



The Importance of Quality Improvement Projects in CSSD

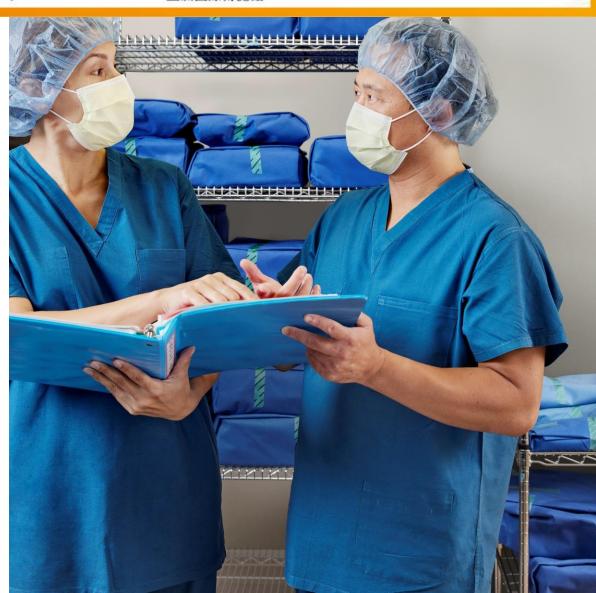
Prof. Seto Wing Hong

Director,

WHO Collaborating Center,

University of Hong Kong.















歡迎....











First Avian Flu case in Hong Kong, 2005







Do visit University of Hong Kong









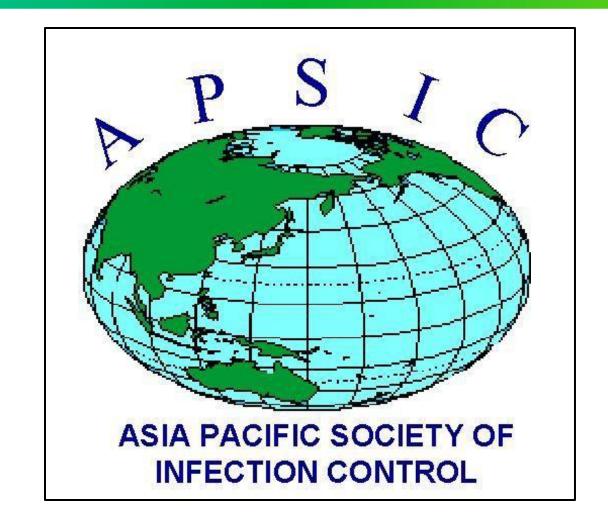












1998 – APSIC initiated in Hong Kong with representatives from 16 Asian Countries at Robert Black College, HKU







Robert Black College





The SWIRE Lounge





The Interest and Initiation of QIP projects

in Implants Surgery – the reasons behind....







Total joint replacement is an amazing advancement in modern medicine.







Joint Replacement Infection

A small number of patients undergoing hip or knee replacement (about 1 in 100, or 1%) may develop an infection after the operation.

- Infections occur in the wound or deep around the artificial implants.
- Develop during your hospital stay or after you go home.
- Joint replacement infections can even occur years after your surgery.





Pirisi et al. BMC Infectious Diseases (2020) 20:337 https://doi.org/10.1186/s12879-020-05065-9

BMC Infectious Diseases

RESEARCH ARTICLE

Open Access

Prevalence and burden of orthopaedic implantable-device infections in Italy: a hospital-based national study



Luca Pirisi¹, Federico Pennestri^{2*}, Marco Viganò² and Giuseppe Banfi^{2,3}

Table 1 Prevalence of infections per type of procedure (2014)

Macro category	Total	With infection	Prevalence (%)
1. Primary hip replacement	89,242	37	0.04%
2. Hip replacement revision	7292	1203	16.50%
3. Other hip procedures	1000	0	0.00%
4. Primary knee replacement	61,923	42	0.07%
5. Knee replacement revision	3017	739	24.49%
6. Other knee procedures	115	0	0.00%
7. Lower limb implantations (femur, tibia, feet)	99,189	20	0.02%
8. Lower limb revisions (femur, tibia, feet)	27,492	448	1.63%
9. Other lower limb procedures	167	0	0.00%
10. Higher limb implantations (shoulder, arm, hand)	7900	18	0.23%
11. Higher limb revisions (shoulder, arm, hand)	12,540	138	1.10%
12. Other higher limb procedures	13,313	7	0.05%
13. Generic musculoskeletal implantation	156	99	63.46%
14. Generic musculoskeletal removal	163	65	39.88%
15. Other orthopaedic procedures	10,449	503	4.81%
16. General procedures associated	2635	1895	71.92%
Total	336,593	5214	1.55%







Surgical Treatment

- Infections gaining <u>deep access</u> to the artificial joint almost <u>always</u> require surgical treatment (single procedure or staged).
- Late infections (those that occur months to years after the joint replacement surgery) always require a two staged surgery.
- Patients who undergo staged surgery typically <u>need a spacer</u> and at least <u>6 weeks of IV antibiotics</u>, before a new artificial joint can be implanted.
- Stage two is revision surgery implanting new joint components





Prevention

- Antibiotics prophylaxis before and after surgery.
- Short operating time and minimal operating room traffic.
- Use of strict sterile techniques and sterilization of instruments.
- Preoperative nasal screening for bacterial colonization.
- Preoperative chlorhexidine wash.
- Long-term antibiotics prophylaxis.

Care is taken to ensure the <u>operating site is sterile</u>, the <u>instruments have</u> <u>been appropriately sterilized</u> and <u>not exposed to any contamination</u>, and the <u>implants are packaged</u> to ensure their sterility



Asia Implant Load Monitoring Survey and Results

Prof. Seto Wing Hong

Director, WHO Collaborating Center University of Hong Kong

June 22, 2023







517 Respondents from10 countries

- ANZ
- India
- Indonesia
- Japan
- Korea
- Malaysia
- Philippines
- Singapore
- Thailand
- Vietnam



Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.journals.elsevier.com/infectiondisease-and-health/



Research paper

Surgical implant sterilization in the Asia—Pacific region: A survey of current practices

Wing Hong Seto*, Patricia Tai Yin Ching

School of Public Health, University of Hong Kong, Hong Kong, China

Received 12 September 2024; received in revised form 25 February 2025; accepted 25 February 2025

KEYWORDS

Equipment sterilization; Surgical implants; Process challenge devices; Biological and chemical indicators; Immediate use steam sterilization Abstract Background: Healthcare-acquired infections are frequently linked to contaminated medical devices such as inadequately sterilized surgical devices, especially surgical implants. To prevent inadequate medical equipment sterilization, various health organizations (eg, World Health Organization) have provided guidance on best practices related to the sterilization monitoring practices of implant-containing loads.

Methods: A survey of sterilization practices, including practices related to monitoring implant-

containing loads, at facilities from seven countries in the Western Pacific Region (WPR) and three countries in the Southeast Asia Region (SEAR) was conducted to assess alignment with health organization guidelines and to elucidate factors impacting sterilization practices. *Results*: Workload distribution was selected by 47 % of respondents when asked what had changed over the past year. Overall, 21 % of respondents were not monitoring each implant-containing load with a PCD (Process Challenge Device) containing a BI (Biological Indicator) with a Type-5 Chemical Indicator (CI), and 27 % of respondents had seen an implant load released prior to receiving BI results. Twenty-nine percent (29 %) of respondents had no placement guide

for CIs when used in multi-level trays. Lastly, 43 % of respondents routinely performed immediate use system sterilization (IUSS), which commonly involved loaner instruments.

Conclusions: The results of this survey study indicate that inappropriate PCD usage in implant loads and frequent IUSS are challenges for some facilities in SEAR and WPR countries. Regional collaboration to produce consensus documents and educational programs may help develop strategies to standardize practice of implant load monitoring and loaner instruments. Thus, a consortium to initiate education programs for SEAR and WPR countries would be worthwhile.

© 2025 Published by Elsevier B.V. on behalf of Australasian College for Infection Prevention and Control

Highlights

 Workload distribution and processing/handoff time were biggest changes from April 2022 to April 2023.

https://doi.org/10.1016/j.idh.2025.02.006

2468-0451/© 2025 Published by Elsevier B.V. on behalf of Australasian College for Infection Prevention and Control.

Please cite this article as: W.H. Seto and P.T.Y. Ching, Surgical implant sterilization in the Asia—Pacific region: A survey of current practices, Infection, Disease & Health, https://doi.org/10.1016/j.idh.2025.02.006

© Solventum 2024. All rights reserved.

Corresponding author.

E-mail addresses: whseto@hku.hk (W.H. Seto), chingpty@yahoo.com.hk (P.T.Y. Ching).





PCD + BI

Written policy for recall

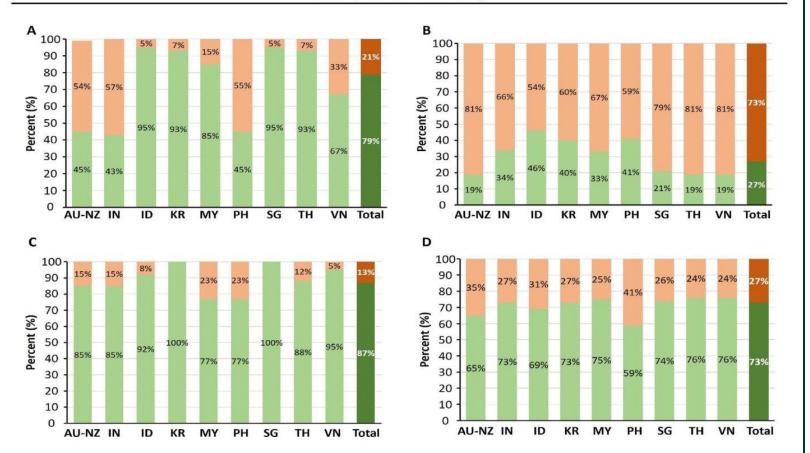


Fig. 2 Responses Related to Implant-Containing Loads. Bar graphs depicting (A) the percentage of respondents that indicated whether each implant-containing load was monitored with a Process Challenge Device containing a Biological Indicator (BI) with a Type-5 Chemical Indicator (CI); (B) the percentage of respondents that had seen an emergency implant load release based on a Type-5 CI result prior to getting a BI result; (C) the percentage of respondents that had a written policy and procedure to recall instruments in the event of a positive BI from Centralized Sterile Processing Department testing; and (D) the percentage of respondents that indicated documentation was maintained to track the incidence of emergency implant load release. Green bar segments = "yes" response; Red bar segments = "no" response.

Emergency release prior to BI result

Documentation of emergency load release







CI type used in every package

Numbers of CI used in multi-level trays

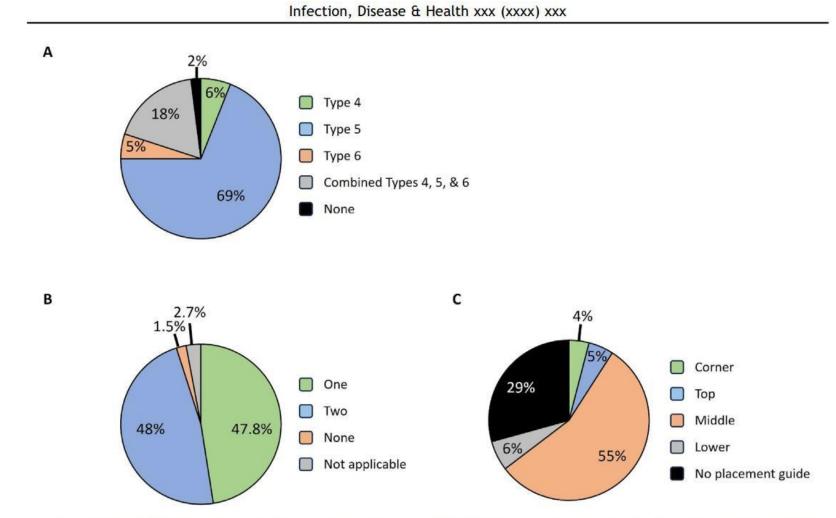


Fig. 3 Chemical Indicator Use and Placement in Centralized Sterile Processing Departments. Pie charts depicting (A) the overall percentage of respondents that use the indicated Chemical Indicator (CI) type(s) inside every package when performing sterilization; (B) the overall percentage of respondents that use the indicated number of CIs inside multi-level trays; and (C) the percentage of respondents that placed the CI in the indicated location in multi-level trays during sterilization.

Location of CI in every levels multi-level trays



In Fig. 4: IUSS - 43% of respondents report that this is still in use.



Asia Safe Surgical Implant Consortium – first meeting 2023







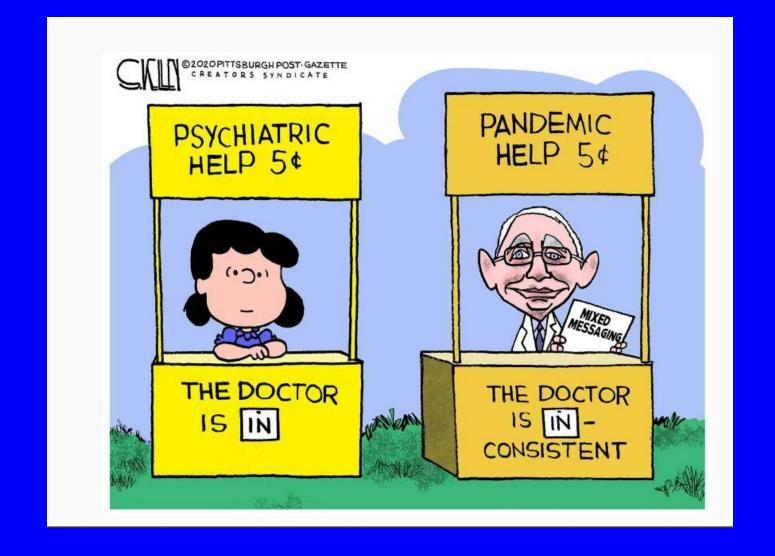
System must be in place to ensure proper management of loan instruments and thus the formation of the

Asia Safe Surgical Implant Consortium

- 2-fold strategies:
 - Consensus Documents
 - Initiation of QIP projects







That is why we need guidelines





So many guidelines



















International Guidelines are available:

Decontamination and Reprocessing of Medical Devices for Health-care Facilities

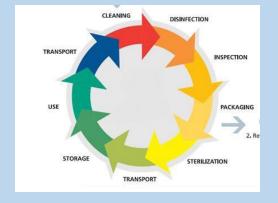


© World Health Organization and Pan American Health Organization, 2016

Decontamination and Reprocessing of Medical Devices

Understanding the WHO Guideline

WH Seto









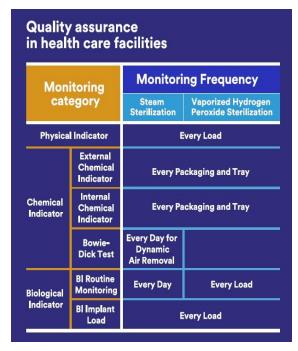
We must focus on what is most important in any guidelines...

Consensus Documents

Recap

Recap of achievements

- 3 Consensus Documents
- 16 associations endorsed
- CSSD, OR, Infection Prevention Association



















Federation of Sterilizing Research and Advisory Councils of Australia















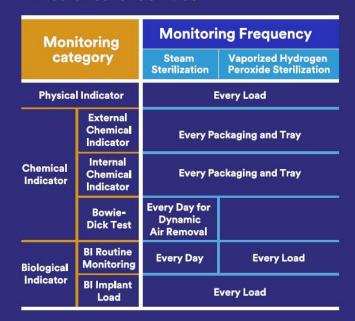






Consensus Documents

Quality assurance in health care facilities





























Supported by 3M

Proper management of loaner instruments and implants

steps



Prior Notification to CSSD: Notify the Central Sterile Supply Department (CSSD) in advance before receiving loaner instruments



Ensure that the instruments are (48 hours) before the scheduled case, in the case of existing sets,

Perform a thorough inventory and inspection of the loaner instruments upon receipt to verify their completeness and condition.

Adhere to the manufacturer's instruction for cleaning and decontamination, following the instrument-specific Instructions for Use (IFU).

Function and Clean ness Inspection Inspect the loaner instruments for functionality and cleanliness after the cleaning and decontamination

appropriately packaged, following recommended guidelines and considering their specific requirement

rifection contact. (KAORN KASDN 병원중앙공급간호사회 (SDN 병원중앙공급간호사회

Endosed by:

Prompt Processing After Case: After the surgical procedure, process the loaner instruments promptly to prevent delays and ensure timely

Sterlize the loaner instruments according to the manufacturer's instructions, using the appropriate

of the loaner instruments before returning them to ensure all items are

monitoring for every load and using Type 5 Chemical Indicators (CI) for every pack

Sterilization recall policy and procedure



The sterilizers are tested with Biological Indicator (Bi) to demonstrate that all of the sterilization parameters have been met.

The following actions are implemented when a positive Biological Indicator test occurs. If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative Bi should be recalled.

Endorsed by:

































VNICS





System must be in place to ensure proper management of loan instruments and thus the formation of the

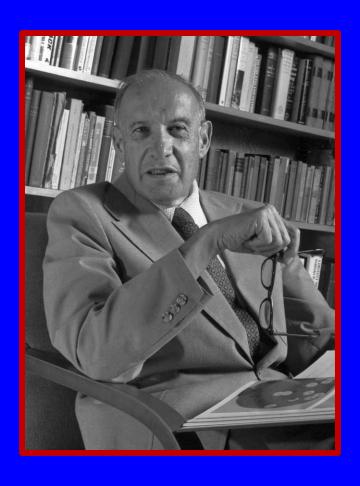
Asia Safe Surgical Implant Consortium

- 2-fold strategies:
 - Consensus Documents
- → Initiation of QIP projects





"The hospital is altogether the most complex human organization ever devised"

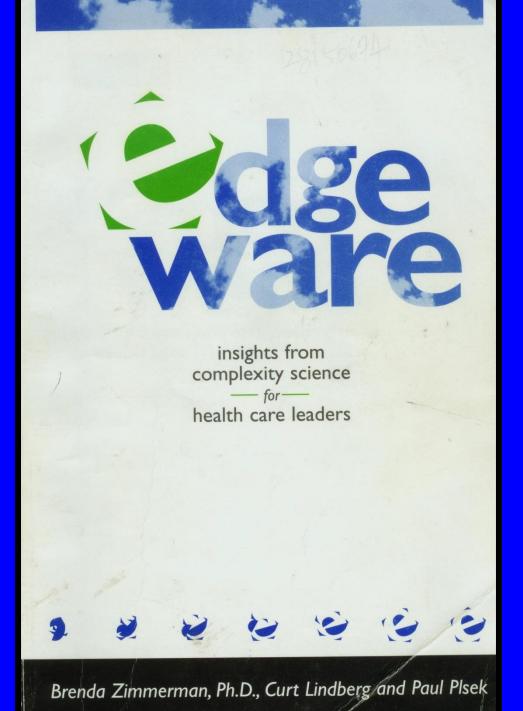


— Peter Drucker









Complexity Science





'Complexity Science'

The study of systems that are

- both dependent and yet independent,
- where consensus are incomplete,
- changes are unpredictable but emerging.

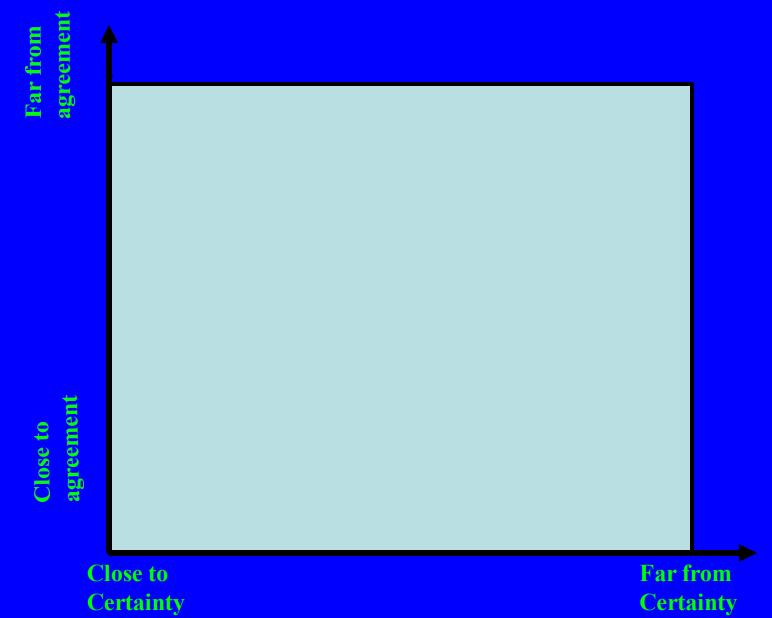


It is not referring to chaotic situations where no system exists



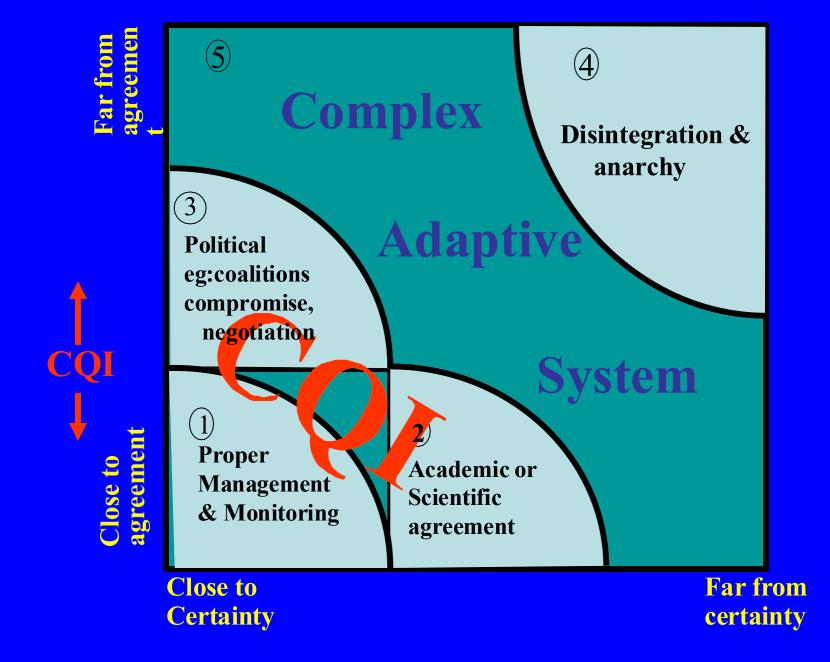


Stacey agreement and certainty matrix













The CSSD is relatively simple compared to the complexity of the hospital







International Guidelines are available:

Decontamination and Reprocessing of Medical Devices for Health-care Facilities

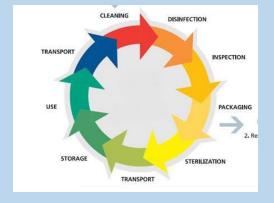


© World Health Organization and Pan American Health Organization, 2016

Decontamination and Reprocessing of Medical Devices

Understanding the WHO Guideline

WH Seto

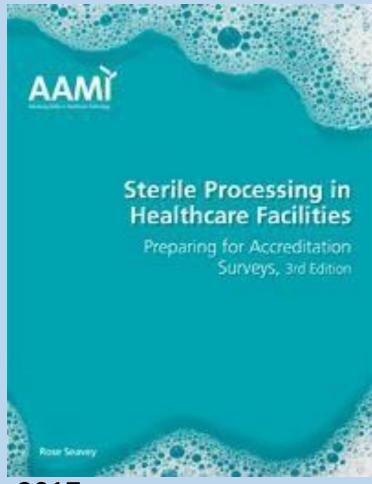


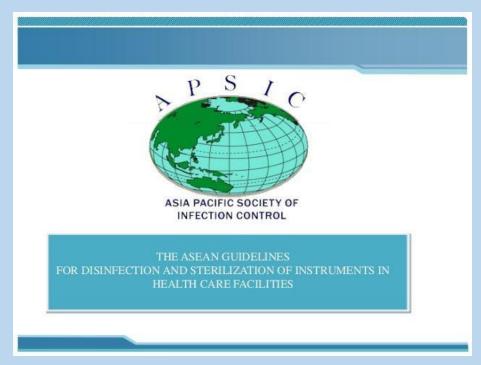






Other Reference Guidelines





2017

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008



Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H. ^{1,2}, David J. Weber, M.D., M.P.H. ^{1,2}, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)³

¹Hospital Epidemiology University of North Carolina Health Care System Chapel Hill, NC 27514

²Division of Infectious Diseases University of North Carolina School of Medicine Chapel Hill, NC 27599-7030

2008





Many things are well defined:

General aspects of sterilization

Definitions

Decontamination: Removes soil and pathogenic microorganisms from objects so they are <u>safe to handle</u>, subject to further processing, use or discard. (Centers for Disease Control and Prevention [CDC] Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008).

Cleaning: The <u>first step required to physically remove contamination</u> by foreign material, e.g. dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a medical device for disinfection or sterilization.

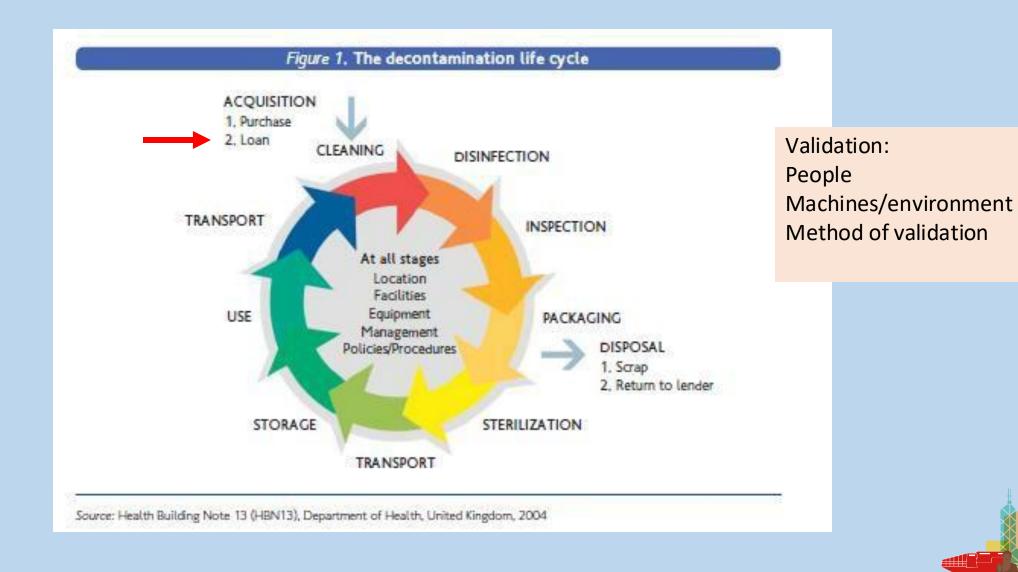
Disinfection: A process to reduce the number of <u>viable microorganisms to a less harmful level</u>. This process may not inactivate bacterial spores, prions and some viruses.

Sterilisation: A validated process used to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.





Processes are generally well defined and in place....







RISK ASSESSMENT IN STERILE SERVICES

Table 2. Policy for the local decontamination of reusable equipment according to the Spaulding classification

Risk category	Recommended level of decontamination	Examples of medical devices
High (critical) Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (semi-critical) Items in contact with mucous membranes or body fluids	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, bedpans, urine bottles
Low (non-critical) Items in contact with intact skin	Cleaning (visibly clean)	Blood pressure cuffs, stethoscopes



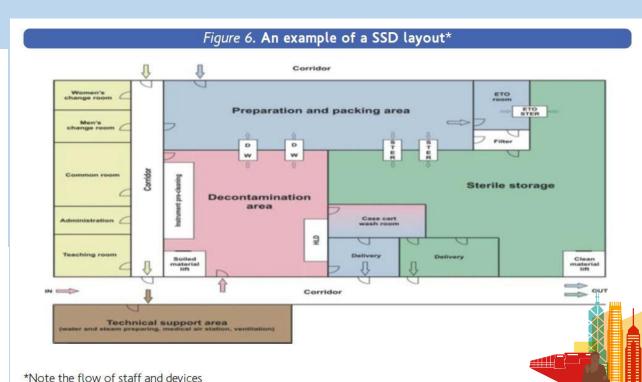


The Sterile Services Department (SSD)

- Advantages and disadvantages of a SSD
- Layout and space planning of SSD
- Design of the SSD
- Air and water quality
- The SSD environment structures, ventilation, humidity, temperature
- Specific areas e.g. dirty area, packaging area, sterilization area
- Occupation health and safety

Ten Rules for the SSD location

- The SSD is designed so that it is physically separated from all other work areas and does not interfere
 with routine clinical practice,
- 2, The SSD is not an integral part of any other service user or treatment area, such as operating theatres.
- 3. The SSD is not to be used as a thoroughfare.
- 4. The SSD is purpose-specific and built for reprocessing devices with clearly demarcated areas.
- 5.The SSD is designed to allow segregation of "dirty" and "clean" activities.
- 6. The SSD is designed to facilitate a unidirectional flow from the "dirty" area to the "clean" area.
- 7.The SSD will have a dedicated staff area in proximity for changing into work wear, which includes a shower, toilet facilities and lockers.
- Access to the dirty and "clean" areas, such as the IAP room, should be through separate, dedicated gowning rooms provided with hand hygiene facilities.
- The dirty area, IAP, sterilizing and sterilizer unloading area should be free from windows that can be opened, ledges and difficult-to-clean areas.
- 10. The dirty area, clean area room, IAP area and sterilizing area should be designed to minimize the ambient sound levels within the rooms. This will require particular attention to the installation of equipment, building finishes and maintenance of machines.



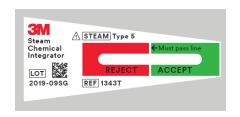




Sterilization Procedures - the Perfect Area for CQI in the Hospital

























Asia Safe Surgical Implant Consortium

2023 ASSIC Tokyo, Japan

2024 ASSIC Seoul, Korea 2025 ASSIC March 25-27 Bangkok, Thailand

Sterilization Consensus

























10 Countries

16 Organizations

20 Delegates

10 Countries

organizations

23 QIP completed

17 Organizations

Consensus documents endorsed by 12

41 Delegates

10 Countries

16 Organizations

42 Delegates The Bowie-Dick 3M Attest eBowie-Dick Test Card

Consensus documents endorsed by 17 organizations

28 QIP











- Developed 3 consensus documents
- Endorsed by **10** organizations
- 10 QIP completed

Sterilisation Assurance Resource Hub Page

Solving What Matters, Advancing Together Spotlight on the Inspiring ASSIC Program!





2025 ASSIC Delegates

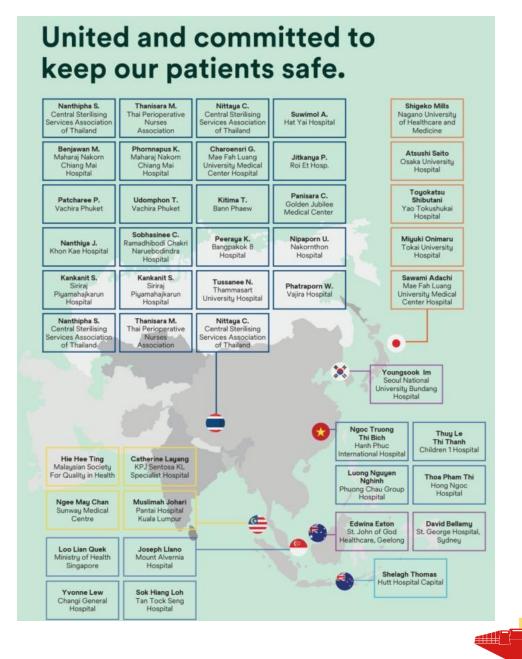
10
Countries

42Delegates

282025 WHO
QIP#



*Included WHOCC & Speaker, #Interested to conduct QIP







Honoring the Attendees Behind This Outstanding Event: 2025 ASSIC



WHO CC, Asia & Global Team



Australia & New Zealand



Japan



Korea



Singapore



Thailand



Malaysia



Vietnam

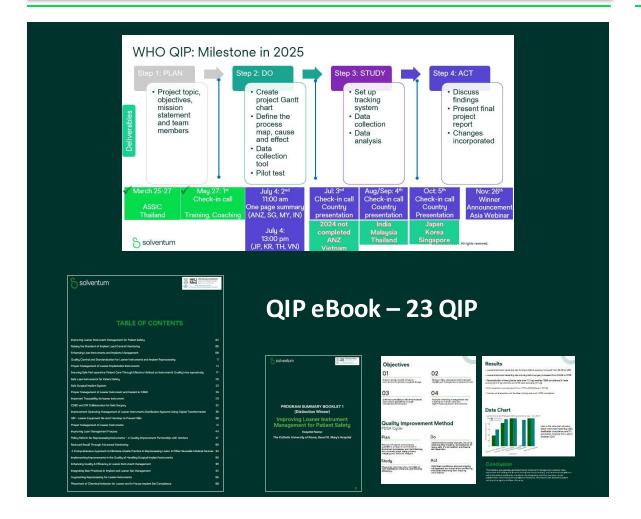






WHO CC QIP, Education & Training

Continuous Improvement through WHO CC QIP



Leverage Education & Training







Description of the 23 QIPs in 2024

- All on loan instruments or improvements on recall.

TABLE OF CONTENTS

Improving Loaner Instrument Management for Patient Safety	02
Raising the Standard of Implant Load Control Monitoring	
Enhancing Loan Instruments and Implants Management	
Quality Control and Standardization for Loaner Instruments and Implant Reprocessing	
Proper Management of Loaner Implantation Instruments	14
Ensuring Safe Peri-operative Patient Care Through Effective Method on Instrument's Quality Intra-operatively	17
Safe Loan Instruments for Patient Safety	20
Safe Surgical Implant System	23
Proper Management of Loaner Instrument and Implant in CSSD	26
Important Traceability for loaner instrument	
CSSD and OR Collaboration for Safe Surgery	32
Improvement Operating Management of Loaner Instruments Sterilization Systems Using Digital Transformation	
QIP - Loaner Equipment Re-start Nonstop to Prevent SSIs	38
Proper Management of Loaner Instruments	41
Improving Loan Management Process	44
Policy Reform for Reprocessing Instruments - A Quality Improvement Partnership with Vendors	47
Reduced Recall Through Advanced Monitoring	50
A Comprehensive Approach to Eliminate Unsafe Practice in Reprocessing Loans & Other Reusable Medical Devices	53
Implementing Improvements in the Quality of Handling Surgical Implant Instruments	56
Enhancing Quality & Efficiency in Loaner Instrument Management	59
Integrating Best Practices in Implant and Loaner Set Management	62
Augmenting Reprocessing for Loaner Instruments	
Placement of Chemical Indicator for Loaner and In-House Implant Set Compliance	





2025 QIP Program Brochure



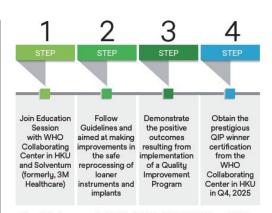
Quality Improvement Programs (QIPs) are of utmost importance as they play a crucial role in driving several key factors:

- Improved outcomes for patients
- Improved efficiency of staff and saving cost, special for loaner instruments and implants

QIP programs ensure that the focus remains on continuously improving the quality of care provided to patients.



Scan QR code to join QIP



We will help you apply WHO, AORN, AAMI, APSIC, and CDC guidelines, along with standards and consensus documents, to implement best practices in your facility.

This will support your organization's patient safety goals, with a special focus on the safe reprocessing of loaner instruments and implants in 2025.







WHO QIP: Milestone in 2025

Step 1: PLAN Step 3: STUDY Step 2: DO Project topic, Create Set up objectives, project Gantt tracking mission chart system **Deliverables** statement Data Define the and team collection process members map, cause Data and effect analysis Data collection tool Pilot test Jul: 3rd March 25-27 May 27: 1st Aug/Sep: 4th July 4: 2nd Oct: 5th Check-in call

ASSIC Thailand Check-in call

Training, Coaching

11:00 am One page summary (ANZ, SG, MY, IN)

> July 4: 13:00 pm (JP, KR, TH, VN)

Step 4: ACT

- Discuss findings
- Present final project report
- Changes incorporated

Check-in call Country presentation

Country

presentation

Check-in call Country Presentation

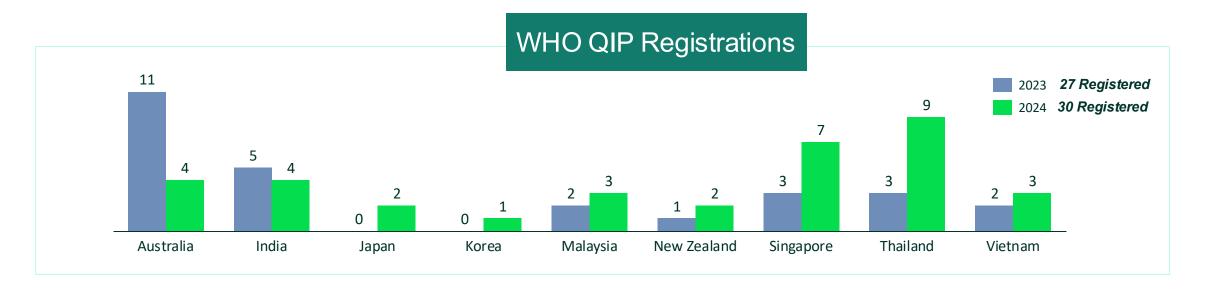
Nov: 26th Winner Announcement Asia Webinar

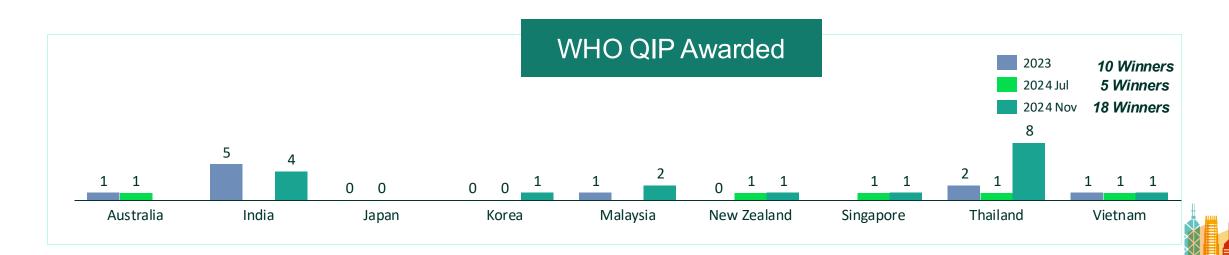






2023 - 2024 WHO QIP Submission – 35 Hospitals

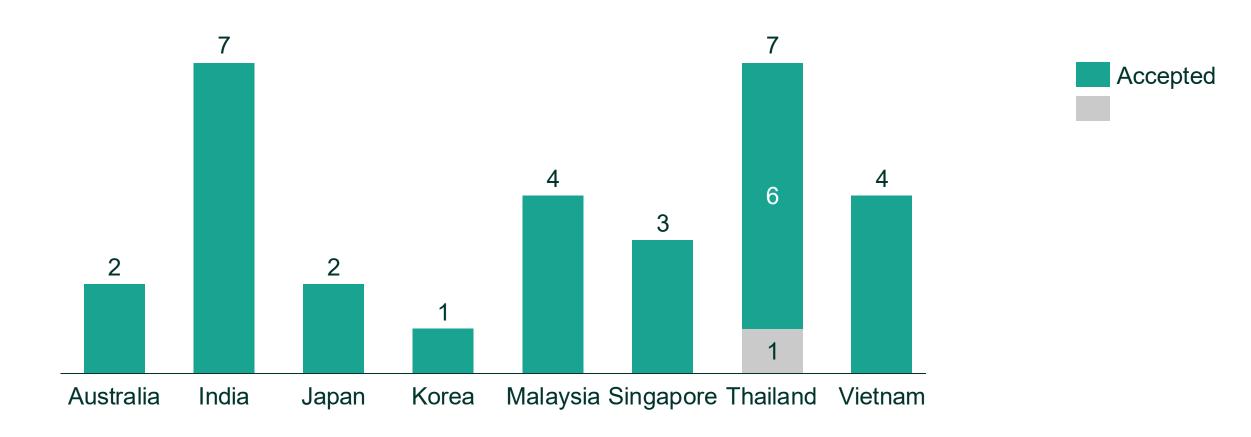








2025 QIP Registrations32 Registrations29 Accepted



12 winners with 3 distinctions, announced on 26th November 2025





ASSIC Community

Asia Safe Surgical Sterilisation Assurance Knowledge Hub



Association Endorsement Asset



Interview Videos







Social Media Post (During and Post Event)



2025 Asia Safe Surgical Implant Consortium

m March 25 - 27, 2025 2025 | Bangkok, Thailand

Bringing together leaders in sterilisation monitoring and safety practices

In collaboration with the WHO Collaborating Centre HKU, #Solventum is bringing together experts at the Asia Safe Surgical Implant Consortium from 25-27 March, With implant surgeries carrying the highest risk of infection, ensuring every load is properly sterilised is a non-negotiable step in #patientsafety.



2025 Asia Safe Surgical Implant Consortium.mp4

CCO You and 87 others 3 comments · 9 reposts

C Like

Comment Comment

Repost

◀ Send

A Transformative Surgical Sterilisation Experience at the Asia Safe Surgical Implant Consortium: A Unified Effort to Patient Safety We have successfully concluded an insightful and impactful Asia Safe Surgical Implant Consortium in collaboration with the WHO Collaborating Centre HKU. Leaders from across Asia have registered for the WHO Collaborating Centre HKU Quality Improvement Project (QIP) to elevate monitoring practices in implant load and the management of loaner instruments. Thank you for attending the Solventum Asia Safe Surgical mplant Consortium. CCO You and 136 others 5 reposts C Like Comment Comment Repost 1 Send

Advancing Sterilisation Quality Assurance

Ensuring the highest standards in medical instrument sterilisation is essential for patient safety. In collaboration with leading experts, we are proud to introduce three key consensus documents that establish new benchmarks for sterilisation quality assurance:

- ✓ Quality Assurance in Sterilisation Monitoring Frequency Providing guidelines for consistent and effective sterilisation monitoring.
- ✓ Sterilisation Recall Policy & Procedure Defining clear protocols to manage and mitigate risks associated with sterilisation failures.
- ✓ Proper Management of Loaner Instruments & Implants A 10 step guide to improving. processes, handling, and monitoring to ensure compliance and patient safety.

We endorse these critical frameworks to strengthen global sterilisation practices. Together, we can drive meaningful improvements in patient safety and infection

#SterilisationQuality #PatientSafety #MedicalStandards #SterilisationMonitoring #ImplantLoad #LoanerInstruments #HealthcareInnovation

Introducing Sterilisation Consensus Documents

Strengthening infection prevention, risk management, and patient safety.

- ✓ Consistent sterilisation checks
- ✓ Clear recall protocols
- ✓ Safe loaner instrument handling





BRING THE STERILIZATION SCIENCE TO THE NEXT LEVEL

3RD TO 6TH DECEMBER

