质量改进项目在消毒供应中心的重要性

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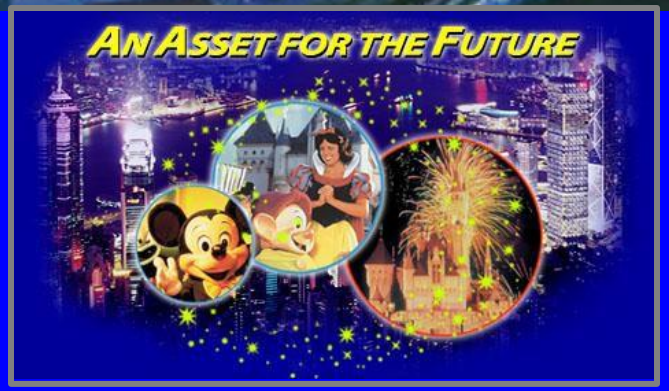
WHO Collaborating Centre for Infectious Disease Epidemiology and Control

歡迎....



香港首例禽流感病例, 2005

请参观
香港大学

香 港 大 學
THE UNIVERSITY OF HONG KONG

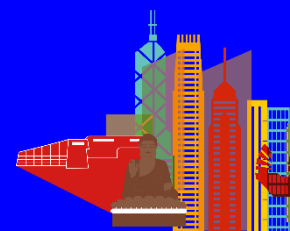
1937

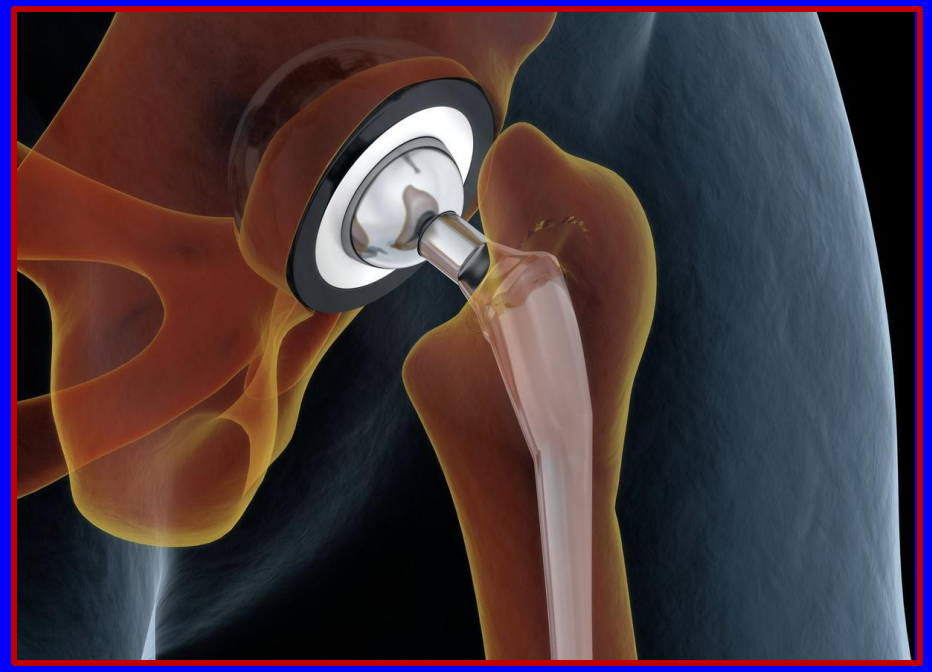
1998年 – APSIC（亚太感染控制学会）在香港大学罗伯特·布莱克学院（Robert Black College, HKU）发起，有来自16个亚洲国家的代表参加

罗伯特·布莱克学院

太古酒廊

在植入物手术中开展质量改进项目（QIP）的兴趣与启动——背后的原因





全关节置换术是 现代医学
一项 了不起的进步

关节置换感染

少数接受髋关节或膝关节置换手术的患者（大约**100人中有1人，即1%）可能在术后出现感染**。

- 感染发生在伤口内或人工植入物周围的深处；
- 感染可能发生在住院期间或出院后；
- 关节置换感染甚至可能在手术后的数年内发生。

2023年2月

BMC 感染性疾病

意大利骨科植入物相关器械感染的流行率和负担：一项基于医院的全国性研究

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

BMC

RESEARCH ARTICLE

Prevalence and burden of orthopaedic implantable-device infections in Italy: a

表1 各类手术感染的流行率 (2014)

宏观类别	总数	感染数	流行率 (%)
1. 初次髋关节置换			
2. 髋关节置换翻修			
3. 其他髋关节手术			
4. 初次膝关节置换			
5. 膝关节置换翻修			
6. 其他膝关节手术			
7. 下肢植入 (股骨、胫骨、足部)			
8. 下肢翻修 (股骨、胫骨、足部)			
9. 其他下肢手术			
10. 上肢植入 (肩部、手臂、手部)			
11. 上肢翻修 (肩部、手臂、手部)			
12. 其他上肢手术			
13. 一般肌肉骨骼植入			
14. 一般肌肉骨骼移除			
15. 其他骨科手术			
16. 相关的一般性手术			
总计			

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%**

手术治疗

AAOS
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

- 感染**深入**人工关节的病例，几乎**总是需要手术治疗**（单次手术或分期手术）；
- **晚期感染**（发生在关节置换手术后数月至数年的感染）**总是需要进行两阶段手术；**
- 接受分期手术的患者，通常需要**使用间隔器（spacer），**并在植入新人工关节之前，接受至少**6周的静脉注射抗生素；**
- 第二阶段是翻修手术，**植入新的关节部件。**

预防

AAOS
American Academy of Orthopaedic Surgeons

- 术前和术后抗生素预防
- 缩短手术时间，尽量减少手术室人流
- 使用严格的无菌操作技术和无菌器械
- 术前鼻腔细菌定植筛查
- 术前使用洗必泰（氯己定）清洗
- 长期抗生素预防

采取措施确保**手术部位无菌、器械**经过适当灭菌且**未暴露于任何污染**，并且**植入物**经过包装以确保其无菌性。

亚洲植入物负载监测调查与结果

司徒永康 教授

主任,

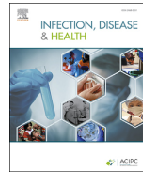
香港大学世卫组织合作中心主任

2023年6月22日

来自10个国家的517个回复

- ANZ 澳大利亚和新西兰
- India 印度
- Indonesia印尼
- Japan 日本
- Korea 韩国
- Malaysia 马来西亚
- Philippines 菲律宾
- Singapore 新加坡
- Thailand 泰国
- Vietnam越南

Available online at www.sciencedirect.com
ScienceDirect
journal homepage: http://www.journals.elsevier.com/infection-disease-and-health/



Research paper

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

Wing [redacted] *

School of

亚太地区手术植入物灭菌：现行实践调查

Received

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.

Highlights

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

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https://doi.org/10.1016/j.idh.2025.02.006
2468-0451/

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

PCD + BI

过程挑战装置 + 生物指示剂

Written policy for recall

召回的书面政策

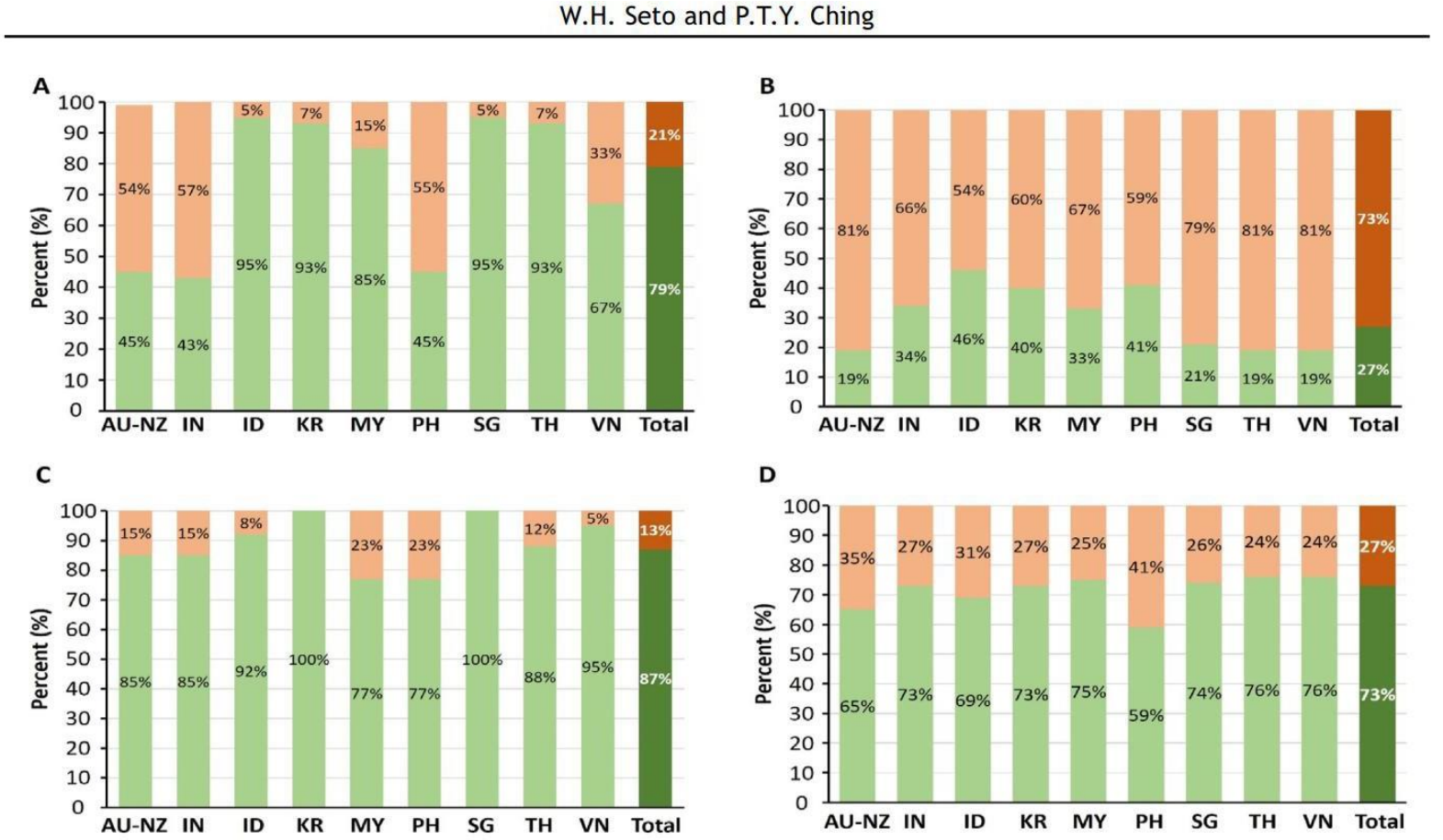


图 2 **与含植入物批次相关的回复。** **柱状**图描绘了 (A) **受**访者表示每批含植入物的批次是否用含有**生物指示**剂 (BI) **和 5 型化学指示**剂 (CI) **的**过程挑战装置 (PCD) 进行监测的百分比；(B) **受**访者**表示在**获得 BI 结果之前，根据 5 **型** CI 结果进行过紧急植入物批次放行的百分比；(C) **受**访者表**示是否有**书面政策和程序，用于在集中CSSD监测中出现 BI **阳性**时召回器械的百分比；以及 (D) **受**访者表示保持记录以追踪紧急植入物批次放行事件发生率的百分比。绿色条段 = **“是”的回复**；红色条段 = **“否”的回复**。

Emergency release prior to BI result

在生物指示剂 (BI) 结果出来前紧急放行

Documentation of emergency load release

紧急放行批次的**文件**记录

CI type used in every package

每个包中使用的化学指示剂 (CI) 类型

Numbers of CI used in multi-level trays

多层托盘中使用的化学指示剂 (CI) 数量

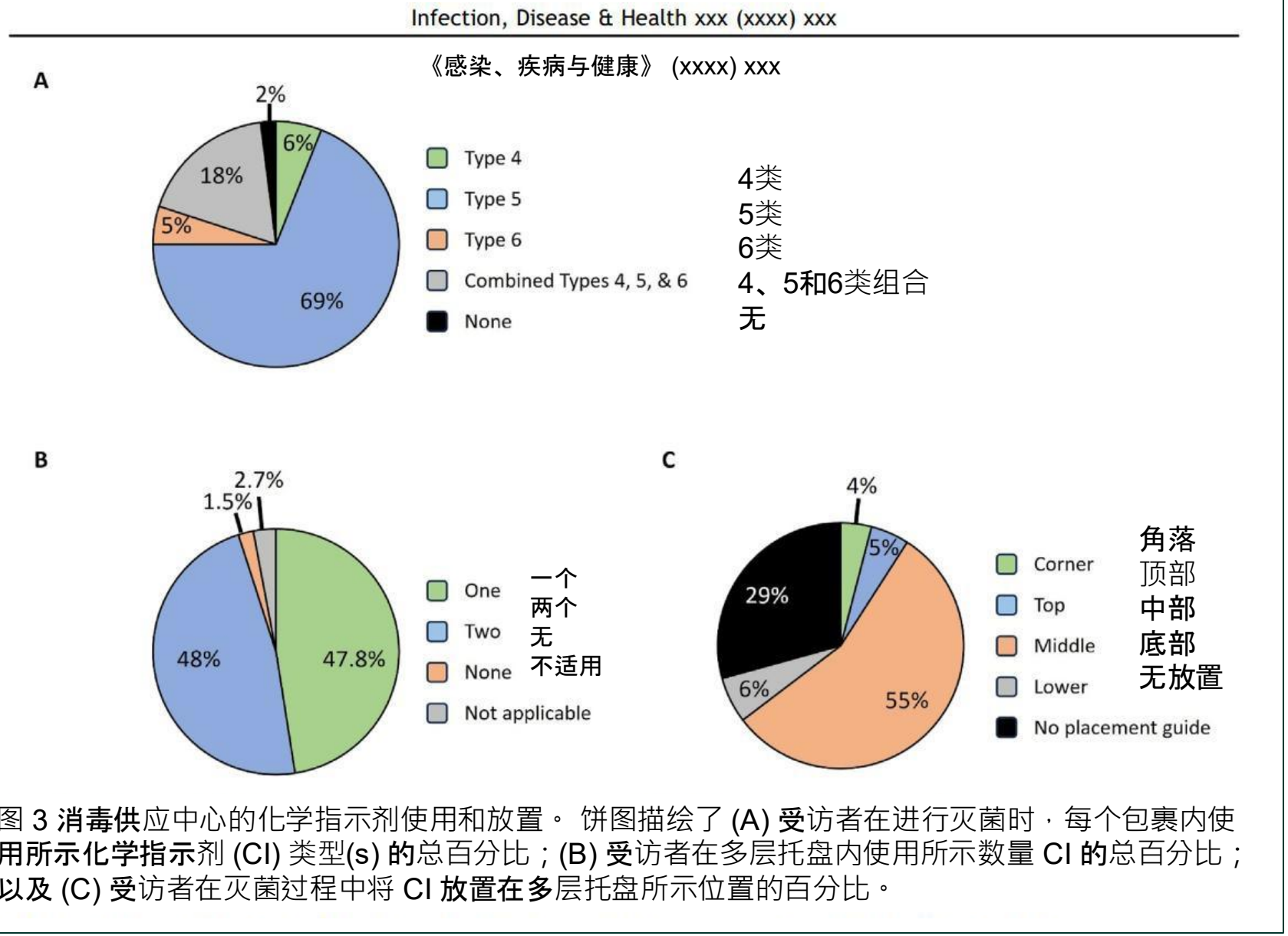
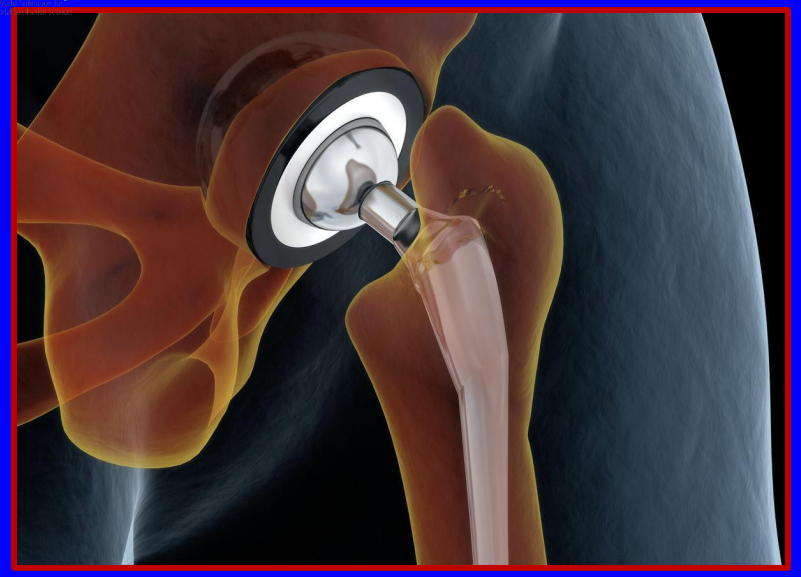


图 3 消毒供应中心的化学指示剂使用和放置。 饼图描绘了 (A) 受访者在进行灭菌时，每个包裹内使用所示化学指示剂 (CI) 类型(s) 的总百分比；(B) 受访者在多层托盘内使用所示数量 CI 的总百分比；以及 (C) 受访者在灭菌过程中将 CI 放置在多层托盘所示位置的百分比。

多层托盘中化学指示剂 (CI) 的放置位置

Location of CI in multi-level trays

亚洲安全手术植入物联盟 – 2023年第一次会议

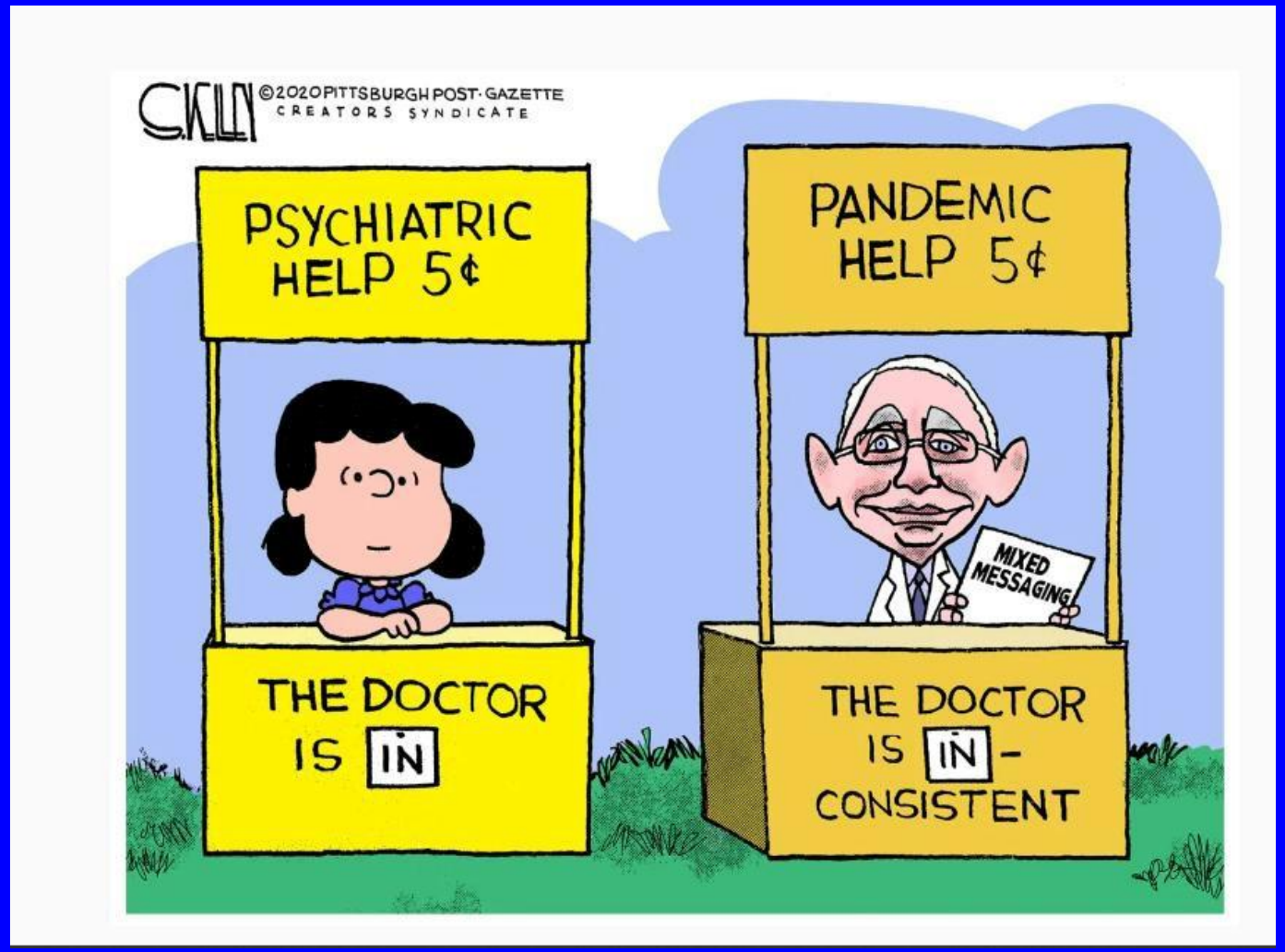


必须建立系统，以确保对外来器械进行妥善管理，从而形成.....

<u>亚洲安全手术植入物联盟</u>

双重战略:

- 共识文件
- 启动 QIP 项目 （质量改进项目）



这就是为什么我们需要指南

如此多的指南 .....

CDC

GB 国家标准

World Health Organization

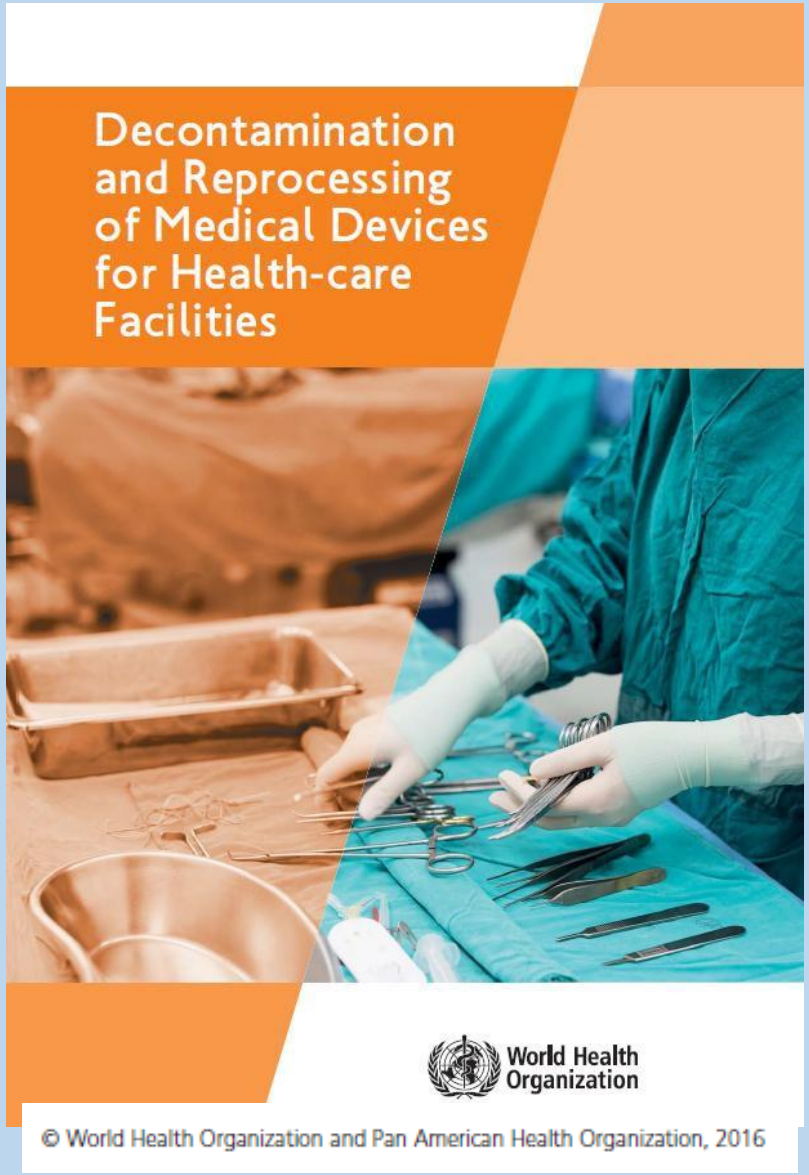
AORN SAFE SURGERY TOGETHER™

APSIC ASIA PACIFIC SOCIETY OF INFECTION CONTROL

AAMI

TGA Health Safety Regulation

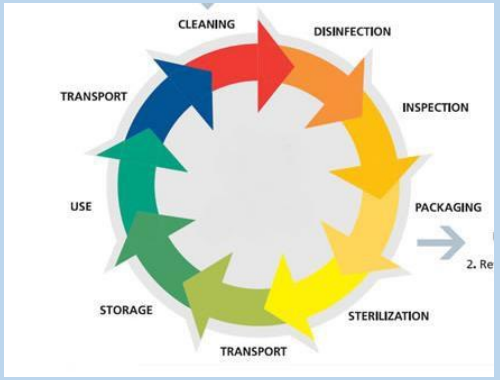
国际指南已发布/可供查阅:



医疗机构医疗器械的去污和再处理

理解世卫组织指南

司徒永康



这是美国疾控中心（CDC）、美国食药监局（FDA）、美国职业安全与健康管理局（OSHA）以及州消毒指南的合订本第一卷。您想把它放哪儿？

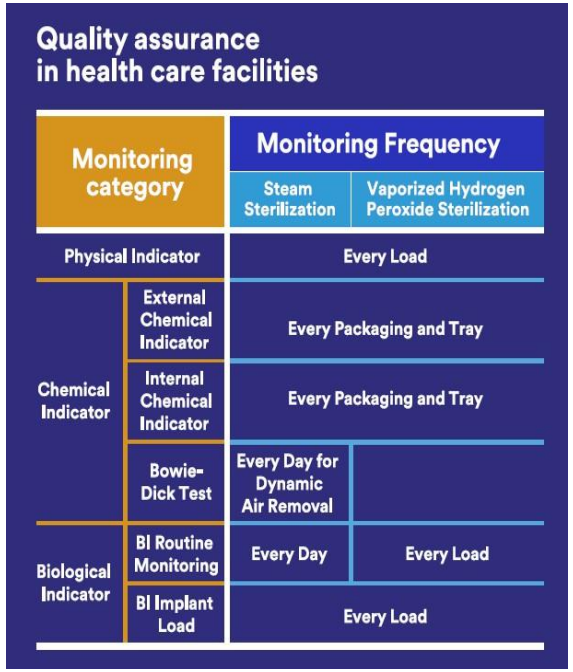
我们必须关注任何指南中最重要的地方...

共识文件

回顾

成就回顾

- ***3*** 份共识文件
- ***16*** 个协会认可/批准
- CSSD, OR, 感染防控协会



HKU Med LKS Faculty of Medicine School of Public Health 香港大學公共衛生學院 WHO Collaborating Centre for Infectious Disease Epidemiology and Control

wfhss World Federation for Hospital Sterilisation Sciences

APSIC ASIA PACIFIC SOCIETY OF INFECTION CONTROL

ACORN AUSTRALIAN COLLEGE OF PERIOPERATIVE NURSES

SSA

Federation of Sterilizing Research and Advisory Councils of Australia

INFECTION CONTROL ASSOCIATION (SINGAPORE)

KAORN Korean Association of Operating Room Nurses

KASDN 병원중앙공급간호사회 Korea Association of Central Supply Department Nurses

NEW ZEALAND STERILE SCIENCES ASSOCIATION

PPSSI

OPERATING ROOM NURSES CHAPTER SINGAPORE

VNICS Viet Nam Infection Control Society Hội Kiểm Soát Nhiễm Khuẩn Việt Nam

共识文件：

医疗机构的质量保证

Quality assurance in health care facilities

Monitoring category		Monitoring Frequency	
		Steam Sterilization	Vaporized Hydrogen Peroxide Sterilization
Physical Indicator		Every Load	
Chemical Indicator	External Chemical Indicator	Every Packaging and Tray	
	Internal Chemical Indicator	Every Packaging and Tray	
	Bowie-Dick Test	Every Day for Dynamic Air Removal	
Biological Indicator	BI Routine Monitoring	Every Day	Every Load
	BI Implant Load	Every Load	

Endosed by:

Supported by 3M

外来器械和植入物的妥善管理

Proper management of loaner instruments and implants

steps 10

1 **Prior Notification to CSSD:** Notify the Central Sterile Supply Department (CSSD) in advance before receiving loaner instruments or implants.

2 **Timely Receipt of Instruments:** Ensure that the instruments are received within 2 working days (48 hours) before the scheduled case, in the case of existing sets.

3 **Inventory and Inspection:** Perform a thorough inventory and inspection of the loaner instruments upon receipt to verify their completeness and condition.

4 **Follow Manufacturer's Instructions:** Adhere to the manufacturer's instructions for cleaning and decontamination, following the instrument-specific instructions for use (IFU).

5 **Function and Cleanliness Inspection:** Inspect the loaner instruments for functionality and cleanliness after the cleaning and decontamination process.

6 **Proper Packaging:** Ensure that the loaner instruments are appropriately packaged, following recommended guidelines and considering their specific requirements.

7 **Sterilization Process:** Sterilize the loaner instruments according to the manufacturer's instructions, using the appropriate sterilization method.

8 **Quality Assurance Monitoring:** Implement quality assurance measures, such as performing Biological Indicator (BI) monitoring for every load and using Type 5 Chemical Indicators (CI) for every pack containing implants.

9 **Prompt Processing After Case:** After the surgical procedure, process the loaner instruments promptly to prevent delays and ensure timely availability for future cases.

10 **Inventory Check before Return:** Conduct an inventory check of the loaner instruments before returning them to ensure all items are accounted for and properly organized.

Endosed by:

Supported by 3M

灭菌召回政策和程序

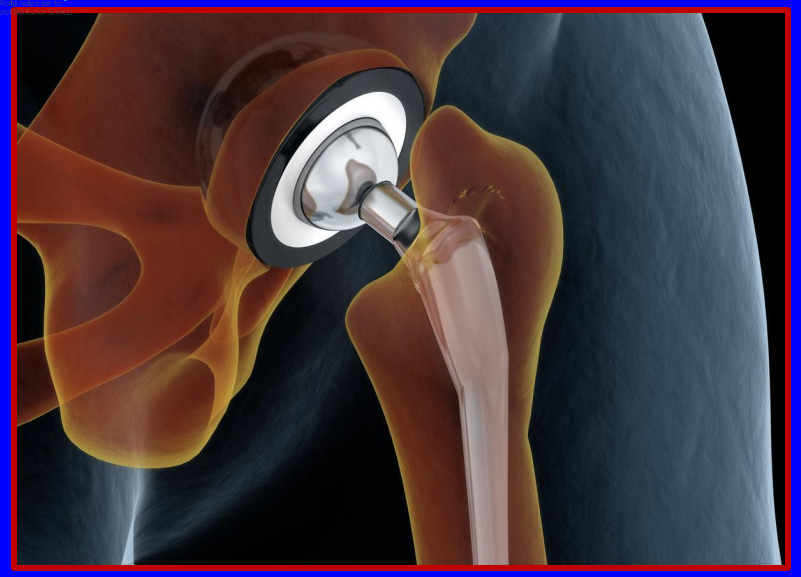
Sterilization recall policy and procedure

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:

Supported



必须建立系统，以确保对外来器械进行妥善管理，从而形成.....

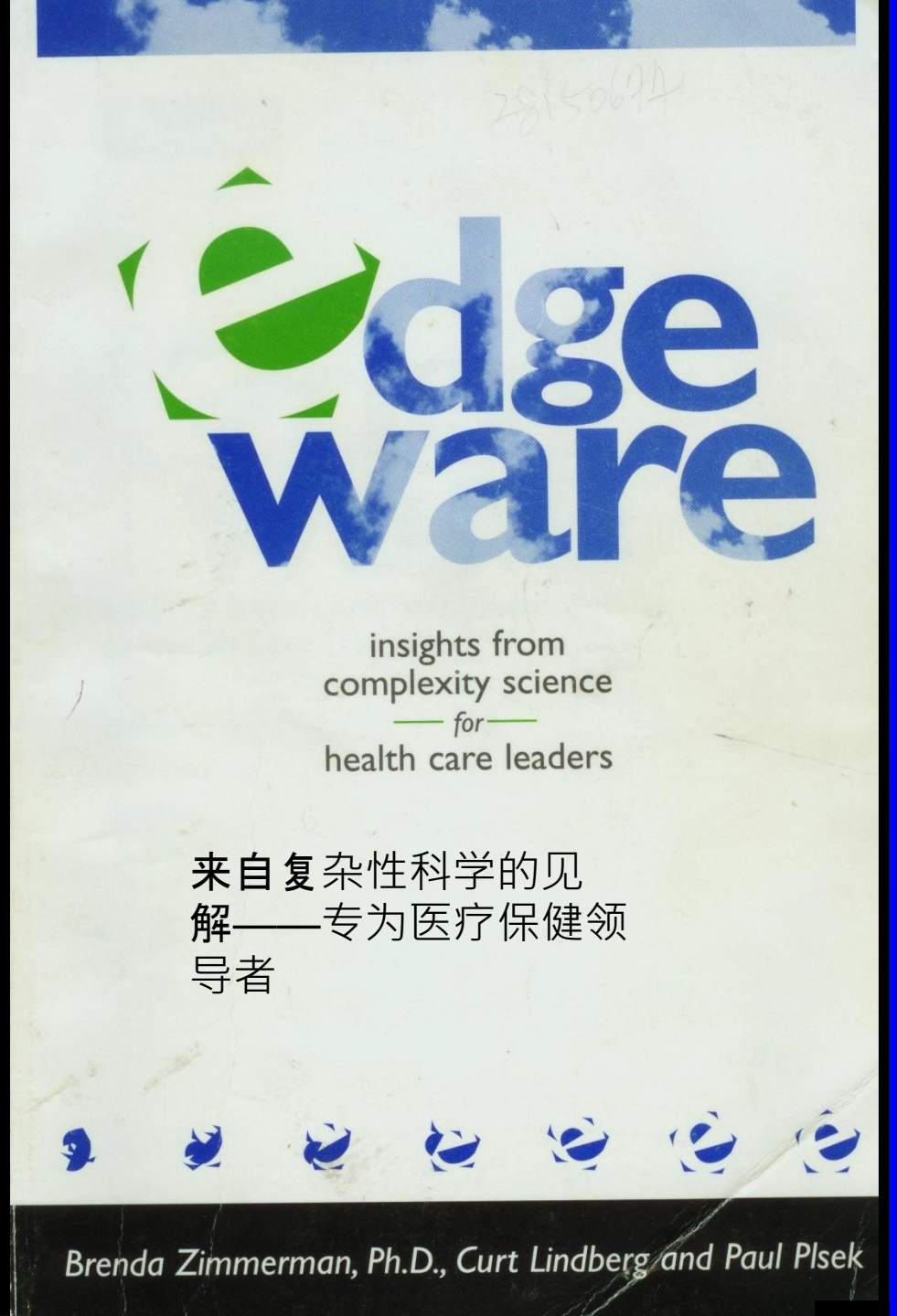
亚洲安全手术植入物联盟

双重战略:

- 共识文件
- 启动 QIP 项目 （质量改进项目）

“医院是迄今为止设计出的最复杂的人类组织”

— 彼得·德鲁克



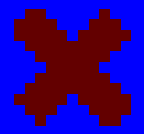
复杂性科学

来自复杂性科学的见解——专为医疗保健领导者

‘复杂性科学’

对以下系统的研究

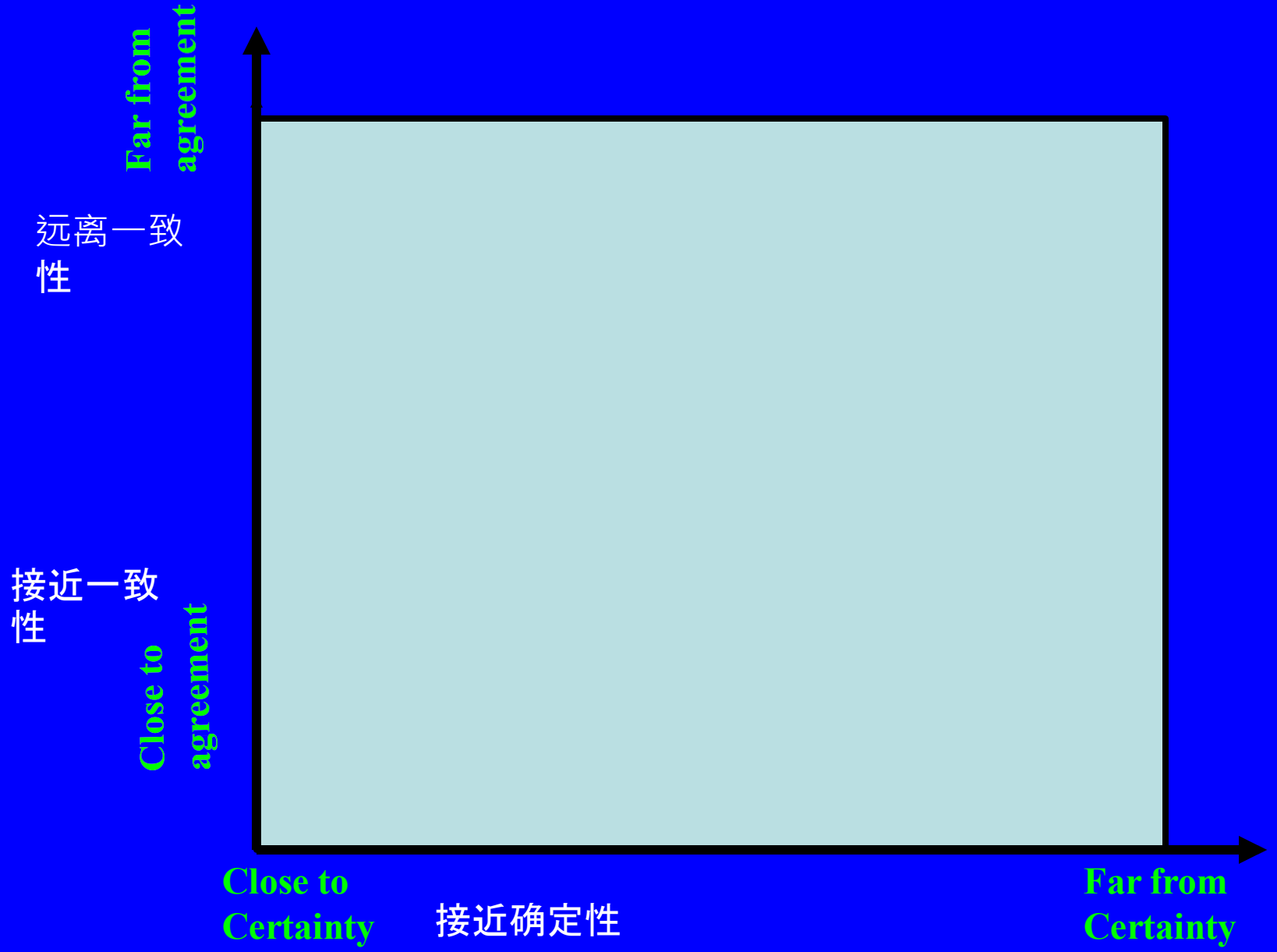
- 既相互依存又相互独立，
- 共识尚未完全形成，
- 变化不可预测但正在涌现。



它并非指不存在任何系统的混乱情况

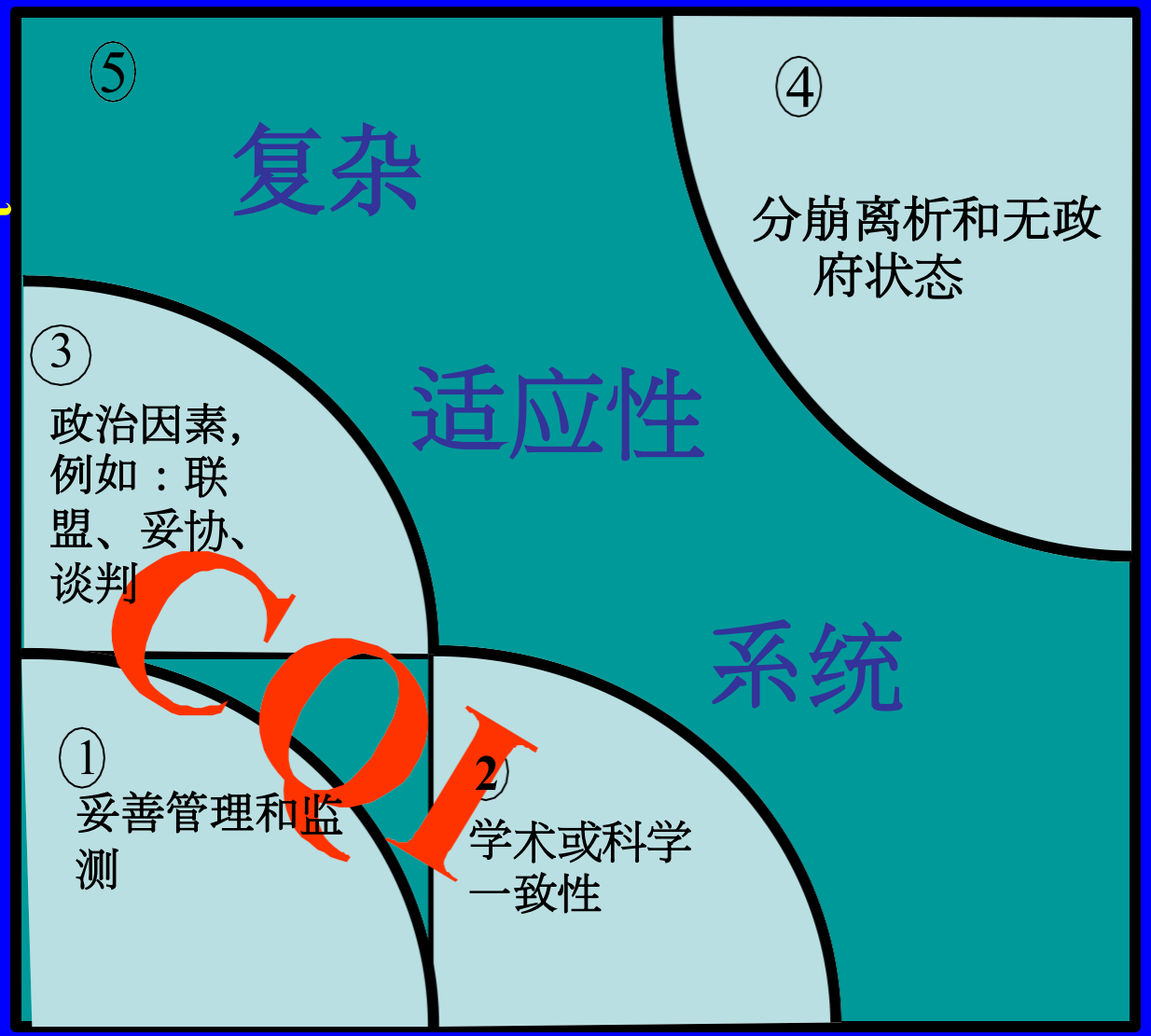
Zimmerman

Stacey 一致性和确定性矩阵



远离一致性

Far from agreement



CQI (持续质量改进)

CQI

接近一致性

Close to agreement

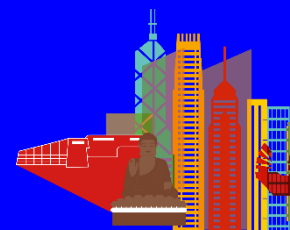
Close to Certainty

接近确定性

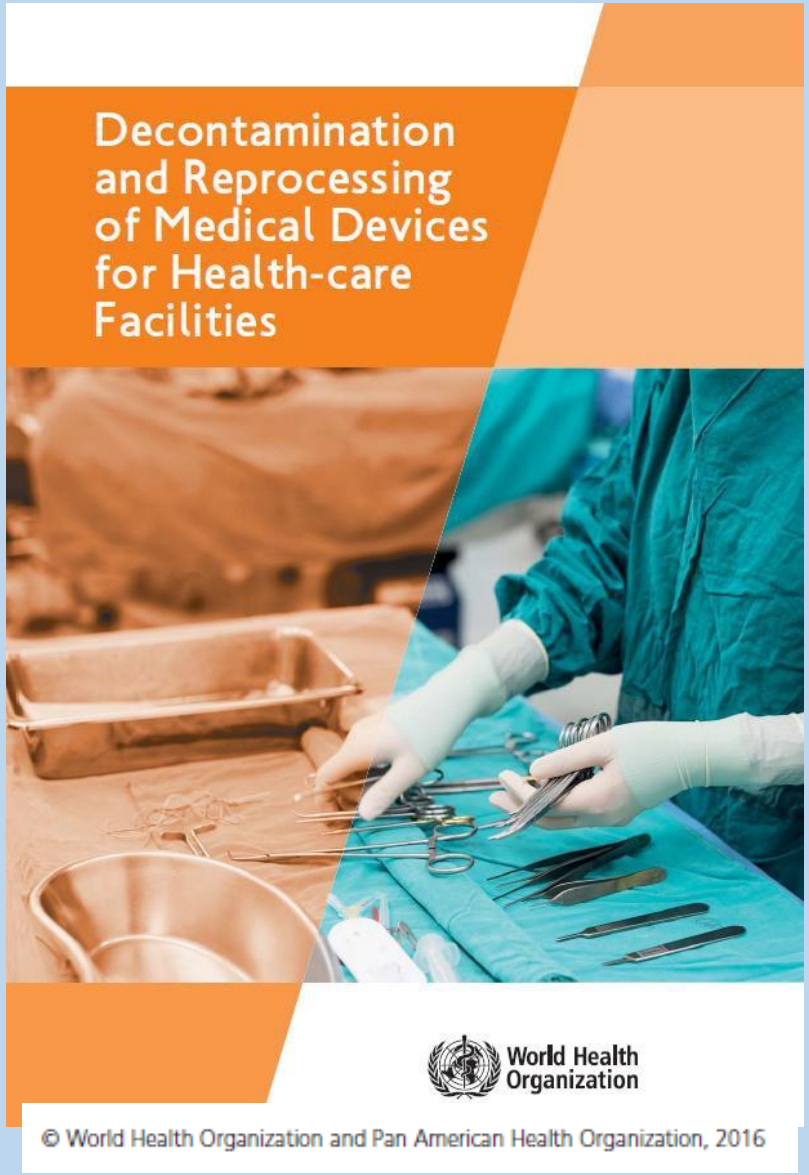
Far from certainty

远离确定性

与医院的复杂性相比，CSSD相对简单。



国际指南已发布/可供查阅:



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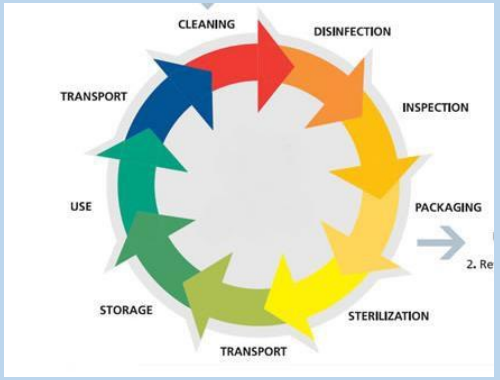
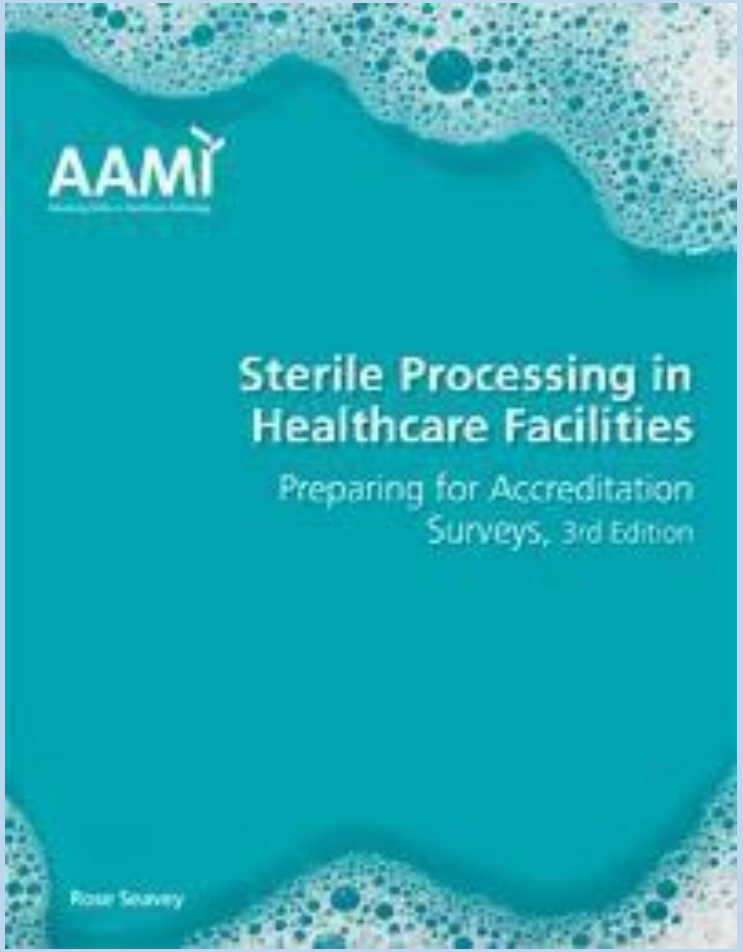
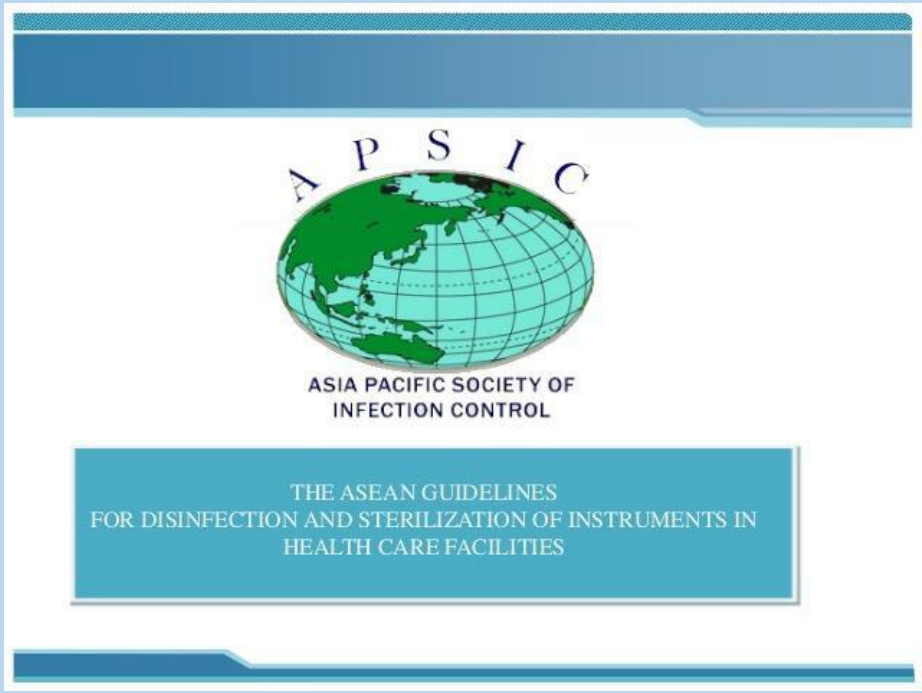


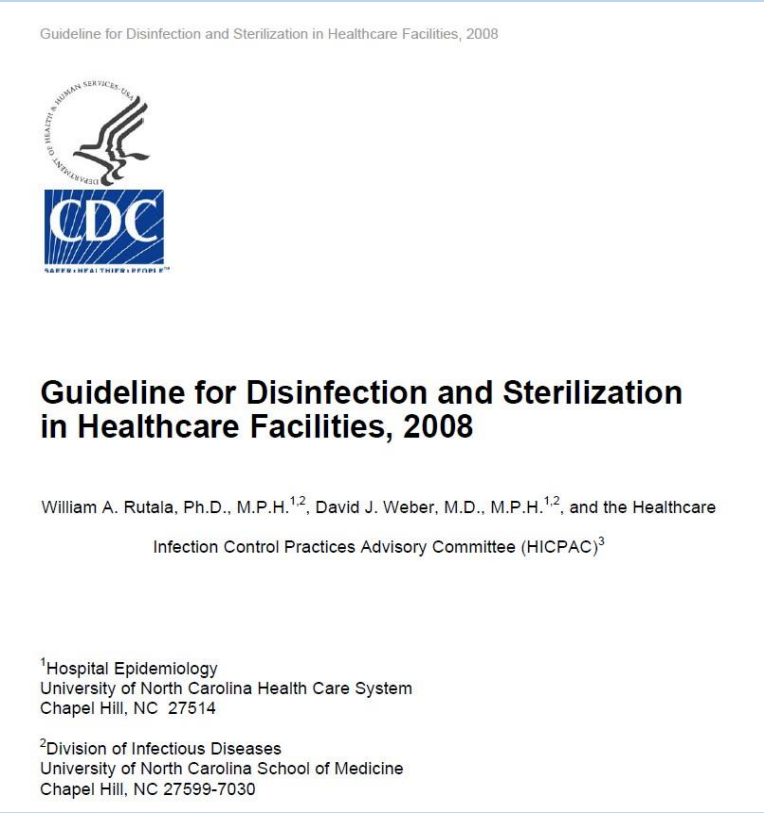
其它参考指南



2017



2017



2008

许多事项都有明确定义:

关于灭菌的常识

定义

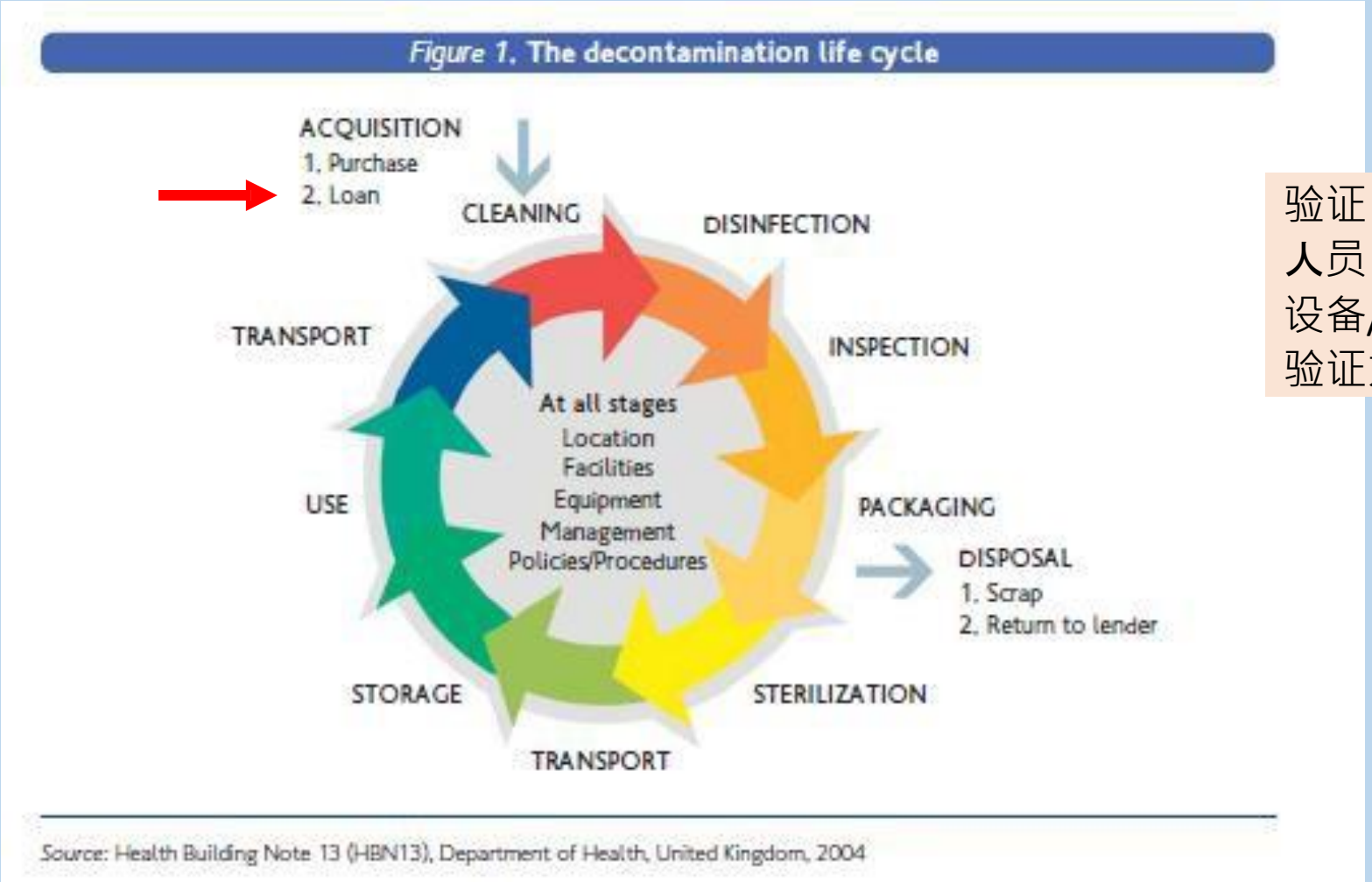
去污（Decontamination）：从物品上清除污垢和致病微生物，使其可以安全处理，以便进行进一步处理、使用或丢弃。（摘自美国疾病控制与预防中心 [CDC] 2008年《医疗机构消毒和灭菌指南》）。

清洗（Cleaning）：通过物理方式清除异物（例如灰尘、污垢）污染所需的第一步。它还将清除有机物，例如血液、分泌物、排泄物和微生物，以准备对医疗器械进行消毒或灭菌。

消毒（Disinfection）：一种将活微生物数量减少到危害较小水平的过程。该过程可能无法灭活细菌孢子、朊病毒和某些病毒。

灭菌（Sterilisation）：一种经过验证的过程，用于使物品不含活微生物，包括病毒和细菌孢子但不包括朊病毒。

流程通常是明确界定且已到位的....



验证：
人员
设备/环境
验证方法

无菌服务中的风险评估

表2. 根据Spaulding分类法对可重复使用器械进行本地去污的政策

风险类别	推荐的去污水平	医疗器械举例
高风险（关键） 涉及皮肤或粘膜破损或进入无菌体腔的物品	灭菌	手术器械 植入物/假体、硬式内窥镜 注射器、针头
中风险（半关键） 接触粘膜或体液的物品	消毒 （高水平）	呼吸设备、非侵入性柔性内窥镜、便盆、尿壶
低风险（非关键） 接触完整皮肤的物品	清洗（视觉清洁）	血压袖带、听诊器

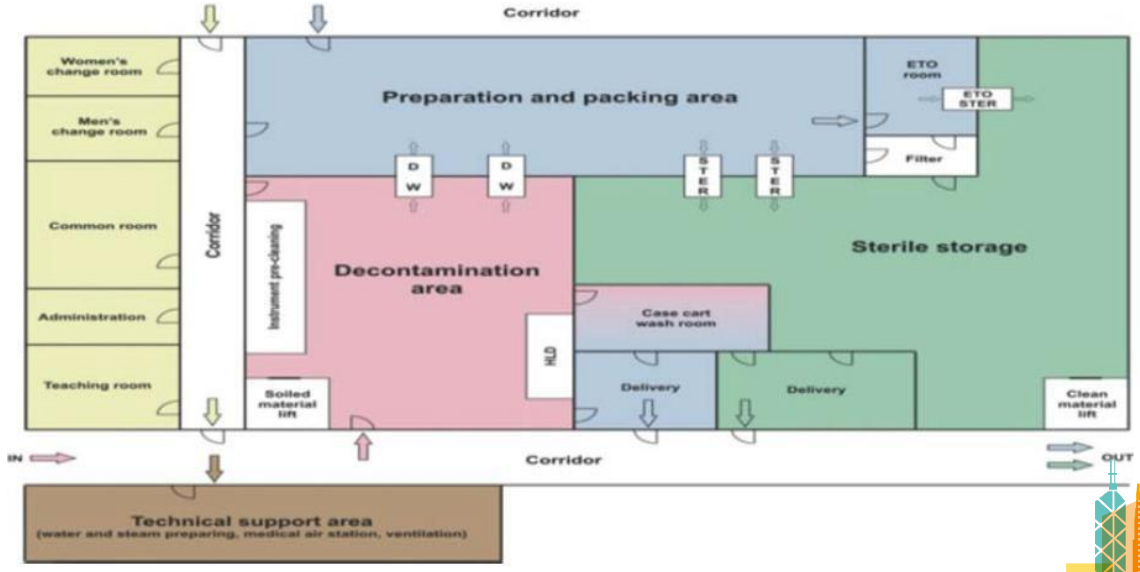
消毒供应中心（SSD）

- SSD的优点和缺点
- SSD的布局和空间规划
- SSD的设计
- 空气和水质
- SSD环境——结构、通风、湿度、温度
- 特定区域——例如，污区、包装区、灭菌区
- 职业健康和安全

Ten Rules for the SSD location

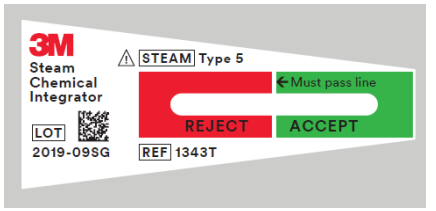
1. The SSD is designed so that it is physically separated from all other work areas and does not interfere with routine clinical practice.
2. The SSD is not an integral part of any other service user or treatment area, such as operating theatres.
3. The SSD is not to be used as a thoroughfare.
4. The 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.
8. Access to the dirty and "clean" areas, such as the IAP room, should be through separate, dedicated gowning rooms provided with hand hygiene facilities.
9. 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.

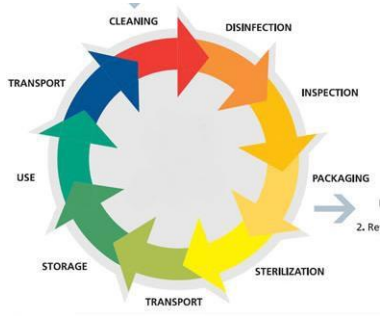
Figure 6. **An example of a SSD layout***



*Note the flow of staff and devices

灭菌程序— 医院持续质量改进（CQI）的完美领域





亚洲安全手术植入物联盟

2023 ASSIC
日本 东京

10 *国家* | **16** *组织* | **20** *代表*

- **制定了 3 份共识文件**
- 获得 10 个组织的认可/批准
- 10 项 QIP（质量改进项目）已完成

2024 ASSIC
韩国 首尔

10 *国家* | **17** *组织* | **41** *代表*

- 共识文件获得 12 个组织的认可/批准
- 23 项 QIP 已完成

2025 ASSIC 3月 25-27
泰国，曼谷

10 *国家* | **16** *组织* | **42** 代表

- 共识文件获得 17 个组织的认可/批准
- 28 项 QIP

灭菌共识

Asia Safe Surgical Implant Consortium
Bangkok, Thailand – 25-27 March 2025

Bringing together leaders in sterilisation monitoring and safety practices

Key Discussions:

- Accelerating Best Practices for Every Implant Load Monitoring
- New Evidence in Sterilisation and Quality Assurance
- Adoption of New Technology
- Sustainability Initiatives and Directives

[Sterilisation Assurance Resource Hub Page]

解决重要问题，共同进步
聚焦鼓舞人心的 ASSIC 项目！

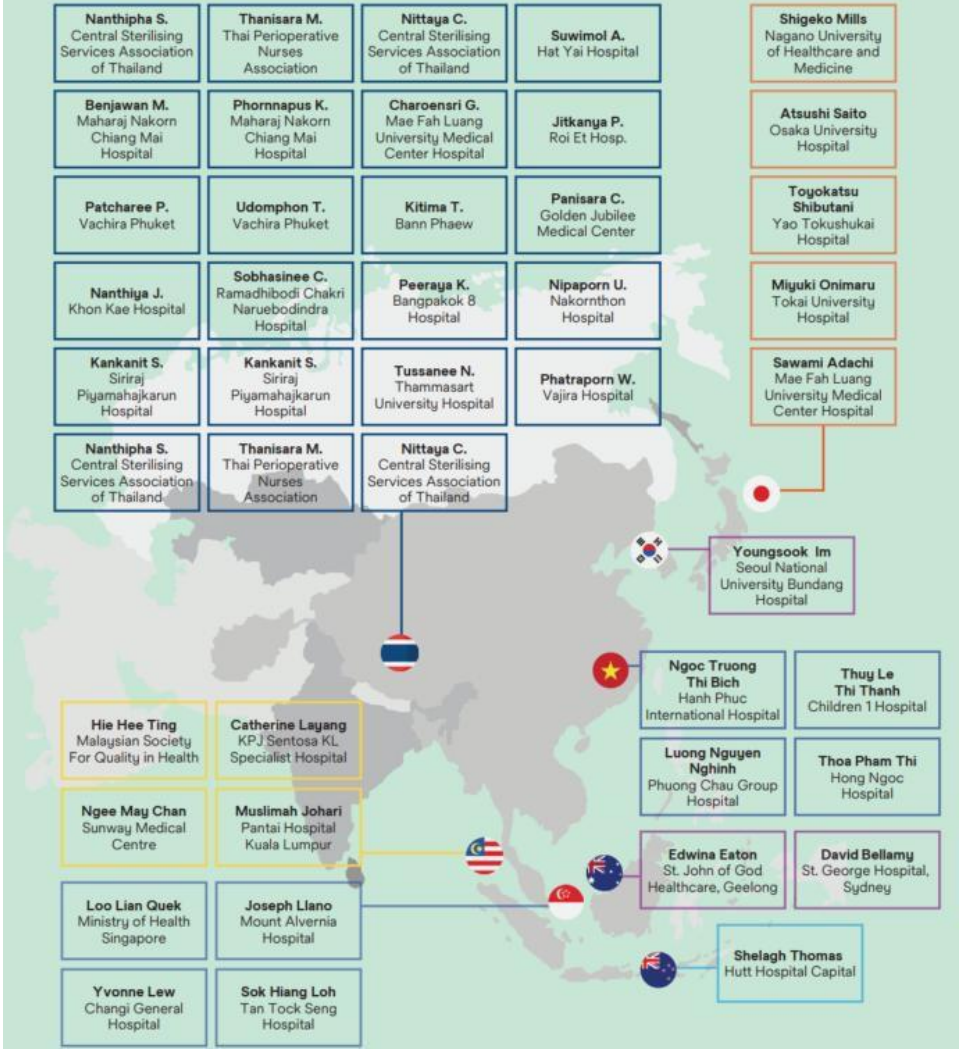
2025年 ASSIC 代表

10
国家

42
代表

28
2025 WHO QIP#

团结一致，
致力于保障患者安全。



包括世界卫生组织合作中心（WHO CC）和演讲者。
#有兴趣开展QIP

向本次杰出活动的幕后参会者致敬：2025年 ASSIC

WHO CC（世界卫生组织合作中心）、亚洲和全球团队

澳大利亚和新西兰

日本

韩国

新加坡

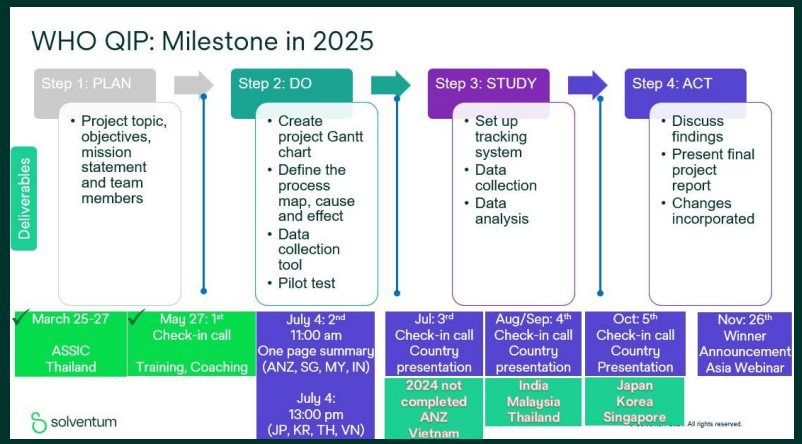
泰国

马来

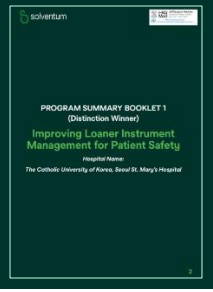
越南

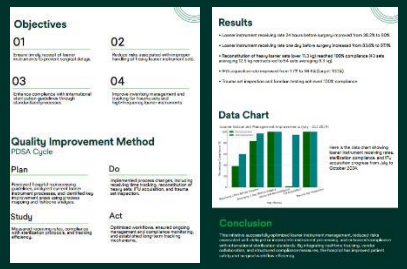
世界卫生组织合作中心（WHO CC）的持续质量改进（QIP）、教育与培训

通过 WHO CC QIP 实现持续改进



QIP 电子书 – 23个 QIP





利用教育与培训

2024年 23个 QIP（质量改进项目）的描述
- 全部是关于外来器械或召回改进的项目。

TABLE OF CONTENTS

2025 QIP（质量改进项目）项目手册

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

1 STEP	2 STEP	3 STEP	4 STEP
Join Education Session with WHO Collaborating Center in HKU and Solventum (formerly, 3M Healthcare)	Follow Guidelines and aimed at making improvements in the safe reprocessing of loaner instruments and implants	Demonstrate the positive outcomes resulting from implementation of a Quality Improvement Program	Obtain the prestigious QIP winner certification from the WHO Collaborating Center in HKU in Q4, 2025

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.

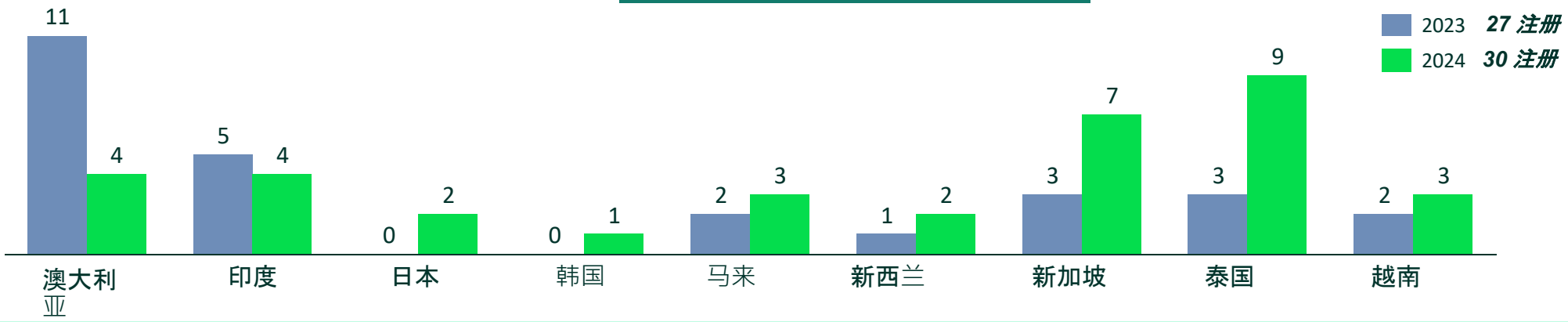
QIP Program Process

世界卫生组织持续质量改进项目（WHO QIP）：2025年里程碑

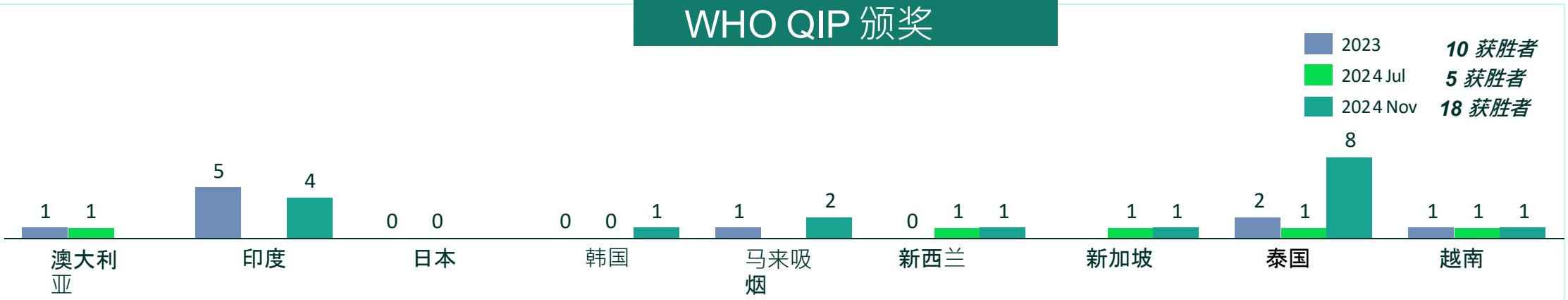
	步骤 1：计划	步骤 2：执行	步骤 3：研究	步骤 4：行动
可交付成果	• 项目主题、目标、使命宣言和团队成员	• 创建项目甘特图 • 定义流程图、原因和效果 • 数据收集工具 • 试点测试	• 建立跟踪系统 • 数据收集 • 数据分析	• 讨论结果 • 提交最终项目报告 • 整合变更
	✓ 3月 25-27 ASSIC 泰国	✓ 5月 27: 第一次签到 培训 教练	✓ 7月4日: 第2次 11:00 am 一页综述 (ANZ, SG, MY, IN) 7月 4日: 13:00 pm (JP, KR, TH, VN)	✓ 7月第3次 签到 国家演示 ✓ 8/9月 第4次 签到 国家演示 ✓ 10月第5次 签到 国家演示 ✓ 11月26日 获胜者公布 亚洲网络研讨会

2023 - 2024年 世界卫生组织持续质量改进项目（WHO QIP）提交情况 – 35家医院

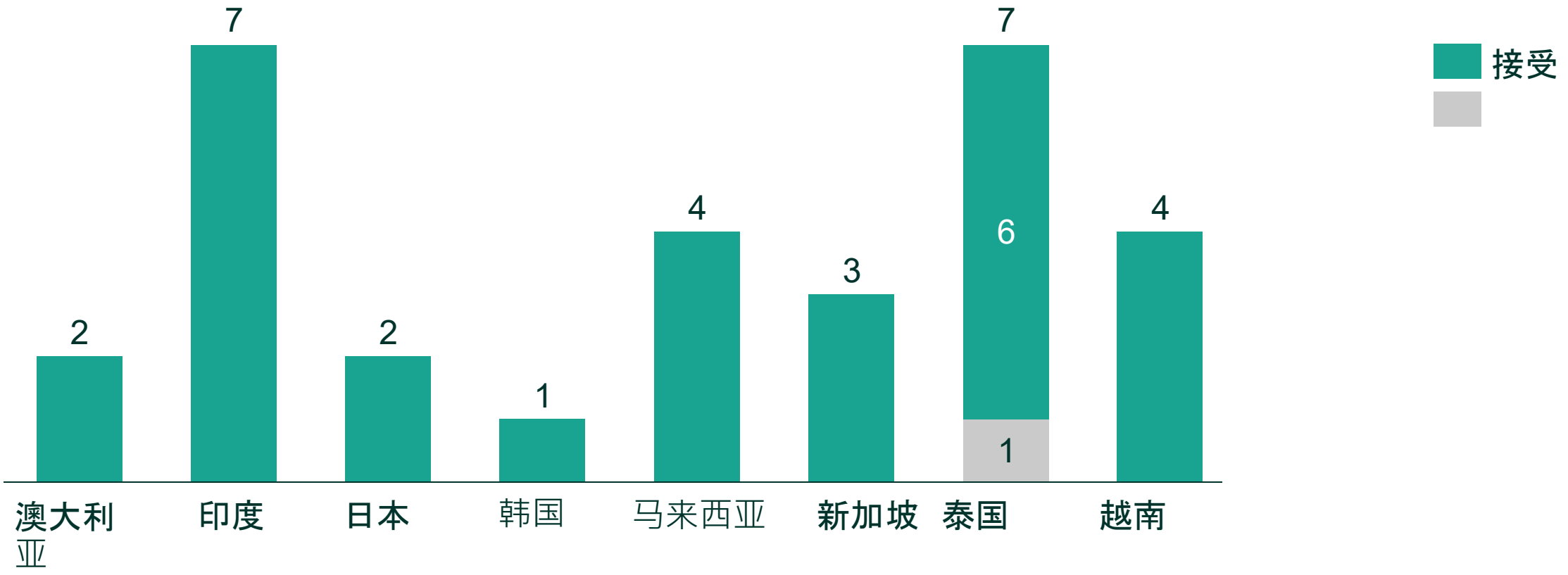
WHO QIP 注册数量



WHO QIP 颁奖



2025年 世界卫生组织持续质量改进项目（QIP）
注册情况 32个注册 29个接受



12个获奖者（其中3个获得杰出奖），2025年11月26日公布

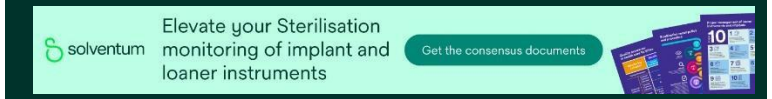
ASSIC 社区

亚洲安全手术 灭菌保证知识中心

[Solventum Asia Safe Surgical Sterilisation Assurance Hub]

销售团队和协会认可资产

Email Signature Banners



Association Site Banners

Social Media Post Content & Email Template

访谈视频

社交媒体帖子（活动期间和活动后）✔

2025 Asia Safe Surgical Implant Consortium

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

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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.

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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 prevention.

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

BRING THE STERILIZATION SCIENCE TO THE NEXT LEVEL
將滅菌科學提升到新水平

26TH WORLD STERILIZATION CONGRESS

3RD TO 6TH DECEMBER 2025 | HONG KONG ASIAWORLD-EXPO 亞洲國際博覽館

欢迎到到香港

谢谢您!