Risk Management on Reuse

Single Use Medical Device (SUD)
Hong Kong

7 millions population
1104 KM²
A statutory body manages 42 public hospitals and institutions

Established in 1990 under the Hospital Authority Ordinance
Distribution of 42 Public Hospitals and Institution in 7 Clusters in Hong Kong

- Pok Oi Hospital
- Tuen Mun Hospital

Legend:
- Purple: Hong Kong West
- Green: Kowloon East
- Red: Kowloon Central
- Pink: Kowloon West
- Gray: New Territories West
- Blue: New Territories East
- Black: Hong Kong East
What we are going to discuss?

1. Introduction
2. International Perspectives
3. Hong Kong Practice 2004-2009 (6-year)
4. Background of HK Experience
5. Formulation of Risk Management
   Registration system
6. Milestone of Reuse SUD in HK
7. Audit Report and Recommendation
8. Achievement in New Territories West Cluster
9. Role of CSSD Manager
Reuse SUD is a controversial subject worldwide.

Long-standing Practice all over the world, including UK, USA, Australia, France, Hong Kong.

Cost-saving

Environmental Benefits
INTRODUCTION

Problems on Reuse of SUD

- Performance and effectiveness
- Patient Safety
- Improper decontamination
- Ethics
- Legal implication
- Negligence
Single Use Device
Single Use Device
INTERNATIONAL PERSPECTIVE
United Kingdom

- Extent of Reuse: 10% of hospital
- SUD must not be reused
- The one who reused SUD bears fully for the associated safety and effectiveness
USA (FDA survey)

- 25% reuse and 87% go for third party
- FDA regulated manufacturers not hospitals
- In 2000, FDA published “Enforcement Priorities for SUD Reprocessed by Third Parties and Hospitals.”
- Ensure reprocessed SUD afforded same level of safety and effectiveness for patients as when receiving new devices.
Australia

- Extent of reuse: 15%
- Reuse should be licensed and comply with specific national standards and procedures
France

- No reuse
- Strictly Single Use
Background of HK Experience
Before 2004

- No Rule and regulation
- No systematic control
- Extremely limited resources in healthcare system
Health Service Expenditure (Percentage of GDP)

4.7% = 2.2% + 2.5%

GDP 国民生產總值  Public 公營  Private 私營

資料來源/Source: (1) Census and Statistics Department (2) OECD Health Data 2007
Hong Kong Healthcare System – Dual System

PUBLIC
Highly subsidized by government

PRIVATE
Self-financed by patients

2.1% GDP
79% inpatients
29% outpatients
Public Health

2.5% GDP
21% inpatients
71% outpatients

(1) GDP: Year 2007.
(2) Inpatient (secondary & tertiary care): “Public-private share by inpatient treated in 2007” from HA and Department of Health.
• Healthcare worker has tendency to reuse SUD as far as possible in order to save cost
• Whenever there was adverse event related to reuse of SUD, the incident was reviewed and regulated at departmental level
Risk management managers, microbiologists, doctors & nurses are reluctant to deal with this issue.

- Fear to be liable for negligence
- Repeated incidences
- Patient at risk
- Increase awareness of senior hospital management
Background of HK Experience

- After SARS attack in 2003
- I am nurse in-charge of cluster infection control team and CSSD in Tuen Mun Hospital in New Territories West Cluster
- Assigned to develop a system to tackle reuse of SUD
- Major objective – develop a systemic framework to reduce the risk of reuse
No extra resources
Be conservative, never be aggressive
Be supportive, seek cooperation
Form a working group comprising with microbiologist, infection control nurse, CSSD manager and major SUD users
Literature search to review the practice of other countries
Formulate a systematic framework on risk management on reuse SUD
Formulation of Risk Management Registration System
Formulation of Risk Management Registration System

A. Cost benefit analysis
B. Risk Assessment
C. Risk Stratification
D. Risk Management
E. Device Registration
F. Device Tracking
G. Functional Performance
H. Incident Reporting and regulatory
I. Audit checklist to ensure compliance
A. Cost Benefit Analysis

- Unit cost of SUD
- Benefit to use
- Safety risk to patient
- Potential cost of device failure – staff, hospital image
- Labor costs
- Administrative costs
- Reprocessing costs
- Availability of departmental budget
B. Risk Assessment

• Single Use design – reprocessing may damage the quality (definitely unsafe to reuse)

• Although the potential risks on re-using SUD can never be eliminated, health care providers should try every effort to minimize the potential risks to ensure patient safety.
B. Risk Assessment

2 major risks

- Focus on risk of **material defect**
- Focus on risk of **cross infection**
B. Risk Assessment

Major Risk - Material Defect (Intrinsic Quality)

• Mechanical characteristic (e.g. bending strength, tensile strength)
• Geometric characteristic (e.g. Blade geometry, balloon profile)
• Optical characteristic eg. Transmittance)
• Electrical characteristic (e.g transmission rate)
• Material nature – coating (eg. Aging, corrosion)
• Movable Joints (eg. Adhesion)
• Biocompatibility (eg. Toxicity due to leaching of low molecular component)
C. Risk Stratification

• Dealing with the intrinsic quality of SUD (material defect / product design)

• Adopt U.S. Food and Drug Administration (FDA) classification of SUD to stratify the potential risk

Food and Drug Administration URL: <http://www.fda.gov/cdrh/reuse/1168.html>
## FDA Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low risk</td>
<td>Minimal potential harm to patients Assured by “General Control” e.g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>orthopedic surgical drill</td>
</tr>
<tr>
<td>Class II</td>
<td>High risk &amp;</td>
<td>Pose potential risks to patients Assured by “Special controls” e.g.</td>
</tr>
<tr>
<td></td>
<td>Moderate risk</td>
<td>cardiac mapping catheter</td>
</tr>
<tr>
<td>Class III</td>
<td>Very High risk</td>
<td>Insufficient information exists to assure safety and effectiveness sole</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ly through general or special controls.</td>
</tr>
</tbody>
</table>
B. Risk Assessment

Major Risk - Cross Infection

- Inability to clean and decontaminate
- Residue of chemical disinfectant (use thermal disinfection method)
- Endotoxin – Gram negative bacterial breakdown
- Incompatible for decontamination method
• Dealing with the Cross infection risk

• Adopt Spaulding’s classification in decontamination of medical device

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-critical</td>
<td>Topical contact and not penetrate intact skin. Thorough cleansing. Low level disinfection.</td>
</tr>
<tr>
<td>Semi-critical</td>
<td>Contact intact mucous membranes and not penetrate normally sterile areas of the body. High-level Disinfection (thermal disinfection).</td>
</tr>
<tr>
<td>Critical</td>
<td>Contact normally sterile tissue or body spaces. Sterilization.</td>
</tr>
</tbody>
</table>
C. Risk Stratification

FDA and Spaulding Classification

• Based on the FDA and Spaulding classification
• Develop a matrix system in stratifying the SUD with potential risks to patients and its usage.
## C. Risk Stratification

### FDA and Spaulding Classification

<table>
<thead>
<tr>
<th>FDA Class</th>
<th>Spaulding Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Non-critical: Very low risk</td>
</tr>
<tr>
<td></td>
<td>Semi-Critical: Low risk</td>
</tr>
<tr>
<td></td>
<td>Critical: Moderate risk</td>
</tr>
<tr>
<td>Class II</td>
<td>Non-critical: Low risk</td>
</tr>
<tr>
<td></td>
<td>Semi-Critical: Moderate risk</td>
</tr>
<tr>
<td></td>
<td>Critical: Moderate-high risk</td>
</tr>
<tr>
<td>Class III</td>
<td>Non-critical: No such item</td>
</tr>
<tr>
<td></td>
<td>Semi-Critical: High risk</td>
</tr>
<tr>
<td></td>
<td>Critical: High risk</td>
</tr>
</tbody>
</table>
D. Risk Management

- All Class III (FDA classification) items are not allowed to be reused
- Focus on high – moderate risk items
- Prioritize the risk based on matrix
- Maintain the decontamination standard as recommended by Spaulding classification
- Any SUD that cannot be effectively cleansed or decontaminated should not be reused
D. Risk Management

• If reusable medical device is available in the market, switch back to use reusable item

• All reuse SUD must be registered

• A reprocessing protocol must be kept in working place

• User to determine the maximum number of time to reuse based on practical experience. Cross departments and cross hospital comparison are feasible for the best practice.
D. Risk Management

- Any incident related to reuse SUD must be reported
- Working group visit departments with reuse SUDs to educate, review and advise their practices in a supportive manner
- Conduct audit report to assure compliance
<table>
<thead>
<tr>
<th>No.</th>
<th>Hosp</th>
<th>Dept</th>
<th>Spec.</th>
<th>Full Name (Cat. No.)</th>
<th>Unit</th>
<th>Manufacturer</th>
<th>Brand</th>
<th>Supplier</th>
<th>Avg. Unit Cost ($)</th>
<th>Class (N/SC)</th>
<th>FDA</th>
<th>Re-processing Cleaning Location</th>
<th>Detect. Method above C</th>
<th>Tracking System (If Yes)</th>
<th>Functional (If Yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>TMH</td>
<td>OT</td>
<td>EN</td>
<td>Tricut Blade Sims</td>
<td>EA</td>
<td>Ossur</td>
<td>Ossur</td>
<td>Anaheim</td>
<td>720</td>
<td>C</td>
<td>I</td>
<td>S</td>
<td>S</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>6</td>
<td>TMH</td>
<td>OT</td>
<td>EN</td>
<td>Colorado Micro Needle</td>
<td>EA</td>
<td>Stryker</td>
<td>Stryker</td>
<td>Stryker</td>
<td>450</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
<tr>
<td>7</td>
<td>TMH</td>
<td>OT</td>
<td>EN</td>
<td>Standard Prass Probe Tip</td>
<td>EA</td>
<td>Nuine Pulse</td>
<td>Nuine Pulse</td>
<td>Anaheim</td>
<td>240</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
<tr>
<td>8</td>
<td>TMH</td>
<td>OT</td>
<td>EN</td>
<td>Prass Standard Monopolar Stimulating Package &amp; Co Lead Handle</td>
<td>EA</td>
<td>Nuine Pulse</td>
<td>Nuine Pulse</td>
<td>Anaheim</td>
<td>540</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
<tr>
<td>9</td>
<td>TMH</td>
<td>OT</td>
<td>EN</td>
<td>Prass Paired EMG Electrode &amp; Protected Lead 2 Channel</td>
<td>EA</td>
<td>Nuine Pulse</td>
<td>Nuine Pulse</td>
<td>Anaheim</td>
<td>850</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
<tr>
<td>10</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>MRI marker</td>
<td>EA</td>
<td>Brain lab</td>
<td>Brain lab</td>
<td>Brain lab</td>
<td>100</td>
<td>N</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>N</td>
</tr>
<tr>
<td>11</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>Cusa Tip</td>
<td>EA</td>
<td>Valley Lab</td>
<td>Valley Lab</td>
<td>Tyco</td>
<td>2963</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>Y</td>
<td>C</td>
</tr>
<tr>
<td>12</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>Cusa CEM Nosecone</td>
<td>EA</td>
<td>Valley Lab</td>
<td>Valley Lab</td>
<td>Tyco</td>
<td>771</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>Y</td>
<td>C</td>
</tr>
<tr>
<td>13</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>Cusa Tubing pack</td>
<td>EA</td>
<td>Valley Lab</td>
<td>Valley Lab</td>
<td>Tyco</td>
<td>2459</td>
<td>N</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>Y</td>
<td>C</td>
</tr>
<tr>
<td>14</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>Prass Mono Nerve Stimulator &amp; Accessories</td>
<td>EA</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>Medtronic</td>
<td>441</td>
<td>C</td>
<td>II</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
<tr>
<td>15</td>
<td>TMH</td>
<td>OT</td>
<td>N</td>
<td>Tech Attach Disposable Connector</td>
<td>EA</td>
<td>AD-Tech</td>
<td>AD-Tech</td>
<td>Trionda</td>
<td>305</td>
<td>S</td>
<td></td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>Y</td>
</tr>
</tbody>
</table>
E. Device Registration

Fields to be entered for registration

- Number
- Hospital
- Department
- Specialty
- **Product full name** (use the name printed on the package for registration)
- **Product Category number** (neglect the size – same nature of raw material)
- **Manufacturer** (different manufacturer = new item)
- Average unit cost
Fields to be entered for registration

- Spaulding Classification
- FDA Classification
- Decontamination method
- Functional Test (visual / tension)
- Tracking system (by cost / by lot by time)
- **Number of time of reuse** (based on user experience – for comparison)
- Annual Consumption quantity if not reuse
F. Device Tracking

• By Lot by Time (for low risk items)
  ✓ Open new lot of SUD and dispose after certain period of time

• By code
  ✓ Bear a unique code showing the sequence of reuse
  ✓ Dispose it after the expected reusable time
  ✓ Strap patient ID into the protocol for traceability
Protocol on Reprocessing Single Use Devices (SUD)

1. FDA Classification:
   1. Class I, Low risk
   2. Class II, Moderate risk
   3. Class III, High risk

2. Spawning Classification:
   - Critical
   - Non-critical
   - Semi-critical
   - Sterile tissue
   - Contact
   - Skin
   - Mucous membrane
   - High/Intermediate level disinfection
   - Sterilization

3. Reduction in Potential Hazard of Cross Infection:
   All SUDs must be cleansed thoroughly with soapy water either mechanically or manually prior to disinfection or sterilization.

3.1 Sterilization (Critical items):

<table>
<thead>
<tr>
<th>Method of sterilization</th>
<th>Packing material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma sterilization</td>
<td>Tyvek Pouch</td>
</tr>
<tr>
<td>Steam sterilization</td>
<td>View pack</td>
</tr>
<tr>
<td>Hot air sterilization</td>
<td>Glass tube</td>
</tr>
<tr>
<td>Ethylene oxide (EO)</td>
<td>Pouch</td>
</tr>
<tr>
<td>Others, please specify</td>
<td></td>
</tr>
</tbody>
</table>

3.2 Disinfection (Semi-critical and non-critical items):

- High level (Semi-critical items):
  - Codex, 20 mins
  - Thermal disinfection 93°C, 10 mins
- OPA, 5 mins

- Intermediate level (Semi-critical items):
  - Codex, 10 mins
  - OPA, 5 mins

- Low level (Non-critical items):
  - 70% Alcohol, 10 mins
  - 1000 PPM Hypochlorite solution, 30 mins

- Others, please specify

4. Maximum number of time to be reused:

5. Reduction in Potential Hazard of Material Defect

5.1 Tracking system:
   - By Code (Assign code for counting the number of time used e.g. Code ID = A001, A002)
   - Others, please specify

<table>
<thead>
<tr>
<th>Freq.</th>
<th>Patient's Gum Label</th>
<th>Freq.</th>
<th>Patient's Gum Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td></td>
<td>6th</td>
<td></td>
</tr>
<tr>
<td>2nd</td>
<td></td>
<td>7th</td>
<td></td>
</tr>
<tr>
<td>3rd</td>
<td></td>
<td>8th</td>
<td></td>
</tr>
<tr>
<td>4th</td>
<td></td>
<td>9th</td>
<td></td>
</tr>
<tr>
<td>5th</td>
<td></td>
<td>10th</td>
<td></td>
</tr>
</tbody>
</table>

- By Lot and time (Use time frame to replace all re-circulating SUDs)
  - Time frame:
    - 1 month
    - 3 month
    - 6 month
    - Others: __________
  - Number of new SUDs put into circulation: __________

5.2 Functional Performance:

- Visual Defect
- Tension (e.g. bending strength, tensile strength)

- Others Please specify

Name: ____________________
Department: ______________
Rank: ____________________
Date: ____________________
G. Function Test

(1) Material defect (intrinsic quality)

- Mechanical (bending strength, tensile strength)
- Geometric characteristic (e.g. Blade geometry, balloon profile)
- Optical characteristic (e.g. Transmittance)
- Electrical characteristic (e.g. transmission rate)
- Material nature (coating (e.g. Aging, corrosion)
- Movable Joints (e.g. Adhesion)
- Biocompatibility (e.g. Toxicity due to leaching of low molecular component)
Limited Knowledge to assure the integrity of the material

- Visual inspection
- Tensile test
H. Adverse Incident Reporting

- All adverse event on reuse SUD should be captured for regulatory
- Staff are encouraged to report through a computer system for any incident related to SUD
- Incident would be reviewed and followed by recommendation from working group to prevent reoccurrence
H. Adverse Incident Reporting

Hospital Authority
Advanced Incidents Reporting System

Login Authentication

Please enter the Domain Id and Password

Domain Id: 
Password: 

Submit  Reset

1. Technical problems in AIRS (e.g., Login problem), please contact our IT colleagues (Mr. Eric Chan at 2456 7872 or Miss Yuki Chan at 2468 5419) during the office hours.

2. During the non-office hours, very urgent and serious incidents can be informed to duty PRM through hospital operator.

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## I. Audit

### Audit Checklist on Reprocessing of Single-use Devices (SUD) in NTWC

**Date:**

**Staff Name:**

**Date:**

**Ward:**

**Auditor 1:**

**Department:**

**Auditor 2:**

### PART I

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Reprocessing system</th>
<th>Tracking system</th>
<th>Functional Test</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Method</em></td>
<td>In-place</td>
<td>IF YES</td>
<td>In-place</td>
<td>IF YES</td>
</tr>
<tr>
<td>S=Self</td>
<td>Y=Yes</td>
<td>L=by lot</td>
<td>Y=Yes</td>
<td>V=Visual</td>
</tr>
<tr>
<td>O=Others</td>
<td>N=No</td>
<td>C=by code</td>
<td>N=No</td>
<td>T=Tension</td>
</tr>
<tr>
<td>(specify)</td>
<td>Refer to below codes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reprocessing *Method*: CO=Cleansing only; TD(X)=Thermal Disinfection(T°); CD(X)=Chem Disinfectant(Name); C(X)=Chem (Min); O(X)=OPA (Min); S=Steam Steril.; P=Plasma Steriliz.; EO=Ethylene Oxide; LT=Low T° Steam Formaldehyde; HA=Hot Air Sterilization

### PART II

<table>
<thead>
<tr>
<th>Compliance Assessment</th>
<th>YES</th>
<th>NO</th>
<th>O/A</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol for SUD management is enforced in workplace?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staffs understand the protocol?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol is regularly reviewed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper decontamination can be achieved?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Risk Assessment

<table>
<thead>
<tr>
<th>Reprocessing is constrained by nature of material e.g. Bio-active coatings; Surface lubricants; Insulating coating (tonsillectomy forceps); Bovine or porcine; Absorbable components or coatings; Latex rubber; Any plastics that become brittle; cracked or crazed after reprocessing</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>The length of catheter is longer than 1 meter?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The lumen is narrower than 2 mm?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi-lumen: closed end lumen or twisted lumen?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple joints: movable parts that cannot be disassembled?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With balloon?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Items with lumen containing blade and coiled wire?</td>
<td></td>
<td></td>
<td></td>
<td></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>Apr 04</td>
<td>Formation of a working group to develop a registration system in Tuen Mun Hospital</td>
</tr>
<tr>
<td>Aug 04</td>
<td>Conducted a seminar to introduce the registration system in Tuen Mun Hospital</td>
</tr>
<tr>
<td>Oct 04</td>
<td>Completed pilot registration project in major users (operating theatre, Electro-diagnostic Unit, Cardiac Catherization unit) in Tuen Mun Hospital</td>
</tr>
<tr>
<td>Nov 04</td>
<td>Conducted internal audit to assure compliance in Tuen Mun Hospital</td>
</tr>
</tbody>
</table>
Recommendation of pilot study

1. To roll out to other cluster hospitals
2. To develop database system to capture registration data
3. To develop corporate protocol, guideline and policy
4. To coordinate bulk purchasing of SUD
5. To conduct regular audit to assure compliance
6. To phase out reuse SUD according to risk priority
### MILESTONE OF REUSE SUD IN HK

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</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>
IIA 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 advantages are cost-saving and reducing medical waste. Many countries have looked into concerns about patient safety (e.g., risk of infection and device malfunction), the ethics of the practice, and legal liability, but different countries have different approaches. There is no standardized practice.

Although SUD reprocessing does pose theoretical risks, clinical studies show conflicting results. There is an overall lack of patient outcome evidence to support general clinical recommendations regarding the reuse of SUDs. Some evidence suggests that if the appropriate cleaning, testing, and sterilization procedures are followed, some SUDs can be safely reprocessed.

Approaches in Hospital Authority.

The approaches adopted is to reprocess and use selected items with a system in place (low risk – lowest cost), this involves:

1. Risk Assessment.
2. Cost & Risk Benefit Assessment.
3. A proper system in place for reprocessing and use of Single-Use Medical Devices.

Risk assessment by FDA classification and Spaulding Classification.

<table>
<thead>
<tr>
<th>FDA Classification</th>
<th>Non-critical</th>
<th>Semi-critical</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Very low risk</td>
<td>Low risk</td>
<td>Moderate risk</td>
</tr>
<tr>
<td>Class II</td>
<td>Low risk</td>
<td>Moderate risk</td>
<td>Moderate-high risk</td>
</tr>
<tr>
<td>Class III</td>
<td>No such item</td>
<td>High risk</td>
<td>High risk</td>
</tr>
</tbody>
</table>

The general recommendations are:

- No reuse on “High risk” (Class III) items.
- Critical review on “Moderate risk and moderate – high risk” items for re-use.
- Generally, “Very low risk and low risk” items can be reprocessed and reused safely.

III. Cost & Risk Benefit Assessment.

In addition to the material cost for reprocessing, any cost-benefit analysis would necessarily include labor costs, program costs, documentation costs, and the potential cost of device failure.

III. System to ensure patient safety.

The primary goal is to protect the health of patients by ensuring that the practice of reprocessing and using single-use devices (SUDs) is safe and based on good science. The component of the quality system for reprocessing SUDs is in Appendix 2.

Reference:

1. D. Faigle, Director FDA’s Center for Devices & Radiological Health (CDRH).
**MILESTONE OF REUSE SUD IN HK**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 Jul 06</td>
<td>Opened <strong>corporate forum</strong> to introduce the registration system</td>
</tr>
<tr>
<td>Aug 07</td>
<td>Initiated <strong>corporate registration</strong> of all reuse SUDs in all departments among all Hong Kong public hospitals</td>
</tr>
<tr>
<td>Jan 08</td>
<td>develop of <strong>corporate criteria</strong> for risk priority in order to phase out high risk SUDs</td>
</tr>
</tbody>
</table>
Criteria for risk prioritization in order to phase out registered reuse SUD

1. Multiple joints
2. Movable parts
3. Lengthy and narrow lumen
4. Closed end lumen
5. Balloon.
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Jun 08</td>
<td>Conducted <strong>corporate-wide audit</strong> by corporate audit team</td>
</tr>
<tr>
<td>Jul 08</td>
<td>Allocated HK$840,000 for 14 high risk items in Tuen Mun Hospital</td>
</tr>
<tr>
<td>Sep 08</td>
<td>Published of the first <strong>corporate internal audit report</strong>: Management of Single Use Medical Device</td>
</tr>
</tbody>
</table>
Internal Audit Report

Internal Audit:

Management of Single Use (Medical) Devices (SUDs)

Audit Team
Po Yu Chan
Cecilia Yeung
Rob Burns

September 2008
5 Major Audit Observations and recommendations

Report raised some crucial points for improvement

Establishing structures and processes to initiate a risk-based approach to controlling the risks associated with the reuse SUDs

Defined the key role of Advisory Group is to give advice for reprocessing of re-use SUDs
1st observation - SUD Policy & Guidelines

- Do not establish a timescale or targets for restricting the majority of higher risk items
- One of the HA hospitals still re-use of FDA class III devices after the issuing of the Guidelines for over 2 years

Recommendation:
- Revisit & review the HA SUD policy & guidelines
Total 1856 reuse SUDs in all HA hospitals

**Table 1: Registered re-used devices by risk category**

<table>
<thead>
<tr>
<th>Numbers / % of devices by category</th>
<th>Spaulding Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-critical</td>
</tr>
<tr>
<td><strong>FDA Class</strong></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>Very low risk</td>
</tr>
<tr>
<td></td>
<td>9% (174)</td>
</tr>
<tr>
<td>Class II</td>
<td>Low risk</td>
</tr>
<tr>
<td></td>
<td>1% (19)</td>
</tr>
<tr>
<td>Class III</td>
<td>No such item</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>At most low risk</td>
</tr>
<tr>
<td></td>
<td>6% (114)</td>
</tr>
</tbody>
</table>

Source: 2007 Register of Re-used SUD - All clusters. Total 1856 items.
2nd observation

- Unclear corporate direction

Uncertainty about funding for phase-out reuse of higher risk devices may be holding back progress in some clusters.
Recommendation

- Head Office should clarify the position on funding for phasing out of reuse of higher risk devices (allocated 14 millions HK$ in 0910)

Table 2: Estimated cost of phasing out registered re-used devices by risk category (based on raw unaudited data from registration database)

<table>
<thead>
<tr>
<th>Numbers / % of devices by category</th>
<th>Spaulding Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-critical</td>
</tr>
<tr>
<td><strong>FDA Class</strong></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>Very low risk</td>
</tr>
<tr>
<td></td>
<td>$29M (162)</td>
</tr>
<tr>
<td>Class II</td>
<td>Low risk</td>
</tr>
<tr>
<td></td>
<td>$2M (19)</td>
</tr>
<tr>
<td>Unknown</td>
<td>At most low risk</td>
</tr>
<tr>
<td></td>
<td>$45M (100)</td>
</tr>
<tr>
<td><strong>Total cost</strong></td>
<td>$76M</td>
</tr>
</tbody>
</table>

Source: 2007 Register of Re-used SUD - All clusters. Based on 1759 items that have adequate costing information. The cost calculated is for the additional devices needing to be purchased over and above those already purchased and re-used.
3rd Observation
- Making best use of the registration database and priority list to reduce inconsistencies in the SUD registration list

Recommendation
- Conduct a top-down review of the priority lists & registration database
4th observation
non-compliance with guidelines

- Guidelines focus on minimizing risk on reuse
- Clusters cannot always comply with guidance on tracking SUD - 16% of registered reuse SUD do not have formal tracking system

Recommendation

- Establish a systematic approach & converting higher risk items to single use
- Ensure compliance with the SUD guideline
5th observation

- Reinforce reporting SUD incidents through Advanced Incidents Reporting System (AIRS)

- Opportunity to explore the feasibility for better procurement through bulk purchase

- Some staff do not have adequate knowledge on the registration system
Recommendation

- Ensure all incidents related to reuse SUD report through AIRS and inform frontline staff the related incident.

- Establish a structure for phasing out high risk SUD in a cost-effective & risk-based manner.

- Develop central registry and compile corporate priority list.

- Explore bulk purchase to trim down the cost.
Achievement in NTW Cluster

- 193 items in Jan/07
- 143 items in Feb/08
- 120 items in Jan/09
• 3 million HK dollars (extra resources) to covert the high risk SUD into disposal ones

• Up to now, 55 SUDs be converted back to strictly single use

• Annual cluster audit for enforcement the compliance of corporate guidelines

• An “Operation Policy on Management of SUDs was developed
Major objective is to prevent introduction of new SUDs
Achievement in NTW Cluster

• In Feb 09, form NTWC SUD committee to manage reuse SUDs

• To prioritize the high risk SUDs in order to phase out them based on the priority

• In Sept 09, a intranet webpage has been developed for sharing the updated information
So far, no incident related reuse of SUD was reported in NTW Cluster
- Decontamination profession
- Provision of professional advice on the choice of proper decontamination method
- Development and review Standard Operating Procedure for reprocessing
- Assurance of reprocessing standard
PLASMA STERILIZATION

**STERRAD 100S - LUMEN CLAIMS**

**For Stainless Steel Lumen**

<table>
<thead>
<tr>
<th>Internal Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mm</td>
<td>125mm</td>
</tr>
<tr>
<td>3mm</td>
<td>250mm</td>
</tr>
<tr>
<td>4mm</td>
<td>400mm</td>
</tr>
<tr>
<td>5mm</td>
<td>500mm</td>
</tr>
</tbody>
</table>

- **No booster**
- **Use Booster**
- **Out of testing range**

**For Flexible Endoscopes (PE/Teflon Lumen)**

<table>
<thead>
<tr>
<th>Internal Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mm</td>
<td>500mm</td>
</tr>
<tr>
<td>3mm</td>
<td>1000mm</td>
</tr>
<tr>
<td>4mm</td>
<td>1500mm</td>
</tr>
<tr>
<td>5mm</td>
<td>2000mm</td>
</tr>
</tbody>
</table>

- **No booster**
- **Use Booster**
- **Out of testing range**
REJECTED SUD

Standard Urinary Tract Occlusion Balloon Catheter

Lumen < 1mm, with balloon, with lumen containing blade and coiled wire
REJECTED SUD
EDU CRE Dilatation Catheter

With balloon, water trapped in balloon after cleansing and disinfection
Keeps an approved and rejected list in CSSD to ensure proper SUD reprocessing
Conclusion:

CSSD Manager plays an important role to assure the safety on reuse of SUD
By
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Hong Kong Sterile Services Management Association
Ltd. Hong Kong
http://hkssma.org/

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Tuen Mun Hospital and Pok Oi Hospital
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E-mail : lawth@ha.org.hk