Sterile Services Development in Hong Kong – Journey to Service Excellence

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7 millions population
During the past 40 years, decontamination practices in Hong Kong hospitals had gone through a lot of advancement and improvement changes.
Four Eras in the past 40 years

1. Manual Operation Era
2. Automation Era
3. Quality Management Era
4. Information Technology Era
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Before 1972
Acute General Public Hospitals of Hong Kong as at 1972

Queen Mary Hospital (QMH) established in 1937
Hong Kong West

Queen Elizabeth Hospital (QEH) started its service 1963
Kowloon Central
Before 1972, there were no sterile single-use products as many as we have today. The sterilization service sections of Hospital Pharmacy were responsible for sterilization practices for the processing of the reusable syringes and needles, reusable surgical rubber gloves, sterile dressings, instrument sets for the clinical users and the theatre cotton drapes for the operating rooms.
Principles and Methods of Sterilization in Health Care Sciences by Dr. J.J. Perkins was published in 1956.

This textbook set the standard and methodology for processing and sterilization of reusable medical devices.
In clinical areas, nurses (mainly the student nurses) would be assigned to manual washing of the reusable MDs, making special dressings from gauze and cotton rolls and even reprocessing single-use devices and packed inside drums, ready for sterilization in CSSD.
The Operating Theater Nurses manually processed the surgical devices in the instrument preparation rooms adjacent to the Operation Rooms and flash sterilization was employed.
In 1972, the sterile service management function was taken over by nurses from hospital pharmacy
The competency of sterilization processing, quality control, inventory control, material management in Central Sterile Supply Department (CSSD) was achieved by adopting the principles and practices in sterile services acquired through sending nurses to overseas (mainly in UK).
All sterile items were processed according to planned, agreed standards and procedures for decontamination, assembling and sterilization practices.
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Since 1975
In 1975, the first purposely-built Central Sterile Supply Department (CSSD) and Theatre Service Centre (TSC) in Princess Margaret Hospital were put into function.
Princess Margaret Hospital

Princess Margaret Hospital (PMH) established in 1975
Kowloon West
The emphasis was the improvements on organization and planning of services, the work flows, production control and management.
Application of Automation

The incorporation of new decontamination machines to optimize productivity:

- Tunnel washer
- Hot air dryer
- Glove washer, dryer and powderer
- Ultra-sonic cleaner
- Pre-vacuum steam sterilizer (Large)
- Dry heat sterilizer

Applying automation - to increase productivity and outcome quality beyond that with human labor levels as well as economies of scale realized
Introduction of Edinburgh pre-set tray system in TSC marked a significant improvement in operating theaters service.
The Standardization of CSSD supplies in 1977 provided standard issues to all customers throughout all public hospitals:

- Instruments & Procedure Sets; Syringes & Needles; Surgeon’s Gloves; Dressings & Linen Packs for the clinical users.

- Syringes & Needles; Surgeon’s Gloves; Dressings & Linen Packs for the Operating Rooms.
Prince of Wales Hospital
An acute general hospital opened in 1984
New Territories East
Introduction of Single-use Disposables available from industry through tendering procedure further assured the supply quality:-

- Syringes & Needles (full range)
- Swabs & Dressings
- Paper & non-woven Wraps and Drapes etc...........
In 1987 the first World Conference on Central Service organized by UK and her international team was held in Hong Kong.
Reference standards were recommended for local practice as far as feasible with sources from Britain (BSI, HTM series and ISSM) and United States (FDA, AORN and AAMI).
Tuen Mun Hospital
An acute general hospital opened in 1990
New Territories West
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Since 1991
Hospital Authority
Hong Kong Statutory Body

- A statutory body tasked to manage all public hospitals and institutions
- Established in 1990 under the Hospital Authority Ordinance
In 1991, the Hospital Authority (HA) after taking over the management of the 41 public hospitals

Created a new corporate culture and introduced scientific management.

http://www.ha.org.hk/visitor/
The Hospital Authority currently manage 42 public hospitals and institutions, 48 Specialist Out-patient Clinics, and 74 General Out-patient Clinics.

These are organized into 7 hospital clusters according to their locations.

Hospital clusters ensure that patients receive a continuum of high-quality care within the same geographical setting and throughout their episode of illness – from its acute phase through to convalescence and rehabilitation, and community after-care.
7 Hospital Clusters

- New Territories West
- New Territories East
- Kowloon West
- Kowloon Central
- Kowloon East
- Hong Kong West
- Hong Kong East
The operation of the Hospitals is fully funded by the Hospital Authority (Public Money)

Hospital Management does not directly create income efficiency but asks for recourse responsible for achieving best professional practices as well as hospital infection surveillance, control and management in order to create an environment for safe health care delivery
Pamela Youde Nethersole Eastern Hospital
An acute general hospital opened in 1993
Hong Kong East
The Hong Kong Sterile Services Management Association founded in 1997 providing training courses, workshops and organizing seminars & conferences for the health-care professionals.

Provider of Continuing Nursing Education Accredited by the Nursing Council of Hong Kong since 20 Dec. 2006
Rationalization of Decontamination Service

The CSSDs decontaminated, assembled, packed and sterilized MDs for the clinical users

The TSSUs process the surgical devices for the operating theaters or in some hospitals, the Operating Room nurses decontaminated, assembled, sterilized instruments for the Operating Room on-site

The process was fragmented. We should rationalize CSSD and OT decontamination processing functions by Merging CSSD/OT/TSSU decontamination Services
Flash Sterilization is not recommended

- lack of timely biological indicators to monitor performance
- absence of protective packaging following sterilization
- possibility for contamination during transportation to the ORs
- sterilization cycle parameters (i.e., time, temperature, pressure) are minimal

Does not comply with the practices advocated in any of the relevant standards

(no vacuum stage, no validation, no documentation, etc.)
Rationalization of Decontamination Service

To establish a separate and distinct Decontamination Processing Department, with specialized expertise and direct responsibility for providing safe and sterile medical devices with appropriate high standards to patient care areas.

All the decontamination processing should be centralized in the Hospital Sterile Services Department (HSSD) and to implement uniform standards of practice and provide for maximum utilization of human and material/machine resources with management under one roof.
Queen Elizabeth Hospital Opened in 1963

Operating Theatre Block
Queen Elizabeth Hospital in 2000

New Operating Theatre Block

HSSD

OT
SARS Outbreak

Between November 2002 and July 2003, an outbreak of Severe Acute Respiratory Syndrome (SARS) in Hong Kong nearly became a pandemic, with 8,422 cases and 916 deaths worldwide (10.9% fatality) according to the World Health Organization (WHO). Within weeks, SARS spread from Hong Kong to infect individuals in 37 countries in early 2003.
Infection Control Branch (ICB)

Infection Control Branch (ICB) of the Centre for Health Protection (CHP), took the initiation in year 2005 of networking the infection control professionals, field specialists, Central Committee on Infectious Diseases and Hospital Authority to develop a territory-wide infection control guidelines in Hong Kong to provide a professional reference to infection control practitioners throughout the healthcare related settings from hospital to community.
Medical Devices

- Never re-use single use items
- Don't re-process single use items

- Phasing out reuse SUD commencing in 2004
- Development of IT management system
# Risk Stratification

## FDA and Spaulding Classification

<table>
<thead>
<tr>
<th>FDA Class</th>
<th>Spaulding Classification</th>
</tr>
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<tbody>
<tr>
<td>Class I</td>
<td>Non-critical: Very low risk</td>
</tr>
<tr>
<td>Class II</td>
<td>Non-critical: Low risk</td>
</tr>
<tr>
<td>Class III</td>
<td>Non-critical: No such item</td>
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SUD Risk Prioritization

Risk – Product Design

- The lengths is longer than 1 meter
- The lumen is narrower than 2 mm in diameter
- Device with multi-lumen, closed end lumen or twisted lumen
- Device with multiple joints or movable parts
- Device with balloon
- Device with lumen containing bladed or coiled wire
- Device with constraint in reprocessing

Risk factors for prioritizing SUD for phasing out
SUD Management Strategy

- Register all reuse SUD into central registration
- Manager/healthcare profession would be responsible if reuse SUD without registration
- Set deadline to cease new registration
- Develop guideline or policy to assure standard of practice
- Train frontlines colleagues to familiar with the new system
- Develop Central List with standardized name
- Neglect the size, shape and type when standardization
- One manufacturer one SUD
SUD Management Strategy

- Develop **Cluster List** with cluster Code – can use (hospital code)
- Set **priority** of SUD by specialty according to the practical experience of nurses and doctor with consideration of potential risk factors
- Initiate **bulk purchase** to trim down the operational cost
- Visit the clinical department to **review** the current reuse practice by committee expert
- Conduct **audit** with improvement recommendation to pressurize management to allocate extra resources in phasing out SUD based on priority
HA Guidelines on the Reuse of Single-Use Medical Devices

Purpose

This guidelines provide a framework to enable hospitals to establish a quality system to reprocess of single-use devices (SUDS).

Definition

Single-use Device (SUD) – A disposable device, intended to be used on one patient during a single procedure

Background, Research & Studies on the Reuse of SUDs

Reuse of SUDs has been practiced in many hospitals all over the world for years. The
The CSSDs further employed HA Corporate Vision as their philosophy, within the constraints of available financial and human resources with outcome focused emphases on cost effectiveness, to manage the CSSDs.
To establish a suitable quality management system to minimize and manage risk within an appropriate and agreed framework, further updated reference standards (British, American & EN/ISO standards) and good manufacturing practices (GMP) were implemented for local practice as far as practicable.
How to maintain and improve the service quality?

CSSD need a Quality Management System.

INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires
Decontamination Life Cycle

ACQUISITION
1. Purchase
2. Loan

CLEANING

TRANSPORT

DISINFECTION
At all stages:
Location
Facilities
Equipment
Management
Policies/Procedures

INSPECTION

STORAGE

TRANSPORT

PACKAGING

DISPOSAL
1. Scrap
2. Return to lender

Quality Management System Application
CSSD Quality Management System

According to ISO 13485: 2003
Quality Management Systems

1. Organization profile
2. Human Resources Management
3. Infection Control System
4. Management Responsibility
5. Resources Management
6. Product Realization
7. Measurement, analysis and improvement
8. Risk Management
9. Document Control
Requirements for Infrastructure

Health Building Note 13 (UK)

- Demarcation of Dirty and Clean in Decontamination area
- ISO 14644 Class 8 Clean room Standard in Inspection Assembly Packing room
- Ventilation and air flow
- Temperature and humidity requirement
- Adequate lighting
- Air exchange rate
Standards for Decontamination

General Requirements

AS/NZS 4187:2003
- Cleaning, Disinfection & Sterilization

DIN 58921
- Validation of medical device simulators (MDS)

EN 556
- Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices

EN ISO 11135-1 -2
- Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices

DIN 58921
- Validation of medical device simulators (MDS)
Standards for Decontamination

General Requirements

EN ISO 17665-1 -2
- Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices

EN 15424 ISO 25424
- Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices
Standards for Decontamination
General Requirements

EN ISO 14937
- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO/ DIS 20857
- Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
Standards for Decontamination

Steam Sterilizer

- EN285 (Large Sterilizer)
- HTM 2010
- EN ISO 17665
- AS1410:2003 (Sterilizer – Steam – Pre-vacuum)
  - EN 13060 (Small Sterilizer)
Standards for Decontamination

EN 14180 - Low temperature steam and formaldehyde sterilizers
EN 1422 - Ethylene oxide sterilizers

Plasma Sterilizer
- ISO 14937
- AAMI
Standards for Decontamination

Washer Disinfector
- EN ISO 15883
- HTM 2030

Ultrasonic Cleaner
- AS 2773
ISO 17664:2004
Information to be provided by the medical device manufacturer

- Reprocessing instructions
- Limitations and restrictions
- Preparation at the point of use
  - Cleansing
  - Disinfection
  - Drying
  - Packing, Sterilization, Storage
- Inspection, maintenance and testing
- Validation of the reprocessing information
- Risk analysis
Quality Manual (Sample)

Establish organizational own Quality Manual
Standard Operation Procedure (SOP)

Cleaning (Ultrasonic Cleaner)
Disinfection (Washer Disinfector)
Packaging (Heat Sealing Machine)
Sterilization (Sterilizer)
Drying Cabinet
Incubator for biological indicator
Standard Operation Procedure (SOP)

**Sample**

**Objective:** to operate the steam sterilizer properly and perform effective sterilization process.

**Responsible Person:** Sterilizer Operator

**Frequency:** Daily and after major repair.

**At the beginning of each day**
1. Switch on the panel.
2. Switch on the main drain.
4. For any troubleshooting, contact person responsible to the sterilizers.
5. Run a warm-up cycle.
6. Run a BD test.
7. Run a leak rate test and microbiological tests on each Monday.
8. If the sterilizer passes the tests according to their specification, the sterilizer is ready for use.

**Loading the Sterilizer**
1. Similar items requiring the same cycle parameters should be grouped together.
2. Load configuration should ensure adequate air removal, penetration of steam into each package, and steam evacuation.
3. Items capable of holding water, such as solid-bottomed pans, basins, and trays, should be positioned so that they are oriented in the same direction and so that condensate can be eliminated (arranged in such a way – normally on their sides – that if water is present, it will drain out).
4. Placing metal items below textile items.
5. Paper-plastic pouches should stand on edge in relation to the cart, with the paper side of one pouch next to the plastic side of the next pouch.

“Detailed, written instructions to achieve uniformity of the performance of a specific function”

International Conference on Harmonisation (ICH)
Four Eras in the past 40 years

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Since 2010
In 2010, the introduction of Hospital Accreditation exercise through Australian Council on Healthcare Standards (ACHS) has initiated CSSD service revolution in Hong Kong.
Australian Council on Healthcare Standards (ACHS)

An independent, non-profit organization, dedicated to improving the quality of health care in Australia through continual review of performance, assessment and re-accreditation.
To improve the quality and safety of health care

Patient Safety

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Principles of Accreditation

- Customer focus
- Effective leadership
- A culture of improving
- Evidence of outcomes
- Striving for best practice
- Sustainable service quality
- Management Review
HA Guideline on Disinfection & Sterilization
18 February 2011

Development of Organizational Quality Management System would be based on Corporate Policy / Guidelines
Further Enhancement of Development of Information Technology Management Systems

Structure, Process and Outcomes Audit

Material, Machine, Method, Money, & Man (HR) Monitoring & Tracking
Information Technology Management System

Sterile Storage  OT Preparation  Theater

Sterilization  Soiled Return

Packaging  Disinfection
Image for Surgical Instrument Set
Electronic Tracking in NTWC
Tracking Reprocessing Cycle
The CSSDs in Hong Kong have implemented quality management system in decontamination practice so as to keep CSSD abreast of the up-dated international standards.
Patients are our basis to strive for continuous quality improvement
Attention to international standards and recommended practices is the duty of our healthcare professionals to retain such competence and skills so as to reduce the potential risks to the organization.
The ISO series of standards are group of quality management and assurance standards.

Our CSSDs are striving to provide quality management system for all our decontamination activities in meeting those standards.
"Are we doing the work relevant to today's and tomorrow's needs?"

1. Managing care cost containment initiatives

2. Advances in technology

3. Standards have changed the way hospital CSSDs deliver services to meet the new needs and expectations.
Modern Technology

New Technology has developed faster than our professions ability to safely reprocess it.
Risk and Decontamination

- Staff inadequately / poorly trained in their roles, responsibilities and duties.
- Poor department design, layout / construction.
- Non compliant decontamination processing equipment.
- Inappropriate environment in which the decontamination life cycle was performed.
- Non compliance with standards, policies and procedures.
ASK - Strength & Weakness

- **Asset**
- **Skill**
- **Knowledge**

Deficiency will post an organization at risk of its survival
Conclusion

Through hospital accreditation exercise, CSSDs have exercise their own initiative in promoting continuous quality management improvement within HA culture.
Our Mission & Vision

Continuing quality improvement within our decontamination practices will lead us keeping pace with the international standards as well as achieving the goal of service excellence!
Quality Improvement as A Culture,
A Continuous Journey Towards Service Excellence
Thank you for your sharing