Sterilization Service Revolution – Service Enhancement in HA Hospitals

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New Territories West Cluster, (NTWC)
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Background

Aim:
To improve the quality and safety of health care

1. Australian Council on Healthcare Standards (ACHS) as accreditation agency
2. In 2010, pilot Hospital Accreditation in 5 HA hospitals: CMC, PYNEH, QEH, QMH, TMH

Patient Safety
Background

ACHS Surveyors recommended Key Address Areas in Sterilization Service of Surgical Instrument

1. Lack of clear demarcation of dirty and clean zones in Operating Theatre for instrument reprocessing

2. Elimination of flash sterilization for surgical instrument

3. Lack of effective tracking and tracing of surgical operation instruments

4. Deficit in Governance Structure
Background

Tuen Mun Hospital also encountered the same issues
Sterilization Enhancement Project
in Tuen Mun Hospital

Aim:

- Conversion of old Central Sterile Supplies Department (CSSD) to a be **Central Decontamination Center** in TMH
- Modernize TMH CSSD to **merge CSSD and Theatre Sterile Supplies Unit (TSSU) functions** together within one department
- Upgrade the quality management system in CSSD to meet with international standard of decontamination practice
Design and Management of new CSSD
(April 2011- Aug 2012)

A. Infrastructure Requirement

B. Decontamination Equipment

C. Quality Management System
Design and Management of new CSSD

Quality Systems
Medical Devices:
EN ISO 13485:2003

Decontamination
Equipment

Washer Disinfecter:
ISO 15883
Steam Sterilizer :
EN 285
Ultrasonic Cleaner :
AS 2773

Quality Manual
Policies and procedures

The Facility

Design :
Hospital Building
Note 13 (UK)
Environment :
ISO 14644

Management

• Training
• Resources Monitoring
• Auditing
• Customer Focus
• Product Realization
• Measure, Analysis and Improvement
• Tracking & Tracing of Instruments

Reference to
Policy of
Corporate

Note 13 (UK)

A. Infrastructure Requirement

Hospital Building Note 13
United Kingdom

1. Clear Demarcation of Dirty and Clean Area
2. ISO 14644 Class 8 Clean Room Standard in Inspection, Assembly & Packing room
3. Temperature and humidity Control
4. Adequate lighting
5. Ventilation and Air exchange rate
Decontamination Area

Set Sterile Store

Before

After
Demarcation of Clean and Dirty Area

Decontamination area

Air-tight Panel

Negative pressure
Demarcation of Clean and Dirty Area

1. Air-tight Ceiling
2. Positive Pressure 10 – 20 Pascal
3. ISO 14644 Class 8 Clean room standard
4. Lighting with 700 lux
Decontamination Area

-ve pressure

Sterile Store

+ve pressure

Inspection Assembly and Packing Room

+++ ve pressure

Sterilization Area

++ve pressure

Plant room

- ve pressure
B. Equipment Requirement

Standards of Steam Sterilizer

ISO 17665 & EN 285
B. Equipment Requirement

Standard of Hydrogen Peroxide Sterilizer

STERRAD 100NX

STERRAD 100S

ISO 14937
B. Equipment Requirement

Standards of Washer Disinfector

- **EN ISO 15883**
- **AS 2773**

Ultrasonic Cleaner
C. Implementation of Quality Management System in CSSD

ACQUISITION / USED

REPAIR / DISPOSAL

PACKAGING

STERILIZATION

TRANSPORT

STORAGE

DISTRIBUTION

TRANSPORT

CLEANING

DISINFECTION

INSPECTION

DISPOSAL / REPAIR

ACQUISITION / USED

包裝

滅菌

運輸

貯存

分發

清洗

消毒
Quality Management System - ISO 13485

To assure quality sterilization service in CSSD
1. Organization Profile
2. Human Resources Management
3. Infection Control System
4. Management Responsibility
5. Resources Management
6. Product Realization (Production Standard)
7. Measurement, Analysis and Improvement
8. Risk Management
9. Document Control
1. Organization Profile

Vision:
Be a professional disinfection and sterilization service provider

Mission:
To provide quality disinfection and sterilization service for reusable medical device
1. Organization Profile - Scopes of Service

A. Thermal Disinfection

Thermal disinfection was used to replace chemical disinfectant so as to ensure staff and patient safety.
1. Organization Profile - Scopes of Service

B. Fade out linen item
Use disposable drapes
1. Organization Profile - **Scopes of Service**

C. **Fade out production dressing item**

Use pre-sterile ones available in the market

→ **Handover delivery role of sterile proprietary consumables to Central Procurement Material Management Unit**
1. Organization Profile - **Scopes of Service**

1. To reprocess surgical instruments

2. Elimination of Flash Sterilization
D. Topping up (Auto-Refill System)

Bar Code Scanner

Bar Code label

Check Quantity

Generate a report and prepare refill items

Synchronize the data of portable scanner to computer
2. Human Resources Management
Training (Supporting Staff and supervisors)

① Steam Receivers Operator Course
② Sterile Service Certificate Course
③ In-housing training
2. Human Resources Management

Staff recognition and boost staff morale
3. Infection Control System

Hand Hygiene Program

Monitor Hand Hygiene and instrument clean efficacy by ATP Swab Test

Swab → Reaction – Click & Shake → Measure & Record
3. Infection Control System

Environmental Control

Monitor Particle Count of an IAP room

Monitor Pressure Difference in Inspection Assembly Packing room

Data logger

spray-form lubricant – in a fume hood
4. Management Responsibility

Quality Manual

1. Quality Objective
2. Quality Policy
3. Customer Care
4. Quality Improvement
5. Resources Management

- Tracking and Tracing System for Surgical Instrument
- Procurement and Materials Management
- Annual Budgeting and Forecasting
- Stock Distribution for Clinical Users
- Internal marketing (cross charging)
5. Resources Management

Specialty

Location

Tracking and Tracing System
6. Product Realization (Production Standard)

Best Practice of Reprocessing:
- Follow Manufacturers’ “Instructions for Use”
- Process Control
- Equipment Validation
6. Product Realization (Production Standard)
Validation of Washer Disinfector

Cleaning Efficacy Test

Soil Test

Test Soil applied to Reference Load

Completely Clean after washing cycle
Report mechanism of nearly missed record

1. Under “No Blame Culture”
2. Real Time Report
3. Daily Report to supervisors & management
7. Measurement, Analysis and Improvement

Measure nearly missed case

### 2013 TMH OT Related Incident

| TMT | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH | TMT | PTH | FMT | PTH |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Jan |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Feb |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Mar |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Apr |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| May |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Jun |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Jul |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Aug |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Sep |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Oct |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Nov |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Dec |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |

- **A**: Assembly wrongly
- **B**: Broken instrument
- **D**: Dirty/Filthy
- **L**: Label defect (e.g., not change color/wrong labeling)
- **M**: Missing item
- **P**: Packing defect
- **W**: Wet load
- **O**: Others

*Monthly Total: 28, 30, 8, 4, 9, 3, 8, 2, 5, 1, 4, 1, 5, 3, 11, 6, 11, 2, 17, 9, 11, 7, 9, 10*
7. Measurement, Analysis and Improvement

Computerize the “Alert” on Packing List

<table>
<thead>
<tr>
<th>Section</th>
<th>Qty</th>
<th>Instrument Description</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>FORCEPS, HOLDING, SPONGE, RAMEPLEY, 250MM, BF118R</td>
<td></td>
</tr>
<tr>
<td>(PRE-OPEN)</td>
<td></td>
<td>CLIP, MINI, 'S'</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>CLIP, MINI, 'L'</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>HANDLE, B.P., NO. 3, BB07-1050</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>HANDLE, B.P., NO. 4, BB08-1140</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>FORCEPS, DISSECTING, A</td>
<td></td>
</tr>
</tbody>
</table>

Checklist of OT Set

<table>
<thead>
<tr>
<th>Section</th>
<th>Qty</th>
<th>Instrument Description</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>CLIP, TOWEL, BACHAU'S, BLUNT, 17, 54, 10</td>
<td></td>
</tr>
<tr>
<td>(PRE-OPEN)</td>
<td></td>
<td>FORCEPS, HOLDING, BONT, SELF-CENTERING '3', 398.83</td>
<td>CHECK SCREW X 1</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>FORCEPS, HOLDING, BONT, SELF-CENTERING '3', 398.83</td>
<td></td>
</tr>
<tr>
<td>TISSUE 6</td>
<td>173</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. Measurement, Analysis and Improvement

Post up the nearly missed cases
7. Measurement, Analysis and Improvement

Review and Training
# 8. Risk Management

## CSSD Risk Register

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Date Risk initially assessed</th>
<th>Risk Description (Refer to &quot;NTWC Common Risks&quot; Sheet)</th>
<th>Risk Category</th>
<th>Related to</th>
<th>Additional remarks / elaboration of risk, if any</th>
<th>Existing Controls/ Measures taken</th>
<th>Risk Profile Checklist</th>
<th>Weighting</th>
<th>Additional Resources /Action(s) required</th>
<th>Initial Cost</th>
<th>Repeated Cost</th>
<th>Annual Cost</th>
<th>Risk Level</th>
<th>Approx. cost (HKS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g.</td>
<td>01-Jan-14</td>
<td>V1. Patient Misidentification</td>
<td>V2. Consultation</td>
<td>Example: Doctors did not click &quot;Next Patient&quot; during consultation</td>
<td>1. Use screen saver to remind staff which patient is being admitted. 2. Produced video to educate staff to click &quot;Next Patient&quot; button</td>
<td>4 5 20</td>
<td>1. Use barcode scanner to activate patient list in the HIS. 2. Install electronic queue system</td>
<td>4 2 8</td>
<td>50.0</td>
<td>100k-1M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E.g.</td>
<td>01-Jan-14</td>
<td>S1. Occupational Safety &amp; Health (Staff)</td>
<td>S9. Workplace Violence</td>
<td>Example: Imprudent patients spoke foul language to staff due to long waiting time for consultation</td>
<td>1. Poster to educate patients. 2. Better workflow design to reduce waiting time</td>
<td>3 3 9</td>
<td>1. Improve Public Announcement (PA) System to reduce noise and improve communication. 2. Provide training to staff on communication</td>
<td>3 2 6</td>
<td>55.3</td>
<td>10k-100k</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>05-Feb-14</td>
<td>P1. Patient Safety</td>
<td>Improper decontamination process</td>
<td>1. Incorporated the risk management into IT tracking system. 2. Maintain regular validation of washers and sterilizers.</td>
<td></td>
<td>3 2 8</td>
<td>1. Enhance supervision of the decontamination process. 2. Provide training to staff</td>
<td>2 1 2</td>
<td>66.7</td>
<td>10k-100k</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>05-Feb-14</td>
<td>P2. Patient Safety</td>
<td>Equipment failure during surgical operation</td>
<td>1. Established report mechanism and action plan to record and report the newly missed items. 2. Alert system in the tracking system.</td>
<td></td>
<td>3 2 8</td>
<td>1. Set up standard operation procedures guide. 2. Provide training to staff</td>
<td>2 1 2</td>
<td>66.7</td>
<td>10k-100k</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>05-Feb-14</td>
<td>N1. Facility</td>
<td>Breakdown of sterilizers and poor steam quality</td>
<td>1. Planned preventive maintenance of steam sterilizer periodically. 2. Validation and calibration system of sterilizers according to standard.</td>
<td></td>
<td>3 3 10</td>
<td>1. To build a water treatment plant in order to maintain quality of steam. 2. CSSD staff should train by repairing the sterilizers when necessary.</td>
<td>3 2 6</td>
<td>50.0</td>
<td>100k-1M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>05-Feb-14</td>
<td>H1. Facility</td>
<td>Breakdown of dumbwaiter or passenger lift</td>
<td>1. Regular preventive maintenance by manufacturer. 2. Contingency plan for transportation of CSSD items.</td>
<td></td>
<td>4 3 12</td>
<td>1. Additional trolleys required for transportation. 2. Extra manpower for transportation</td>
<td>3 2 6</td>
<td>50.0</td>
<td>1k-10k</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>05-Feb-14</td>
<td>N2. Information Technology</td>
<td>Breakdown of ERMS</td>
<td>1. Regular day-end and month-end posting for the system. 2. Backup system for the data.</td>
<td></td>
<td>4 3 12</td>
<td>1. Corporate SIS for the data.</td>
<td>3 2 6</td>
<td>50.0</td>
<td>100k-1M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*To facilitate formulation of Hospital-based Risk Register, the Departmental Risk Register should be relevant to individual hospital's services.*

**Example 1:** If the risks in TMH & POH AED are different, there should be two AED Risk Registers (one for TMH and one for POH).

**Example 2:** If the risks in HR are the same in the NTWC, one single HR Risk Register is accepted.
9. Document Control

Master List of Controlled Documents (Sample)

<table>
<thead>
<tr>
<th>NTWCSID</th>
<th>Document Control Index</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Document Title</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>
9. Document Control

1. Standardization of document format
2. Review regularly
3. Clear document code
Won positive comment from ACHS surveyor as ‘Impressive Achievement’ in 2012

Won NTWC Outstanding Staff and Team Award in 2013

The sterilization enhancement project set a good model to drive sterilization service advancement in Hospital Authority
Corporate Level

1. Task Force on Sterilization Standard of Operating Theatre
   - Setting up Governance structure
   - Development of Tracking and Tracing System
   - Demarcation for Dirty and Clean Area
   - Development of Guidelines on Sterilization

2. Service Advisory Group (Sterile Supply Service) under nursing profession
   - Development of operation standard in sterilization practice
   - Provision of advisory role whenever required
Directors’ Meeting

Corporate Level

Task Force on Sterilization Standard of Operating Theatre

Working Group on Disinfection & Sterilization of Surgical Instrument
- Review standards of practice on disinfection & sterilization of surgical instrument

Working Group on Surgical Instrument Tracking System
- Defined tracking to “Tray Level”
- Agreed on standardization of coding

Governance Structure & Workflow
- Defined governance & workflow

Implementation Working Group
- Defined & worked out scope of improvement work

Cluster representatives to monitor project progress

Guideline on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre was developed & promulgated

WG on Cataloguing

WG for User Spec

Project Steering Committee for Consultancy Study on Sterilization Service Enhancement

WG on governance structure of CSSD/TSSU

WG on Sterilization Service Review

* limited access
** managed by QSD

Last updated: 18 Feb 2014
Guidelines Development

- Meet with international standard of practice
- Guide against construction requirement of CSSD
- Guide against the Quality management system in the reprocessing center
Development of Corporate Surgical Instrument Tracking System (SITs) and Roll out to 22 HA hospitals

### Item Set Count Sheet

**Set ID:** POH.T0001.02 (Version No: 1)
**Legacy Set ID:** 9002
**Locators:** POH.C.SG.7.A1

**Packing Warning:**

[Warning text as per the original document]

**Individual Remark:**

[Remark text as per the original document]

**Checker:** 1 / Checker: CHEUNS NGUI MAN on 2014-03-28 / YIP WANG HANG on 2014-03-31

<table>
<thead>
<tr>
<th>Sec.</th>
<th>Image</th>
<th>Qty</th>
<th>Instrument Name</th>
<th>Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image1.png" alt="Image 1" /></td>
<td>1</td>
<td>FORCEPS, GRASPING, BABCOCK, 10X/30MM HANTOAD MONOPOLAR, ERGO HANDLE, OLYMPUS</td>
<td>A05650A</td>
</tr>
<tr>
<td>2</td>
<td><img src="image2.png" alt="Image 2" /></td>
<td>1</td>
<td>FORCEPS, DISSECTING, MARYLAND, 10X/30MM, 90°, TAPERED MONOPOLAR, ERGO HANDLE, OLYMPUS</td>
<td>A05650A/A05650A/A05650A/A05650A/A05650A</td>
</tr>
<tr>
<td>3</td>
<td><img src="image3.png" alt="Image 3" /></td>
<td>1</td>
<td>FORCEPS, GRASPING, BULLET NOSE, 5X/30MM, A SASU LAP, PUT ON PROTECTIVE CAP, FOI15R, A SASU LAP</td>
<td>P073SR/PW73R/PW73R/PW73R/PW73R</td>
</tr>
<tr>
<td>4</td>
<td><img src="image4.png" alt="Image 4" /></td>
<td>1</td>
<td>APPLICATOR, FOS, LIGAClip 1, AP400S</td>
<td>CHECK SCREW X 2 CHECK CAP X 1</td>
</tr>
<tr>
<td>5</td>
<td><img src="image5.png" alt="Image 5" /></td>
<td>1</td>
<td>APPLICATOR, METAL CLIP MEDIUM L, 10MM, 318</td>
<td>CHECK SCREW X 2</td>
</tr>
<tr>
<td>6</td>
<td><img src="image6.png" alt="Image 6" /></td>
<td>1</td>
<td>APPLICATOR, FOS, LIGAClip 1, AP400S</td>
<td>CHECK SCREW X 2 CHECK CAP X 1</td>
</tr>
<tr>
<td>7</td>
<td><img src="image7.png" alt="Image 7" /></td>
<td>1</td>
<td>ELECTRODE, EPITATHETED LAP, A594</td>
<td>CHECK RING</td>
</tr>
<tr>
<td>8</td>
<td><img src="image8.png" alt="Image 8" /></td>
<td>1</td>
<td>FORCEPS, GRASPING, CLAW, GALL BLADDER 10X/30MM, 45°, TAPERED MONOPOLAR, ERGO HANDLE, OLYMPUS</td>
<td>A05650A/A05650A/A05650A</td>
</tr>
<tr>
<td>9</td>
<td><img src="image9.png" alt="Image 9" /></td>
<td>1</td>
<td>TROCAR &amp; CANNULATORS, 11MM, OLYMPUS</td>
<td>CHECK RING, VALUE OPEN &amp; CLOSE</td>
</tr>
<tr>
<td>10</td>
<td><img src="image10.png" alt="Image 10" /></td>
<td>1</td>
<td>REDUCER, LONG, 5MM, WCA, PA, 5016</td>
<td>CHECK CAP</td>
</tr>
<tr>
<td>11</td>
<td><img src="image11.png" alt="Image 11" /></td>
<td>1</td>
<td>REDUCER, SHORT, OS.03</td>
<td>CHECK CAP</td>
</tr>
<tr>
<td>12</td>
<td><img src="image12.png" alt="Image 12" /></td>
<td>1</td>
<td>PLASTIC, KIDNEY DISH 20CM, BOTTOM WITH HOLES</td>
<td>CHECK CAP</td>
</tr>
</tbody>
</table>

### Photo of Set

[Image of surgical instrument set]

### Label

[Image of label]

---

**Set No.:** 4  
**Max.:** 99999  
**Count:** 2  
**Exp Date:** 2015-03-31  
**No. of Instrument:** 23
Replacement Traditional Linen Wrapper by Sterile Barrier system

Woven Wrapper
Traditional Sub-standard Barrier System

Linen wrapper
Woven Textile

Heat-sealable Pouch
Non woven wrapper
Crepe Paper
Corporate Achievement

Elimination of flash sterilization
Advancement of Sterilization Practice in Corporate Level

1. Eliminate the use of flash sterilization to reprocess surgical implants

2. Eliminate the use of chemical disinfectant to reprocess rigid endoscopes

3. Reduce the use of flash sterilization for elective OT

4. Establish governance structure and revise guidelines

5. Service enhancement for centralized Sterilization Supply Unit in 4 hospitals (KWH, QMH, YCH, QEH) in 13/14

6. Develop Surgical Instrument Tracking and Tracing System (SITs) and pilot it in 3 hospitals (PWH, QMH, UCH) in 12/13. Rollout the SITs to 5 hospitals (PYNEH, DKH, TKOH, NDH, POH) in 13/14 then to all the HA hospitals with operating theatre
Conclusion

- CSSD plays an important role in breaking the nosocomial infection chain through decontamination of reusable medical devices
- CSSD is the heart of a hospital to provide central decontamination service in reprocessing reusable medical devices by steam sterilization and thermal disinfection
Conclusion

Hospital Accreditation trigger the service revolution on sterilization supply services.

CSSD and Theatre Sterile Service Unit (TSSU) should be merged in one department within a regional hospital as far as possible to attain operational efficiency.

More importantly, patient safety can be assured through quality sterilization service enforced in Hong Kong HA hospitals.
End

Thank you for your attention