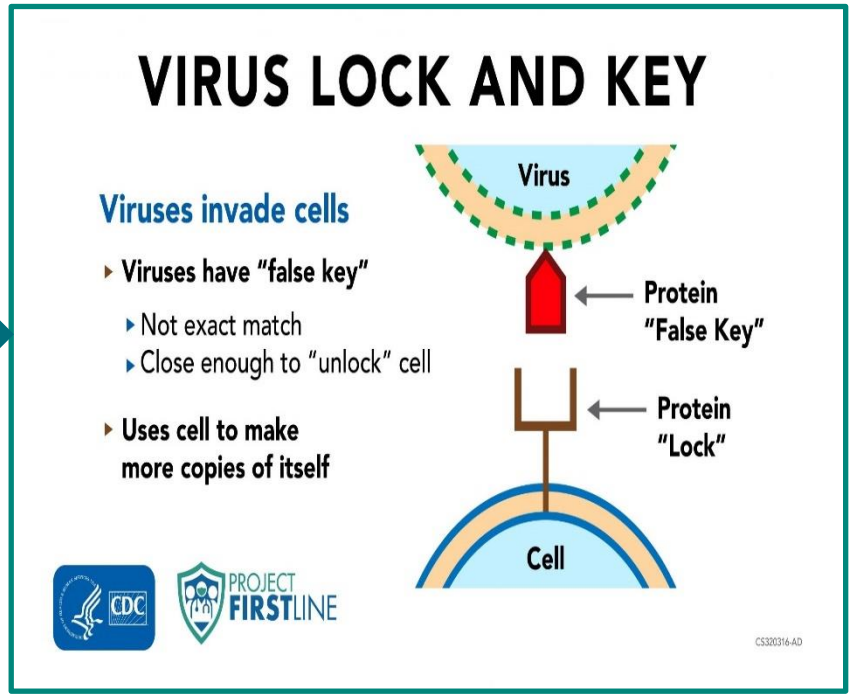


Photo courtesy from google

SARS-CoV-2 – Corona virus family

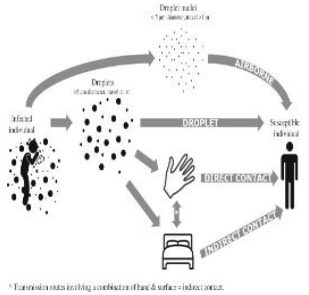




การแพร่กระจายของ SARS-CoV-2

SARS-CoV-2 is transmitted by exposure to infectious respiratory fluid

- การหายใจเอาละอองฝอย droplet and aerosol ที่มีการปนเปื้อนเชื้อเข้าสู่ระบบทางเดินหายใจ (PPE, ventilation)
- เยื่อบุต่างๆ (mucous membrane) เช่น ตา จมูก ปาก สัมผัสกับละอองฝอยของเชื้อ (PPE)
- การสัมผัสเยื่อบุต่างๆ ด้วยมือที่มีการปนเปื้อนเชื้อ (direct and indirect)



Main route : Inhalation of droplet and aerosol

Scientific Brief: SARS-CoV-2 Transmission | CDC

What can we do to protect ourselves and our patients from the **new virus strains (variant)** ?

Adherence to Universal Precautions

Standard Precautions+ Transmission Precautions

Every Patient

Every Instrument

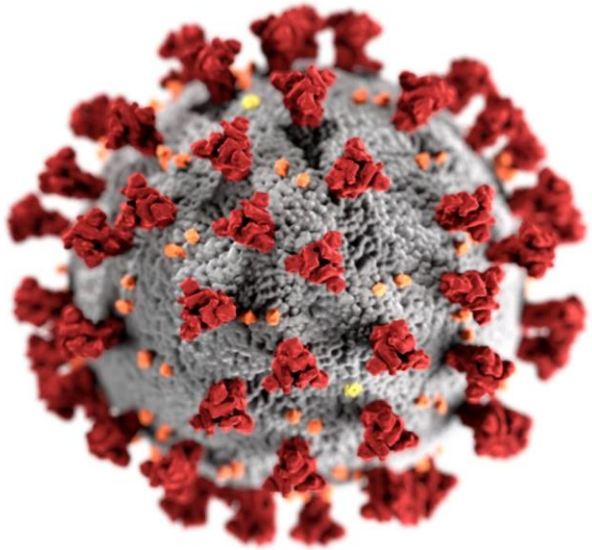
Every Time

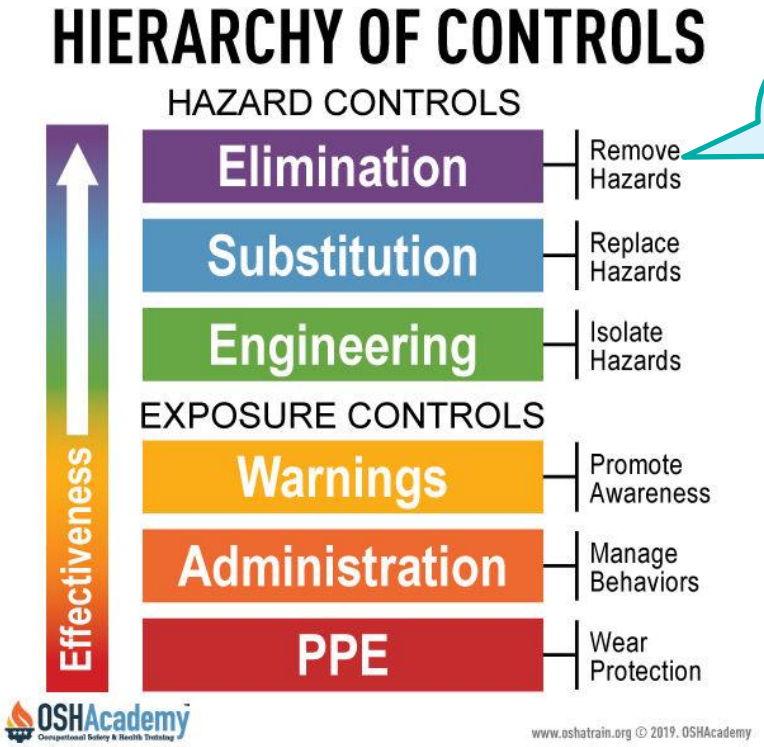
Risk Assessment
Situation Analysis
Prioritization

Going beyond the obvious!

Photo courtesy from google

Hierarchy of Controls to Prevent Transmission

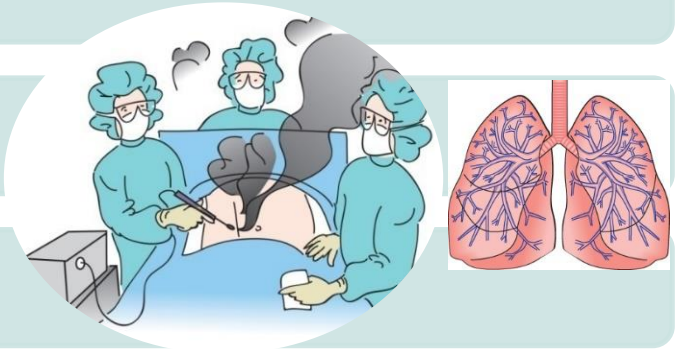




COVID-19 is a big deal, but it isn't the only *scary bug* you face on a daily basis

Surgical Smoke Plume

สารเคมีอันตราย	• VOCs, aromatic hydrocarbons, carbon monoxide
อนุภาคที่อันตรายต่อปอด	• Fine particulate and ultrafine particulate matter
Viruses & Bacteria	• HPV, HIV, HBV
Cellular material	• Cancer cells
เลือด	• Blood-contaminated aerosols in breathing zone



2021 AORN Guideline for Surgical Smoke. In: *Guideline for Perioperative Practice*. Denver, CO: AORN, Inc.

HPV

Human papillomavirus (HPV)

- Detectable in **surgical smoke**
- Potentially infectious

Fox-Lewis et al, 2020

- HPV DNA detected in loop electrosurgical excision procedures (LEEP) surgical smoke and surgeon nasal epithelial cells
- Possibly infectious

Zhou et al, 2019

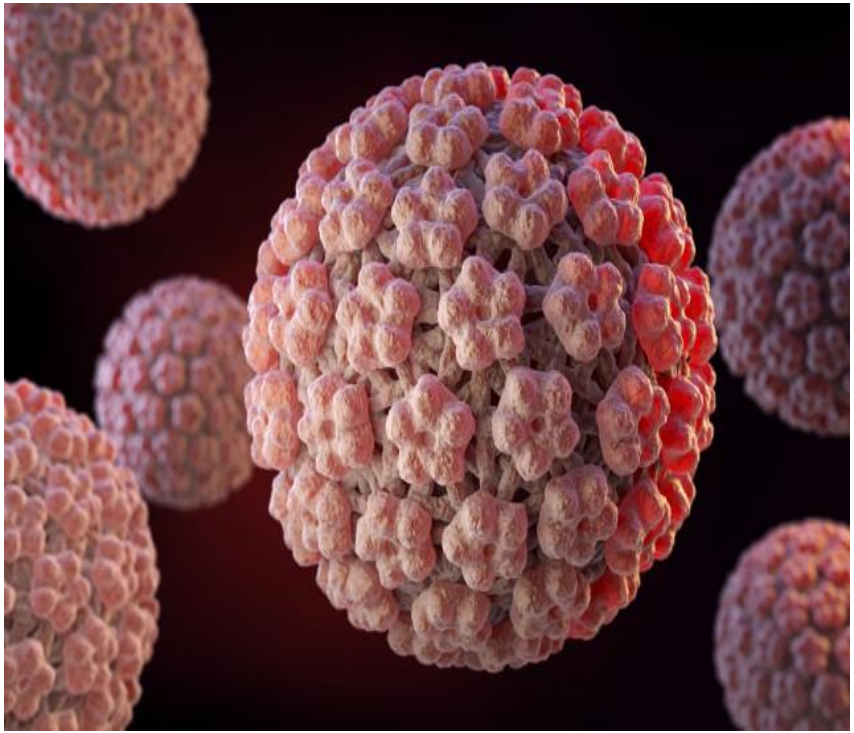
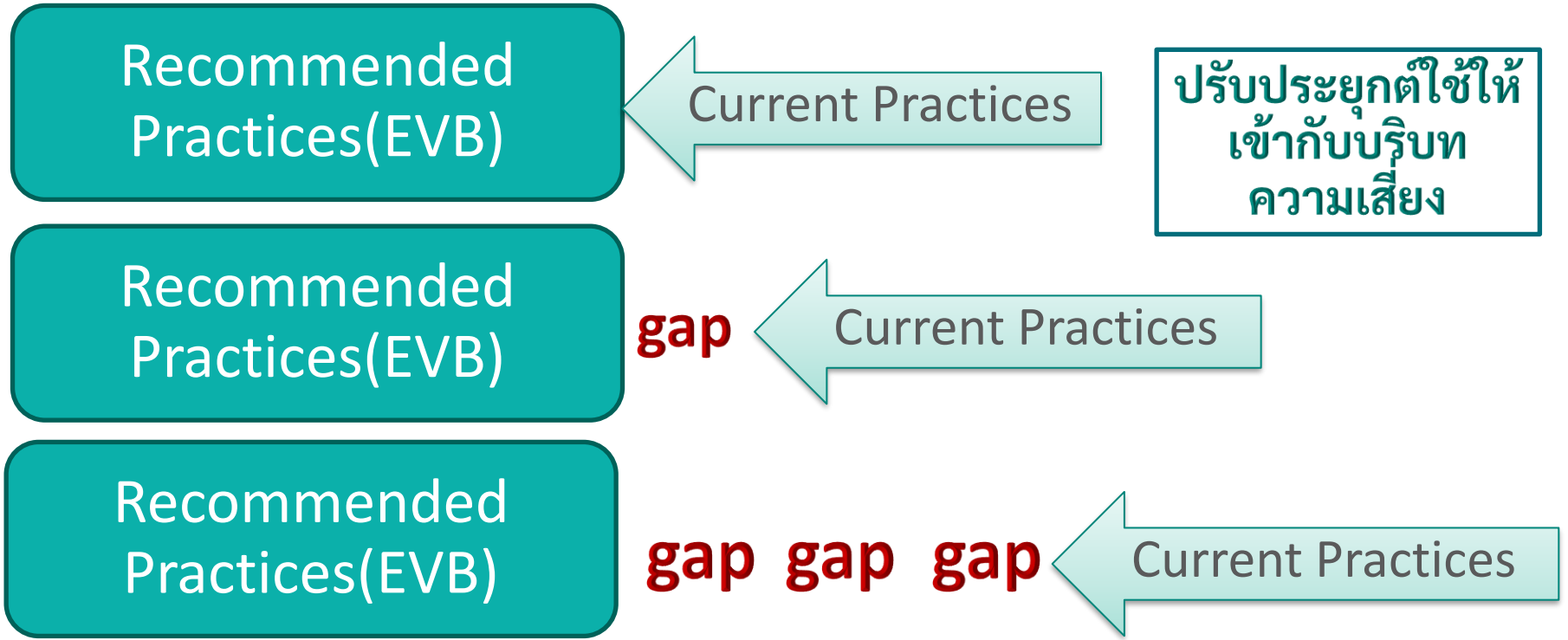


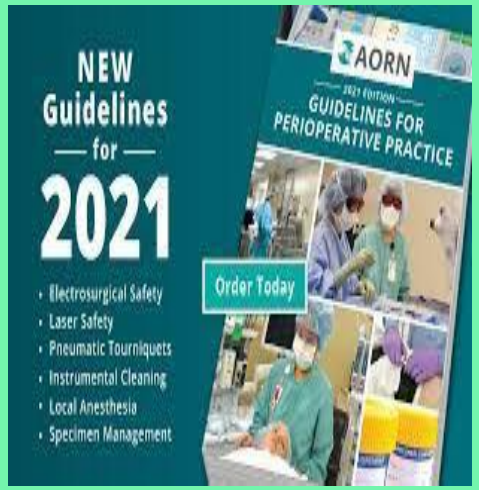
Photo courtesy from google

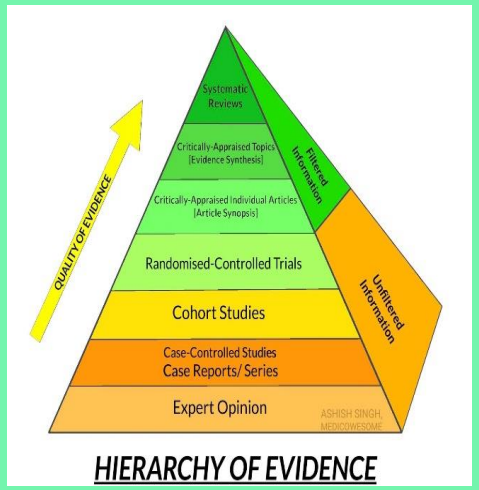
AORN Guideline for Instrument Care and Cleaning. In: *Guideline for Perioperative Practice*. Denver, CO: AORN, Inc.

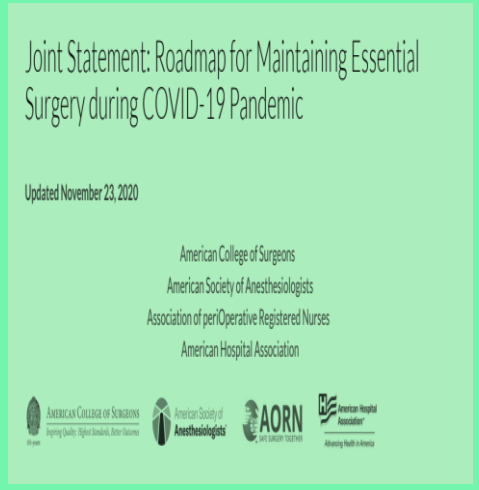
คุณภาพและความปลอดภัย-Gap analysis



2 AORN Guidelines and Update Guidelines in the Era of COVID-19

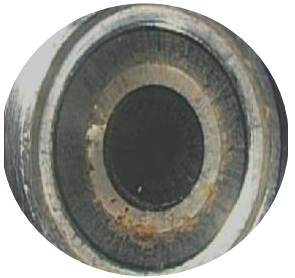






Common Risk Associated with CDS Failures

- **ความคงเส้นคงวา**ในการปฏิบัติตามมาตรฐานวิธีการปฏิบัติ
- ไม่ปฏิบัติตาม**มาตรฐานวิธีการปฏิบัติ**
- ไม่ปฏิบัติตามคำแนะนำของบริษัทผู้ผลิต
- IFU ไม่ update หรือไม่เหมาะสม
- การออกแบบเครื่องมือแพทย์ที่**บกพร่อง**
- การใช้เครื่องมือแพทย์ที่**ชำรุด ขาดการบำรุงรักษา**
- ผู้ปฏิบัติงานขาดการอบรมที่เหมาะสมและ competency
- Time constraint & Resource constraints
- การสื่อสาร ความเข้าใจ และทัศนคติ



CDS : Cleaning Disinfection Sterilization
IFU : Instruction For Use คำแนะนำของบริษัทผู้ผลิต

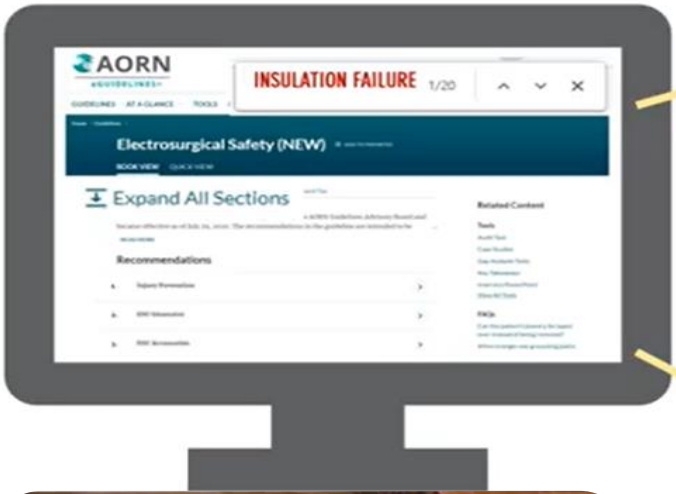
First things first – are the right people at the table?

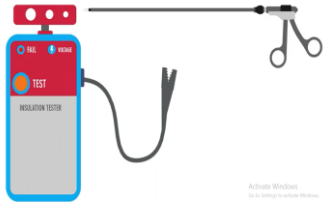
- **Interdisciplinary team members** to be included in the pre-purchase evaluation team:

- *Medical device processing personnel responsible for processing can **read and understand** the manufacturers' instructions for use (IFU).*

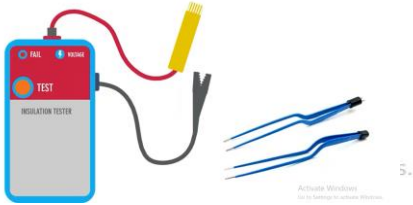
AORN Guideline for Instrument Care and Cleaning. In: *Guideline for Perioperative Practice*. Denver, CO: AORN, Inc.

Insulation Failure





- 3.5 Inspect active electrodes for insulation failure before during and after a procedure.
- 3.5.1 Use an active electrode insulation integrity tester while preparing active electrodes for packaging during processing
- 3.5.2 If an insulation failure is identified during processing, sterile processing personnel should remove the damaged device form service



AORN Guideline for Electrosurgical Safety In: *Guideline for Perioperative Practice*. Denver, CO: AORN, Inc.

3P SAFETY TOGETHER

ลำดับความยากง่ายในการฆ่าเชื้อ

Hard to kill

Bacterial spores	Anthrax, *Clostridioides difficile (C. diff)*
Mycobacterium	Tuberculosis
Viruses without envelopes	Polio, norovirus, adenovirus, rhinovirus
Fungi and fungal spores	*Candida albicans, Aspergillus fumigatus*
Gram negative bacteria	*Klebsiella pneumoniae, Pseudomonas aeruginosa*
Gram positive bacteria	*Staphylococcus aureus, Streptococcus*
Enveloped viruses	COVID-19, measles, influenza, HIV, hepatitis

Easy to kill

GREAT EXPECTATIONS IAHCSMM

Cleaning

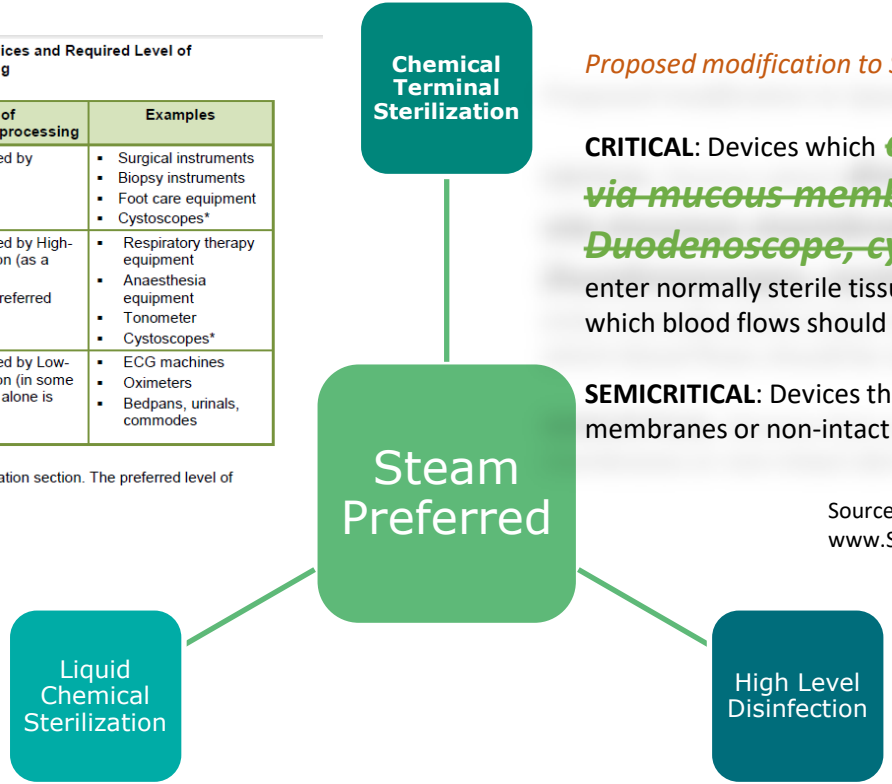
Semicritical items
At least High Level Disinfection(HLD)

Rutala(2015) Proposed Modification of the Spaulding – not accepted

Table 1: Spaulding's Classification of Medical Devices and Required Level of Processing/Reprocessing

Classification	Definition	Level of Processing/Reprocessing	Examples
Critical Device	Device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	▪ Surgical instruments ▪ Biopsy instruments ▪ Foot care equipment ▪ Cystoscopes*
Semi-critical Device	Device that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred	▪ Respiratory therapy equipment ▪ Anaesthesia equipment ▪ Tonometer ▪ Cystoscopes*
Noncritical Device	Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident	Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)	▪ ECG machines ▪ Oximeters ▪ Bedpans, urinals, commodes

*Cystoscopes – 2012 appear in Critical and Semi-critical classification section. The preferred level of reprocessing is sterilization.



Proposed modification to Spaulding's Classification – not accepted

CRITICAL: Devices which ~~*directly or secondarily (i.e. via mucous membrane such as a Duodenoscope, cystoscope, bronchoscope)*~~ enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL: Devices that comes in contact with mucous membranes or non-intact skin but does not penetrate them.

Source: Dr. William Rutala, USA APIC 2017, AJIC 2016:44
www.Sterilizationanddisinfection.org

Source: Berry and Kohn OR Technique 2016

Endoscope is a high-risk proposition even without COVID-19

Endoscope types	Patients infected	Pathogens	Contributing factors	Sources
ERCP	32	MDRO,CRE,VRE,*E.coli*,*E. faecium*	Multiple breaches	FDA 8379810
Broncho	19	CR *K. pneumoniae* MDR *P. aeruginosa*	Defects and visible residue	Galdys 2018
Uretero	14	MDR *P. aeruginosa*	Multiple breaches; damaged scopes	Kumarage 2019
Broncho	6	MDR *P. aeruginosa*	Damaged scopes	FDA 8383689
Gastro, Colono	3	New Delhi strain of CRE	Multiple breaches; cleaning, leak test	FDA 8242610
Cysto	2	*K.pneumoniae*	Multiple breaches	FDA8364744

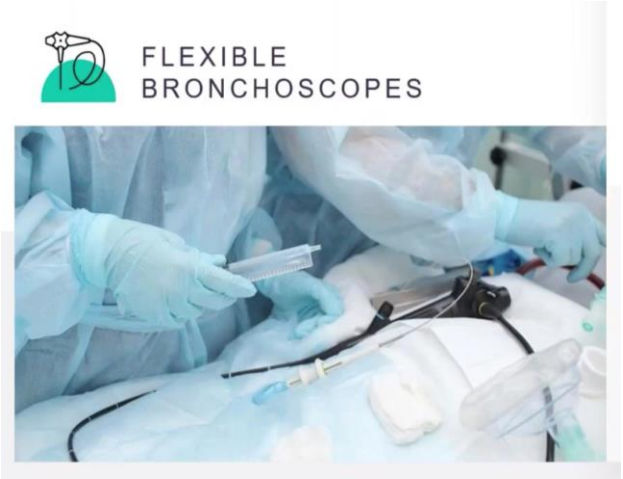
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (reported since 2018)

FDA Safety Communication April 2021

- **From Jan 1, 2017 - Feb 20, 2021, The FDA received 450 MDRs** regarding patient infections or other possible contamination with reprocessing these devices
- **Outside of the U.S.** three reported deaths
- The FDA is emphasizing **the importance of following manufacturer's labeling and reprocessing**
- **Reprocessing steps** should include one of the following two options:
  - Precleaning, leak testing, cleaning, high level disinfection, rinsing and drying
  - Precleaning, leak testing, cleaning and sterilization

https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers

FDA Safety Communication June 2021



- **From January 2010 and June 2015, the FDA received 109 MDRs** related to infections or device contamination
- Three were **seven reports of deaths**
- **Failures to follow IFU**, or continued use despite device integrity, maintenance and mechanical issues
- **Consider using sterilization (safety margin)** instead of HLD when feasible
- **If sterilization is not available** strictly adherence to standard reprocessing procedures

https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication

New Guidelines for COVID-19

Consider to use single use bronchoscope

American Association for Bronchology and Interventional Pulmonology (AABIP) Statement on the Use of Bronchoscopy and Respiratory Specimen Collection in Patients with Suspected or Confirmed COVID-19 Infection

Momen M. Wahidi;* Carla Lamb, MD,* MD, MBA; Septimiu Murgu, MD; Ali Musani, MD; Samira Shojaee, MD; Ashutosh Sachdeva, MD; Fabien Maldonado, MD; Kamran Mahmood, MD; Matthew Kinsey, MD; Sonali Sethi, MD; Amit Mahajan, MD; Adnan Majid, MD; Colleen Keyes, MD; Abdul Hamid Alraiyes, MD; Arthur Sung, MD; David Hsia, MD and George Eapen, MD.

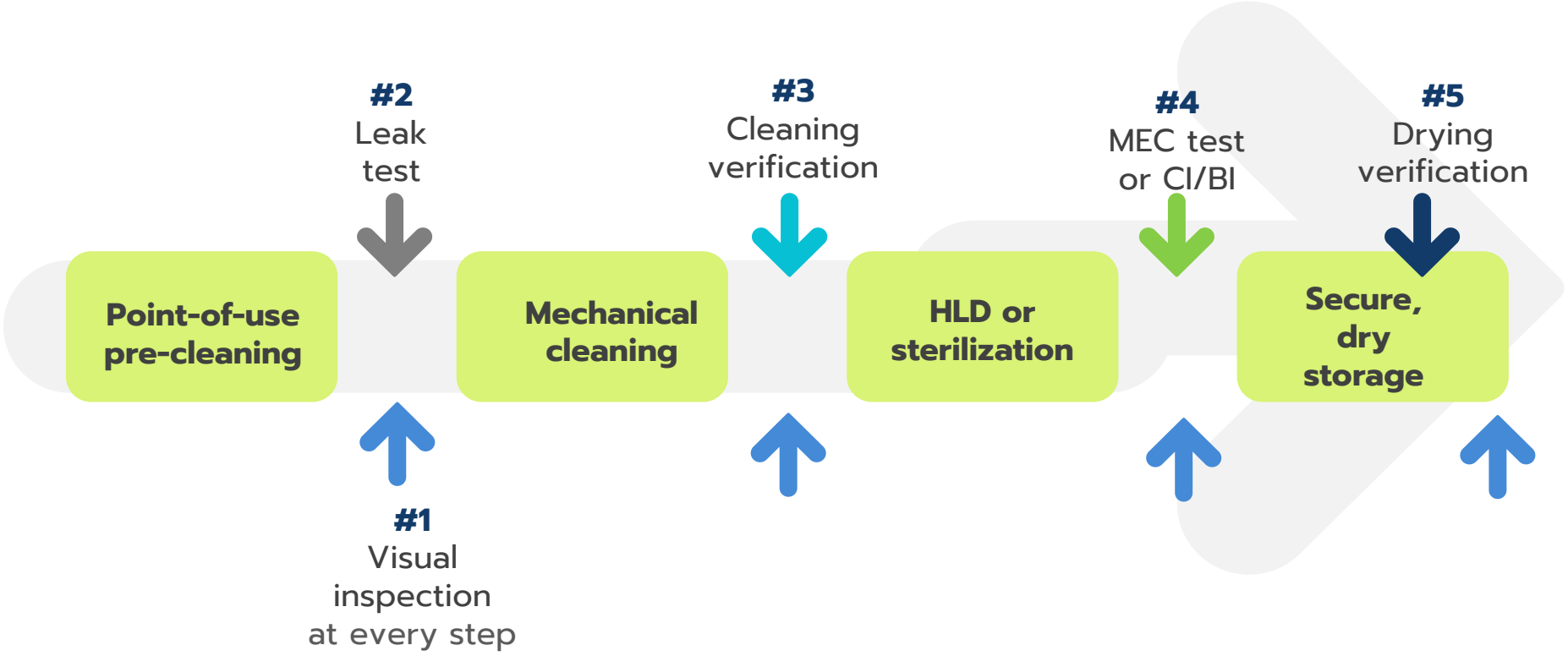
https://journals.lww.com/bronchology/fulltext/2020/10000/american_association_for_bronchology_and.15.aspx

Q: Does standard manual cleaning followed by high-level disinfection eradicated SARS-CoV-2 (bronchoscopes)?

Recommendation:

- Based on available evidence, standard manual cleaning followed by HLD should be effective at eradicating SARS-CoV-2 (Lipid virus)
- No changes: ปฏิบัติตามแนวทางการปฏิบัติ+ระมัดระวัง+ไม่ลัดขั้นตอน + สติ

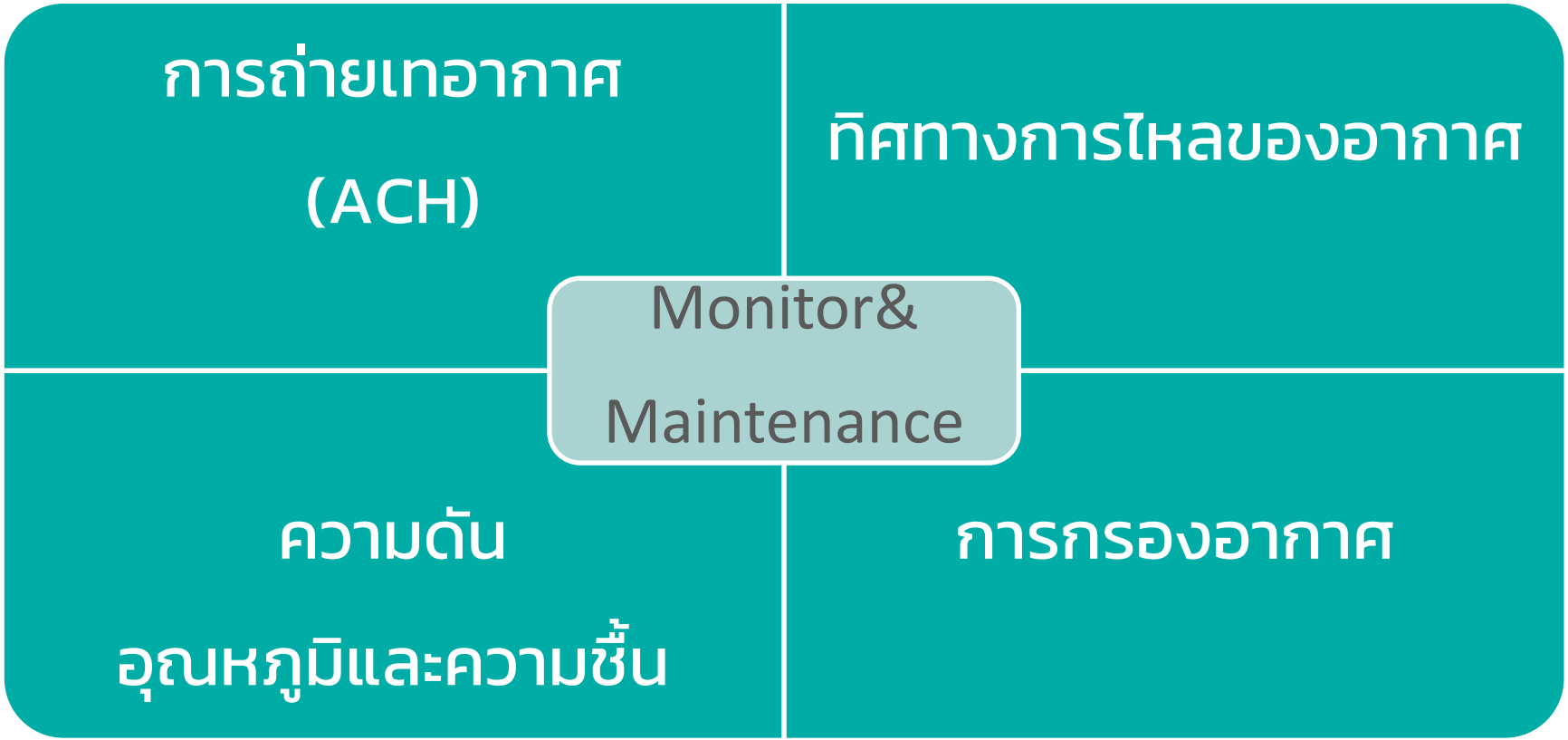
Reprocessing an Endoscope Take> 100 Steps



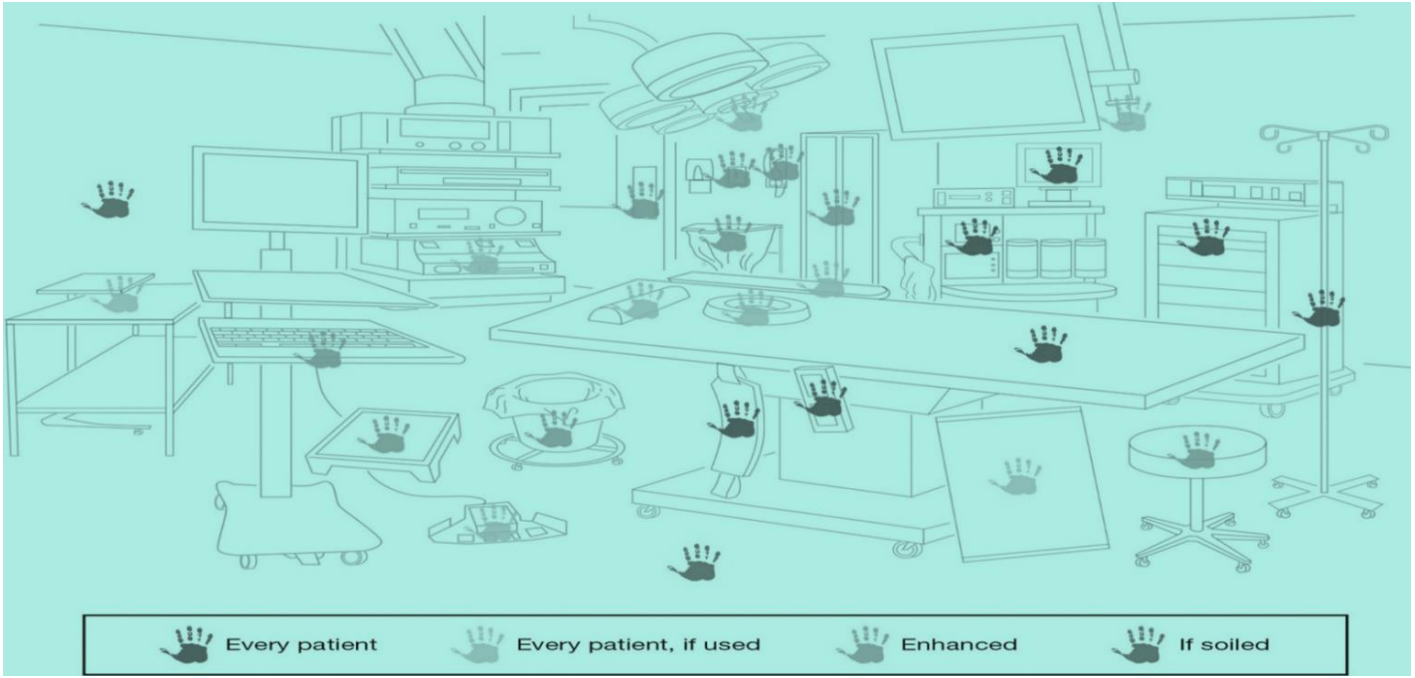
Approach to Improving Endoscope Safety

- **Analyzing the risk** of your process of work.
- Improving the safety of current reusable medical devices by **improving reprocessing (bridging the gap)**
- Evaluate current **training & competency**
- Create new reusable devices with **disposable high-risk components (duodenoscopes)**
- **Increase the reprocessing effort from HLD to sterilization** (high risk + manufactured validated IFU)
- **Automated endoscope reprocessing –**HLD should be provided in approved AER

OR Environment -HVAC



The OR Environment-High Touch Surface



Multiple surfaces + Multiple patient contacts = Greater chance for pathogen transmission

AORN Guideline for Environmental Cleaning. In: *Guideline for Perioperative Practice*. Denver, CO: AORN, Inc.

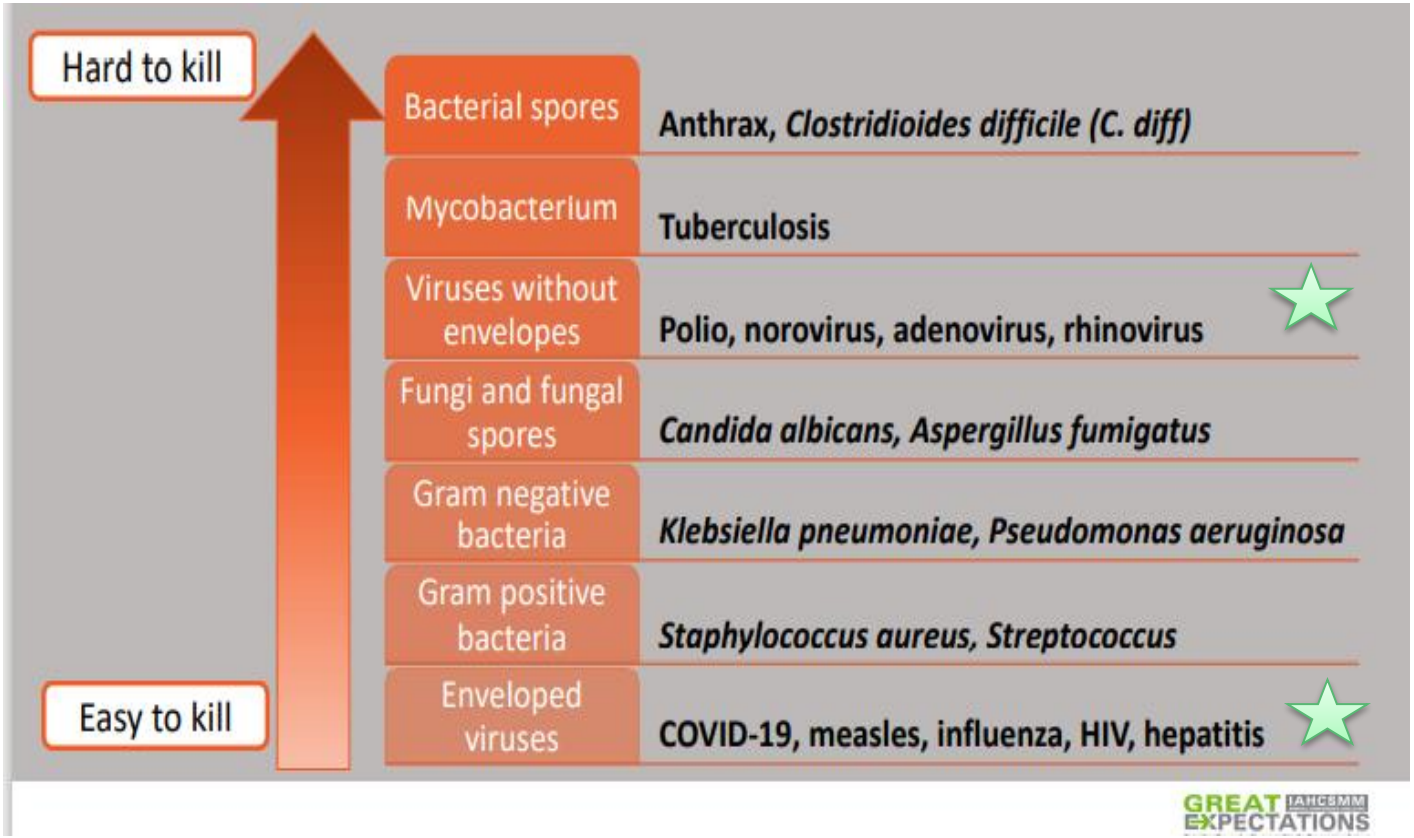
Survival of Common HAI Pathogens

Microorganism	Environmental Persistence
Staphylococcus aureus	7 days to 7 months
Escherichia coli	1.5 hours to 16 months
Enterococcus faecalis	5 days to 4 months
Pseudomonas aeruginosa	6 hours to 16 months

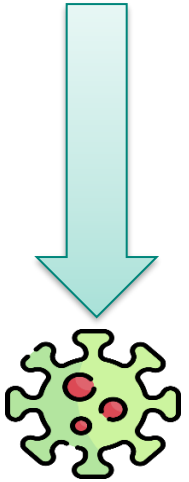
Kramer et al, 2006.

SARS-CoV-2 can be viable on surfaces from hours (cardboard 24 h) to day (plastic, stainless steel 2-3 days) , https://doi.org/10.1093/cid/ciaa1467

ลำดับความยากง่ายในการฆ่าเชื้อ

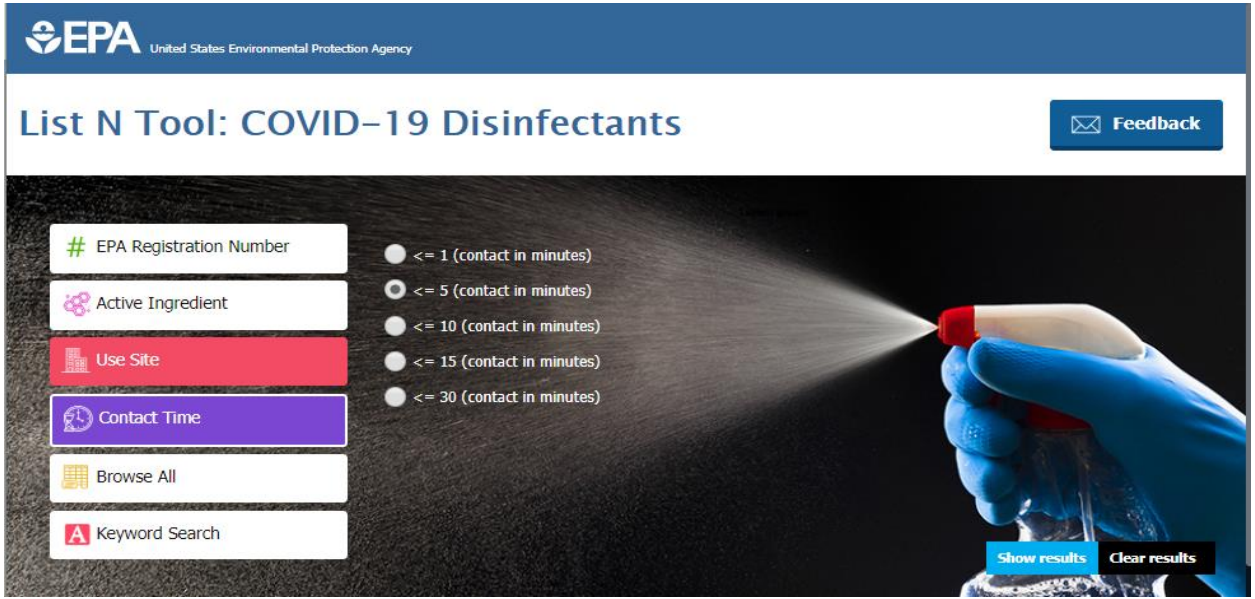


Cleaning+
ILD or LLD



List N Tool : COVID-19 Disinfectant (USA)

- CDC recommended that an EPA –registered disinfectant on the EPA's List N that qualified under the emerging pathogen program



https://cfpub.epa.gov/giwize/disinfecatnts/index.cfm

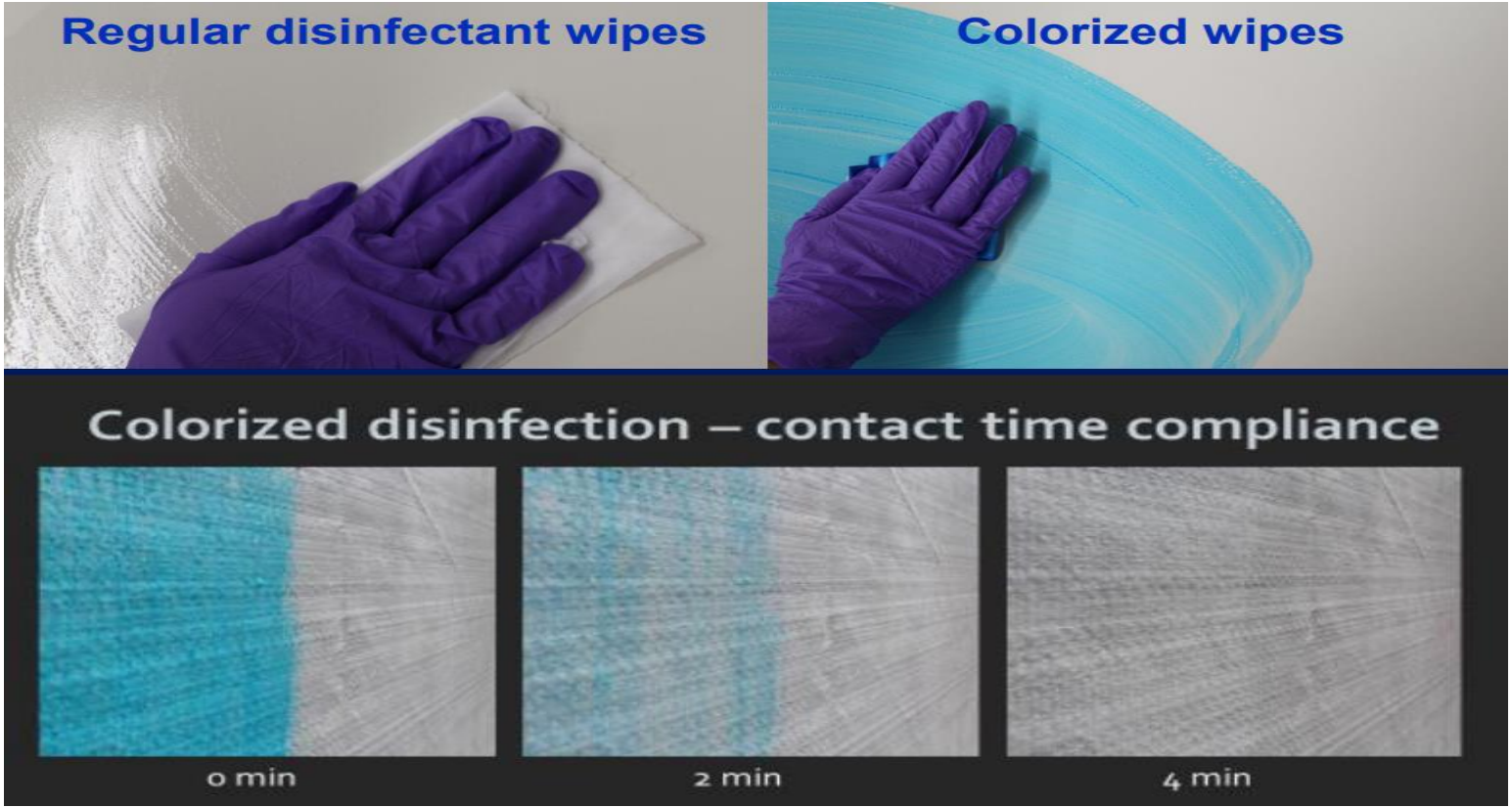
List N Tool : COVID-19 Disinfectant (USA)

32 Active ingredients (Low and Intermediate level disinfectant)

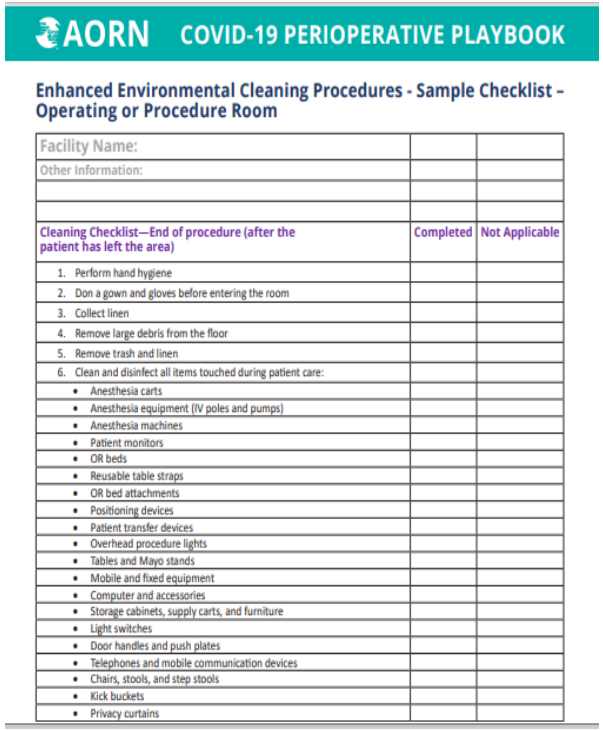
- Ethyl alcohol
- Hydrogen peroxide
- Hypochlorite
- Isopropyl alcohol
- Peracetic acid
- Phenolic
- Quaternary ammonium

People+ Product + Practices (eg. contact time)= Perfect

Future May Have Methods to Ensure Thoroughness Such as Colorized Disinfectant ,Kang et al. J Hosp Infect 2017



Environmental Cleaning of Operating Room



AORN COVID-19 PERIOPERATIVE PLAYBOOK

Enhanced Environmental Cleaning Procedures - Sample Checklist – Operating or Procedure Room

Facility Name:		
Other Information:		
Cleaning Checklist—End of procedure (after the patient has left the area)	**Completed**	**Not Applicable**
1. Perform hand hygiene		
2. Don a gown and gloves before entering the room		
3. Collect linen		
4. Remove large debris from the floor		
5. Remove trash and linen		
6. Clean and disinfect all items touched during patient care:		
• Anesthesia carts		
• Anesthesia equipment (IV poles and pumps)		
• Anesthesia machines		
• Patient monitors		
• OR beds		
• Reusable table straps		
• OR bed attachments		
• Positioning devices		
• Patient transfer devices		
• Overhead procedure lights		
• Tables and Mayo stands		
• Mobile and fixed equipment		
• Computer and accessories		
• Storage cabinets, supply carts, and furniture		
• Light switches		
• Door handles and push plates		
• Telephones and mobile communication devices		
• Chairs, stools, and step stools		
• Kick buckets		
• Privacy curtains		

http:///doi.orh/10.1002/aorn.13331

- นโยบายและวิธีการปฏิบัติ
- การเลือกใช้ผลิตภัณฑ์ในการทำลายเชื้อ
- การฝึกอบรมผู้ที่มีหน้าที่ทำความสะอาด
- Monitor compliance & Feedback
- Enhance cleaning processes for special pathogens (high touch surfaces/every case)
- Minimize the supplies and equipment in the room
- **Sufficient air exchanges** need to occur before cleaning begins (COVID-19)

No touch technology as supplement

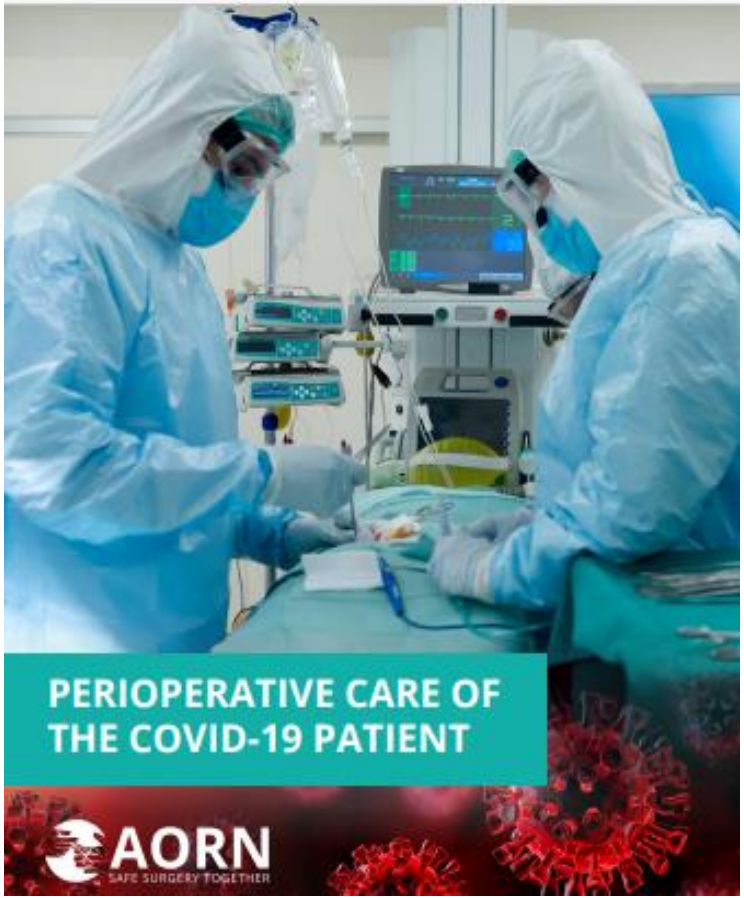
Key Takeaways

- **Standard and Universal precautions** are important all the time, not just during a pandemic
- Superbugs and scary viruses can be eliminated with **normal methods(inanimate items)**
- Stay in tune with update **evidenced-based** practices
- **Multidisciplinary approach** to develop **risk mitigation strategies** while navigating changing conditions and evolving recommendations
- Train your **immune system** to fight COVID-19, flu and other infections

เสริมภูมิคุ้มกันให้ระบบการทำงาน

- Change
- Cleaning
- Critical thinking
- Consciousness
- Communication
- Compliance
- Compassion
- Collaboration
- Consistency

เอกสารอ้างอิงและแหล่งข้อมูล



Joint Statement: Roadmap for Maintaining Essential Surgery during COVID-19 Pandemic

Updated November 23, 2020

American College of Surgeons
American Society of Anesthesiologists
Association of periOperative Registered Nurses
American Hospital Association

American College of Surgeons — Inspiring Quality: Highest Standards, Better Outcomes
American Society of Anesthesiologists
AORN — Safe Surgery Together
American Hospital Association — Advancing Health in America

Centre for Perioperative Care

RCoA Royal College of Anaesthetists · Royal College of Surgeons · Royal College of Physicians · Royal College of Nursing · RCGP Royal College of General Practitioners · Association of Anaesthetists · RCPCH Royal College of Paediatrics and Child Health · Faculty of Public Health

FAQs for patients having an operation during the COVID-19 (coronavirus) pandemic

PREOPERATIVE COVID TESTING: EXAMPLES FROM AROUND THE U.S.

Last updated: November 11, 2020

apsf Anesthesia Patient Safety Foundation
(https://www.apsf.org)

American Society of Anesthesiologists™
(https://www.asahq.org)

แนวทางการดูแลรักษา COVID-19 กรมการแพทย์

https://covid19.dms.go.th/

แนวทางการดูแลรักษา COVID-19 กรมการแพทย์

https://covid19.dms.go.th/

HVAC - Air Change Per Hour (ACH)

ACH	เวลา(นาที) ประสิทธิภาพในการกำจัดอากาศที่ปนเปื้อน 99%	เวลา (นาที) ประสิทธิภาพในการกำจัดอากาศที่ปนเปื้อน 99.9%
4	69	104
6	46	69
8	35	52
10	28	41
12	23	35
15	18	28
20	14	21
50	6	8

Guidelines for Environmental Infection Control in Health-Care Facilities (2003). Appendix B. Air. CDC https:// www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#table 1

Hierarchy of Controls to Prevent Surgical Smoke