Reprocessing of Medical Devices: What is our current practice?

Commissioned Training of Disinfection and Sterilization (27-29 Feb)
Chief Infection Control Office
28 Feb 2012

Mr. Samuel, LAW
Cluster Operation Manager
New Territories West Cluster
1. History of Sterilization Service in Hong Kong
2. Reprocessing centre
3. Method of Decontamination
4. Risk Management on Reuse Single Used Medical Device (SUD)
5. Decontamination Standard in Hong Kong
6. Training and development
7. Service gap analysis
8. NTWC CSSD service model in decontamination service
9. Way forward
(1) History of Sterilization Service in Hong Kong
History of Sterilization Service in Hong Kong

• Central Sterile Service Department (CSSD) was managed by Pharmacist since the establishment of hospital services

• Since 1973, nursing staff took over the management of CSSD in various regional Hospital (QEH, QMH, PMH and PWH)

• Before 70 century, CSSD mainly reprocessed sterile reusable medical devices, like syringe and needle, intravenous set, linen gown & drape, surgical glove and dressing set etc.
Nowadays, sterile commercial products are available in the market.

Some CSSDs are still responsible to purchase and supply sterile syringe & needle, sterile gloves, Intravenous set.

CSSD focuses on the supply sterile linen pack to operating theatre and supplies sterile ward procedure set to ward and clinical area.

Theatre Sterile Supply Unit (TSSU) concentrates on reprocessing of surgical instrument for surgical operation.
History of Sterilization Service in Hong Kong

- Since 1998, CSSD of Tseung Kwan O Hospital CSSD combined the CSSD & TSSU service
- Kowloon West Cluster: Centralized CSSD in Lai King Block, it served 7 hospitals in the cluster, which are KWH, PMH, CMC, YCH, KCH, OLMH, WTS since 2004
- It mainly provided sterile set to ward and clinical areas and provided sterile operation linen packs to operating theatre. However, the OT of these hospitals have reprocess their own OT surgical instruments
(2) Reprocessing Centre

- CSSD
- TSSU
- Electro-Medical Diagnostic Unit (EDU)
- Satellite reprocessing centres in various clinical area, eg. OT, ICU, ward, clinic
CSSD

Heart of Hospital
Customers: wards, clinical areas and operating theatre

- focus on supply of CSSD product including sterile ward procedure set
- Procure and supply of sterile products originally produced in CSSD eg. surgical gloves, intravenous set etc
- supply surgical linen drape and gown to operating theatre
Scope of CSSD Service

Sterile Theatre Linen Drape
Scope of CSSD Service

Sterile Ward Procedure Set

Sterile Supplementary Instrument Packet
Scope of CSSD Service

Sterile Dressing Packets
Scope of CSSD Service

Thermal Disinfection of Plastic Utensils & Tubing
Scope of CSSD Service

To reprocess user-owned reusable medical devices
Scope of CSSD Service

Supply Sterile Commercial Consumables
Customer: Operation Theater (OT)
• Reprocessing surgical instrument
• Fiber-optic endoscope

Remark: Some hospitals in Hong Kong do not have a centralized reprocessing centre. The surgical instrument are sterilized using manual washing and flash sterilization.
Scope of TSSU Service

Focus on surgical implant and instrument
Scope of TSSU Service

Reprocessing surgical instrument and utensils

Extra Surgical lap.
Basic set
Basic Surgical lap
Surgical Major Set
Major Utensil
Endoscopic Unit

- Reprocessing fiber-optic endoscopy and accessory at point of use
- Manual or Automatic
Satellite reprocessing in various ward, clinic

- Department owned medical devices
- Disinfect and sterile medical device locally for their own used
- CIDEX without close system
(3) Method of Decontamination
Washer disinfector
Thermal Disinfection (Mechanical Wash)
Introduction of Tunnel Washer
Steam Sterilization
Low Temperature Sterilization

Hydrogen peroxide

STERRAD® 100NX™ System

Only 2 Ethylene Oxide sterilizers in HA
Endoscopic Instrument
Automatic Endoscopic Reprocessor
Table top autoclave & Chemical Disinfectant
(4) Risk Management on Reuse Single Used Medical Device (SUD)
Risk Management on Reuse Single Used Medical Device (SUD)

With balloon, water trapped in balloon after cleansing and disinfection
Risk Management on Reuse Single Used Medical Device (SUD)

- HA Governance - Quality & Risk Management
- **Major objective** – develop a systemic framework to reduce the risk of reuse
- Develop guideline or policy to assure standard of practice
- Train frontlines colleagues to familiar with the new system
- Develop Central List with standardized name
Risk Management on Reuse Single Used Medical Device (SUD)

- 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
- Conduct audit with improvement recommendation to pressurize authority to allocate extra resources in fading out SUD based on priority
- Faded out SUD based on risk factors
## Risk Stratification

### FDA and Spaulding Classification

<table>
<thead>
<tr>
<th>FDA Class</th>
<th>Spaulding Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-critical</td>
</tr>
<tr>
<td>Class I</td>
<td>Very low risk</td>
</tr>
<tr>
<td>Class II</td>
<td>Low risk</td>
</tr>
<tr>
<td>Class III</td>
<td>No such item</td>
</tr>
</tbody>
</table>
# MILESTONE OF REUSE SUD IN HK

<table>
<thead>
<tr>
<th>Date</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun 04</td>
<td>Develop a registration system for reuse SUD</td>
</tr>
<tr>
<td>Oct 04</td>
<td>Completed pilot registration project in major users (operating theatre, Electro-diagnostic Unit, Cardiac Catherization unit) in TMH and PYNEH</td>
</tr>
<tr>
<td>Nov 04</td>
<td>Conducted internal audit to assure compliance in Tuen Mun Hospital</td>
</tr>
<tr>
<td>Dec 04</td>
<td>Finalized report and recommendation of the pilot study</td>
</tr>
</tbody>
</table>
## MILESTONE OF REUSE SUD IN HK

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 Jan 05</td>
<td>Rolled out registration to other hospitals</td>
</tr>
<tr>
<td>Dec 05</td>
<td>Formation of Advisory Group in Head office</td>
</tr>
<tr>
<td>9 Mar 06</td>
<td>Clarification of personal liability of staff who manage reuse SUD. Insurance covers the liability risk</td>
</tr>
<tr>
<td>19 Apr 06</td>
<td>Launch corporate guidelines</td>
</tr>
</tbody>
</table>
## MILESTONE OF REUSE SUD IN HK

<table>
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<tr>
<th>Date</th>
<th>Event Description</th>
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</thead>
<tbody>
<tr>
<td>17 Jul 06</td>
<td>Opened corporate forum to introduce the registration system</td>
</tr>
<tr>
<td>Aug 07</td>
<td>Initiated corporate registration of all reuse SUDs in all departments among all Hong Kong public hospitals</td>
</tr>
<tr>
<td>Aug 07</td>
<td>HKW established cluster expert group to visit user dept to review their practice</td>
</tr>
<tr>
<td>Jan 08</td>
<td>Develop of criteria for risk priority in order to phase out high risk SUDs</td>
</tr>
</tbody>
</table>
Risk Factors for Prioritization of the SUD for Fading out

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
<table>
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</tr>
</thead>
<tbody>
<tr>
<td>18 Jun 08</td>
<td>Conducted corporate-wide audit by corporate audit team</td>
</tr>
<tr>
<td>Sep 08</td>
<td>Published of the first corporate internal audit report: Management of Single Use Medical Device</td>
</tr>
<tr>
<td>Apr 09</td>
<td>CE HA allocated XX millions to 7 cluster hospitals to phase out 8% of high risk SUDs</td>
</tr>
</tbody>
</table>
Internal Audit:

Management of Single Use (Medical) Devices (SUDs)

Audit Team
Po Yu Chan
Cecilia Yeung
Rob Burns

September 2008
To develop a **database computer system** to manage the SUD registration and develop central list and assign unique code to each cluster SUD

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep 10</td>
<td>Hospital Authority Head Office <strong>stopped registration of new SUD.</strong> Clinical department <strong>should include extra SUD budget for new services.</strong></td>
</tr>
<tr>
<td>Jan 11</td>
<td>Hospital Authority Head Office <strong>published the first corporate policy on SUD</strong></td>
</tr>
<tr>
<td>Apr 11</td>
<td>Hospital Authority Head Office <strong>allocated over XXM to phase out over 60 item of SUD</strong></td>
</tr>
</tbody>
</table>
1 Title

HA Policy on Single Use Devices (SUD)

2 Purpose

Hospital Authority (HA) intends to phase out the reuse of SUD by stages. The hospitals are allowed to reprocess selected SUD ONLY when strict reprocessing procedures are followed (Para. 7). This set of policy aim at assuring the safe reuse of SUD and specifying the general principles for clusters to develop their own operational instructions appropriate to their clinical settings.

3 Scope

A SUD is a disposable device intended to be used on one patient during a single
(5) Decontamination Standard in Hong Kong
Decontamination Standard in HK

- Decontamination manager adopted various international standard
- Validation of decontamination machine is limited
- Only routine tests were performed to assure decontamination quality

For example
- Chemical indicator
- Bowie & Dick Test
- Biological indicator
# Spaulding Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Non-critical** | Topical contact and not penetrate intact skin  
Thorough cleansing  
Low level disinfection |
| **Semi-critical** | Contact intact mucous membranes and not penetrate normally sterile areas of the body  
High-level Disinfection / sterilization (thermal disinfection) |
| **Critical** | Contact normally sterile tissue or body spaces  
Sterilization |
**Bowie Dick Test for steam sterilization**

### How to Read a JM™ Comply™ Bowie-Dick Plus Test Pack

#### Pass:
- **No Air Leaks.** Both tests show good vacuum efficiency: Early Warning Test Sheet indicator spot is black.

#### Pass:
- **Extra-sensitive Early Warning Test Sheet indicator spot** is dark brown, showing reduced vacuum efficiency. Bowie-Dick Test Sheet shows acceptable result.

#### Fail:
- **Bowie-Dick and Early Warning Test Sheets** reveal that sterilizer shutdown is necessary.

#### Fail:
- **Bowie-Dick and Early Warning Test Sheets** indicate that significant air is present.
Compact-PCD®s for the Bowie-Dick-Simulation-Test and the Batch Monitoring System
Performance qualification
Verification of cleansing

Routine testing
Soil Test

Example: Sweden (Annex M)
Decontamination Standard in HK

- ANSI/AAMI ST 58: 2010
- ANSI/AAMI ST79:2010
- AS NZ 4187: 2003
- EN 285
- EN 868
- HA intranet
- Health Building Note 13
- HTM 2010
- HTM 2030
- ISO 11607
- ISO 13485
- ISO 14937
- ISO 15883
- ISO 17665
Standard Packaging Material
Linen Wrapper
Decontamination Standard in Hong Kong

- It varies a lot from cluster to cluster, from hospital to hospital
- Flash sterilization as routine practice
- Satellite reprocessing centres
- Adopt different international standard in daily practice
- Perform routine test to assure sterility quality
(6) Training and Development
Training and development

Before 1991 Hospital Authority: Overseas training (UK)

Operation Management:
- Standardization
- Quality Control
- Material Management
- Inventory Management

In 1991, Hospital Authority is established for managing the public health care system in HK
- Cost consciousness
- Risk Management
- Service quality
- Continue Quality Improvement
Training and development

• Hong Kong Sterile Service Management Association (HKSSMA) is established on 1997
• A local professional association in decontamination practice
• Basic training annually
• Organize 3 - 4 seminars / year
Training and development

- Hospital Authority
- First formal commissioned training on sterilization service on Sept, 2011
- Overseas Training in Health Care Science Limited in UK x 4 nurses in Nov 2011
- Second commission training of sterilization service in Jan, 2012
- Overseas Training in Eastwood Park, UK x 4 nurses in Feb 2012
(7) Service Gap Analysis
ACHS Accreditation

• The Australian Council on Healthcare Standards (ACHS) conducted accreditation exercise locally in 2010
• A Gap analysis was performed to identify the quality gap of CSSD
HA Report

Issues identified

• Routine use of flash sterilization
• No clear demarcation of clean & dirty zone
• Lack of tracking & tracing system
• Governance structure deficiency

(HA intranet)
Flash Sterilization

• Annual Plan:
  ➢ Sterilization Enhancement Program
  ➢ Eliminate the use of Flash sterilization

Governance

• Strengthen governance structure
  ➢ Corporate-wide
  ➢ Cluster-wide
  ➢ Hospital-wide
Key Objective 2: Improve Continuously Service Quality and Safety

Our service priorities for 2011-12

- Strengthen safety culture and risk management
- Enhance quality systems and clinical governance
- Reconfigure services and promote timely intervention

**Strengthen safety culture and risk management**

<table>
<thead>
<tr>
<th>ACTION</th>
<th>TARGET</th>
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</thead>
<tbody>
<tr>
<td>Enhance drug safety in aseptic dispensing service by centralizing high risk preparations such as intrathecal injections, epidural injections and biological preparations at pharmacy operated aseptic dispensing units</td>
<td>Upgrade some of the existing aseptic dispensing suites and expand the central pharmacy aseptic dispensing service to cover high risk preparations by 1Q12</td>
</tr>
<tr>
<td>Ensure safety and quality of pharmacy service in GOPCs by expanding pharmacist coverage at clinic pharmacies during clinic operating hours</td>
<td>Expand the existing pharmacist coverage in GOPC pharmacies by 1Q12</td>
</tr>
<tr>
<td>Provide clinical pharmacists at treatment sites of chemotherapy service to enhance drug safety</td>
<td>Extend the program, which is being piloted in KWC and NTWC, to all clusters by 1Q12</td>
</tr>
<tr>
<td>Eliminate the use of FLASH sterilization methods in surgical operations and enhance sterilization service for operating theatres to align with international standards</td>
<td>Implement a sterilization enhancement program for operating theatres in QMH, QEH, TMH, YCH and CMC by 1Q12</td>
</tr>
<tr>
<td>Continue to implement measures to reduce the re-use of Single Use Devices (SUD)</td>
<td>Phase out the re-use of 5% of class II critical (moderate to high risk) SUDs by 1Q12</td>
</tr>
<tr>
<td>Enhance the quality of blood products provided by the blood transfusion service</td>
<td>Increase the supply of leucofiltered red blood cells by 45,000 units by 1Q12</td>
</tr>
<tr>
<td>Strengthen patient safety culture, situational awareness, team communication and speak-up culture using Crew Resource Management (CRM) training adapted from the aviation industry</td>
<td>Commence a 3-year CRM training program in two acute hospitals by 1Q12</td>
</tr>
</tbody>
</table>
Clear demarcation of clean and dirty area

- Engineering approach
- May be adopted during renovation
- Purposely built a mega centre
Corporate Electronic System

• Development of Tracking and Tracing System
(8) NTWC CSSD service model in decontamination service
Governance Structure of Decontamination Practice in NTWC

Cluster Clinical Governance Committee

Cluster Decontamination Safety Committee
(major user, Infection Control Team, Decontamination Safety Officer)

Wards
OT
CSSD
EDU
Quality Management System

Management
ISO 13485:2003

AS/NZ 4187:2003

Decontamination Equipment

Washer Disinfectors
EN ISO 15883
Sterilizers
EN ISO 17665
Other Technologies (gas plasma)
EN ISO 14937

The Facility

Design Environment
HBN 13 (UK)

Quality Manual,
Policies, procedures and
work instructions

Training
Resources
Monitoring
Auditing
Customer Focus
Tracking & Tracing of Instruments
Record keeping
Conversion CSSD to TSSU/CSSD

- Revamp the scope of CSSD service
- Fade out non value-added service provided by CSSD
- Re-built a new CSSD with advanced instrumentation
- Eliminate flash sterilization for all elective surgical instrument
- Centralized decontamination service
Phase out all linen items

To phase out all linen items by disposable drapes including OT linen and linen wrapper towels.
Changes of ward procedure set

- To convert the ward procedure set by supplying stainless steel instrument peelable pouches
- Use disposable ward dressing set and the peelable pouches instead.
Example: S17 Suture Set
– only provide instrument packet
Changes of ward procedure set

All ward procedure sets were replaced by a basic pack (S25E), the set contents (instruments) will be supplied as an individual packs.
Sterile Supplementary Utensils

Tray  Kidney Dish  Bowl
Use of disposable dressing items

Phase out dressing item. Use pre-sterile ones
Cease reprocessing of single use respiratory tubing and suction tubing
Handover the pre-sterile consumable to Hospital Store
Auto-Refill System

Check any Items insufficient in Qty

Scan the barcode Label if qty. is required auto-refill
Electronic Tracking in NTWC
Tracking and Tracing throughout Decontamination cycle

Sterile Storage

OT Preparation

Theater

Sterilization

Soiled Return

Packaging

Disinfection
Tracking decontamination cycle
Three level of Image

Final Stage

Individual instrument

8 Groups of Instrument
(9) Way Forward
Way forward

• Establish governance structure
• Enhance corporate guidelines
• Develop corporate tracking system
• Eliminate flash sterilization
• Centralization of decontamination centres
• Clear demarcation to segregate dirty and clean
• Fade out linen wrapper
• Foster training and development
• Enhance engineering support
Way forward  ????

Who is the manager?
- Denursing in CSSD
- Sick pool
- Career development

• Pharmacist
• Engineer
• Nurse
• Administrator
Way forward  

• Water Quality – use of Reverse Osmosis water
• Air Quality - Inspection/Assembly/Packing (IAP) room
  ➢ ISO 14644 Class 8 clean room standard
  ➢ Double locking door for IAP room
• Steam Quality – clean steam
• The degree of Centralization
  ➢ Cluster base
  ➢ Hospital base
Way forward ????

• Is it the best practice to extensively use of container system?
• Shall we fade out all linen items?
• Can outsourcing solve the existing problem?
• How to sustain training and development of staff competence?
• Adoption of standard – ISO, EU norm, HTM, AAMI, AS, WS (Chinese standard) etc
Way forward ????

• High volume high turnover (↑ demand)
• What is the best practice?
  ➢ decontamination of endoscope at the point of use
  ➢ Storage of disinfected endoscope
  ➢ Transportation of disinfected endoscope