

Providence Health Care Medical Device Reprocessing Audit

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Disclosure

- Member of 3M Canada Speakers Bureau
 - Receive honorarium for speaking on Medical Device Reprocessing topics
- Member of Getinge's Advisory Board – Canada
- Member of Global Decontamination Discussion Group - Steris

Reprocessing

- Includes **all** steps necessary to prepare a device ready for use on another patient (i.e., cleaning, disinfecting, sterilizing)
- As per the Ministry of Health Service's directive
 - PHC does not reprocess any critical single-use medical devices except by an approved 3rd party reprocessor (*Ascent A Stryker Sustainability Solution*)
- Since 2008 PHC does not reprocess any semi-critical single-use medical devices



Audit Categories

- Single-use medical devices (SUMD's)
- Reusable medical devices
- General
 - PPE
 - Detergents
 - Policies and Procedures
 - Housekeeping
 - Equipment

Audit Categories

- Indications for sterilization or high level disinfection
- Cleaning
- Chemical high level disinfection
 - Manual and automated
- Pasteurization

Audit Categories

- Sterilization (including flash)
- Purchasing & Reprocessing instructions
- Education & Training
- Home care setting
- Dental Clinics

Single Use Medical Devices (SUMD's)

- Since 2005 Providence Health Care has utilized the services of a recognized and FDA cleared third party reprocessor for SUMD reprocessing
 - Benefits include:
 - > \$3.9 million in cost avoidance
 - > 12,255 lbs of waste from the landfill diverted
 - Reverse engineering processes
 - Rigorous cleaning and disinfecting processes



Definitions Critical, Semi-critical & Non-critical Medical Devices

Critical

Devices that penetrate sterile tissues
Present a high risk of infection if the device is contaminated (e.g. surgical instruments, biopsy forceps, foot care equipment, etc.)
KEY - **Cleaning & sterilization is required**

Semi-critical

Devices that contact non-intact skin (e.g. scopes, respiratory therapy items, rectal probes, specula etc.)
KEY - **Cleaning & high level disinfection is required, at a minimum**

Non-critical

Devices/patient care equipment that contact intact skin e.g. stethoscope, bedpan
KEY - **Cleaning & disinfection is required**



Critical Issues

- At least 8 hospitals across Canada received media attention due to reprocessing issues - resulting in identified risks to patients (i.e. CJD, inadequately processed scopes, un-sterile devices, debris on devices).
- East Central Health Region (Vegreville, Alberta) Mar '07 was ordered to close down the hospital Reprocessing Department and not admit new patients due to:
 - a) inadequately sterilized devices (i.e. scopes)
 - b) inability to contain MRSAUpon investigation, the Board was dismissed
- Royal Inland Hospital cancelled surgeries due to issues with debris found on instruments in the Operating Room
- Vancouver Island Health Authority "warns 500 patients of possible blood-borne virus infection"



Rationale for Audits

In 2007 the B.C. Ministry of Health Services mandated all hospitals perform an audit on all critical and semi-critical medical devices being reprocessed



Ministry of Health Services Communiqué

Policy Objective

To protect patient safety by ensuring that all health authorities are in full compliance with established standards for reprocessing of medical devices and patient care equipment [Health Canada and the Canadian Standards Association (CSA)].



Ministry of Health Services Communiqué

Scope

The policy applies to all single use and multiple use devices and patient care equipment used within health authority facilities and programs, as well as private and non-profit facilities providing public healthcare services under contract to health authorities.



Ministry of Health Services Communiqué

Policy

- Health authorities are expected to reprocess medical devices and patient care equipment according to current standards
- While it is expected that health authorities are already meeting these standards, due diligence is required to confirm compliance.



Ministry of Health Services Communiqué

Standards:

- Single use medical devices
- Multiple use medical devices
- Quality assurance



Ministry of Health Services

Mandated 2008

Education & Competency Testing

“ Any individual involved in reprocessing of medical devices must be properly trained and their practice audited on a regular basis to verify that standards are met.”



Recommended Standards

- CSA Z314.3-09 Effective sterilization in health care facilities by the steam process
- CSA Z314.8-08 Decontamination of reusable medical devices
- ORNAC Standards
- CSGNA Standards
- PIDAC – Best Practice Guideline for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities – new 2010 edition

Ministry of Health Services Communiqué

Accountability

Health Authority compliance with this policy will be monitored and publicly reported on by the Patient Safety Division.



Ministry of Health Services Communiqué

Implementation

- By Sept 30, 2007, completion of the 1st comprehensive practice audit and gap analysis... including the use of flash sterilization.
- By Dec 30, 2007, completion of an implementation plan to address any issues identified in the gap analysis, and develop the required QA systems to ensure ongoing safety and quality of reprocessing activities.



Ministry of Health Services Policy

- By January 1, 2008, all authorities must eliminate the reprocessing and reuse of critical single use devices unless they have been reprocessed by a licensed third-party reprocessor...
- By January 1, 2011, all authorities must eliminate the reprocessing & reuse of semi-critical single use devices



Mandated Timelines

- Sept 2007 All Health Authorities complete a comprehensive practice audit
- Nov 14, 2007 Report on gap analysis for all critical & semi-critical medical devices
- Feb 14, 2008 Implement plan to address any issues identified in the findings
- Feb 16, 2009 Re-audit to demonstrate compliance & report to Ministry of Health Services



Development of Audit Tool

- Ontario - Sunnybrook
- Alberta - Calgary Health Region
- Edmonton, Capital Health Region
- Adaptation for BC



Areas Audited

- Sterile Processing or Medical Device Reprocessing
- Operating Rooms & Anesthesia
- Radiology, Diagnostic Imaging, Ultrasound
- Cath Lab
- Clinics (e.g. ENT, Eye, Dental, Podiatry, etc.)
- Endoscopy
- Respiratory Therapy
- Emergency
- Labor & Delivery & Nurseries
- Long Term Care facilities



Why audit?



- To determine if standards and guidelines are being followed
- To identify deficiencies, develop an action plan to address and implement the necessary changes
- To ensure that the appropriate people are doing the job
- To reinforce Best Practices & Standards





Audit Methods

- Met with leaders of each area and asked standardized questions
- Conducted supervised walk-about in areas
- Observed practices & daily reprocessing activities
- Analyzed products being used for reprocessing (e.g., detergents & enzymatics)



Summary of Deficiencies

- Inappropriate use of flash sterilization
- Inadequate training on reprocessing practices
 - using wrong product for cleaning &/or disinfecting
 - not following manufacturers instructions for enzymatic use
 - not cleaning before high level disinfecting or sterilizing
 - not wearing appropriate PPE
- Inadequate quality control
 - Non-SPD managed areas need most improvement
 - only areas with Critical Incidents
 - had greatest # of deficiencies
- Lack of written & documented reprocessing procedures
- Insufficient hand hygiene stations
- Cardboard shipping boxes in sterile & clean storage rooms



Cat #1: Sub-Standard Practice

Gap Analysis

- Pigtail Catheters (removers)
- Foot Care Instruments
- Sterilizer Print-out

Corrective Action

- Buy components separately
- Purchase new instruments & reprocess between patient uses
- Replace outdated Sterilizer



Cat #2: Inadequate High-Level Disinfection (HLD)

Gap Analysis

- Endovag & Rectal Probes
- Nebulizers for Methacholine
- TEE probes

Corrective Action

- Centralize reprocessing
- Reno for new sinks and counter space
- Increase inventory
- Send to SPD for reprocessing
- Increase probe inventory
- Purchase TEE probe disinfectant
- Process all probes in SPD
- Add SPD Techs



Cat #3: Sub-Standard Practice: Dental

Gap Analysis

- Pre Cleaning
- Sterilizer print-out
- Policies & Procedures
- New sink
- Sterilization Monitoring

Corrective Action

- Training & Education
- Retrofit or purchase new
- Develop and implement
- Purchase and install
- Document load contents
- Use labeling system
- Use indicators (BI's & CI's)



Cat #4: Sub-Standard Physical Environment

Gap Analysis

- No clearly designated Reprocessing Area
- Scope cabinets not cleaned routinely

Corrective Action

- Transfer reprocessing to SPD where possible
- Renovate area to delineate clean vs soiled
- Labeling & new sink
- Increase cleaning to weekly



Cat #5: Reuse of Single Use Medical Devices

Gap Analysis

- Cord-clamp removers
- Breast pump parts
- Baby bottle lids
- Respiratory, anesthesia tubing, airways

Corrective Action

- Dispose of after each use
- Dispose of or purchase reprocessable ones
- Purchase pre sterile
- Dispose of after each use



Cat #6: Inappropriate Handling of Contaminated Items

Gap Analysis

- Personal Protective equipment
- Transporting uncovered medical devices

Corrective Action

- Centralize reprocessing to SPD
- Staff education campaign
- Purchase covered containers for use



Cat #7: Documentation Issues

Gap Analysis

- Flash sterilizing traceability
- Reprocessing education
- Expiry Dates
- Quality Control
- Manufacturer's Instructions
- CSA & Best Practices
- Policies & Procedures

Corrective Action

- Document on patient chart
- Centralize reprocessing to SPD
- Staff education campaign
- Test and record HLD results
- Obtain and follow
- Centralize reprocessing to SPD
- Standardize



Cat #8: Inappropriate Material Management

Gap Analysis

- Cardboard shipping boxes
- Items stored on floor
- SPD input prior to device purchases

Corrective Action

- Buy plastic containers
- Staff education campaign
- Modify storage units
- Involve SPD when purchasing new medical devices requiring reprocessing



Cat #9: Inadequate Scope Storage

Gap Analysis

- Scopes stored incorrectly

Corrective Action

- Staff education campaign
- Purchase appropriate scope storage cabinets



Cat #10: Inadequate Equip Maintenance

Gap Analysis

- Long term Capital Planning Process

Corrective Action

- Obtaining funding to allow for timely capital replacement



Costs to Remedy a Critical Incident

Example of a Critical Incident

- Transesophageal Echocardiogram (TEE) probes used to visualize the action of the heart. TEE probes being reprocessed by untrained personnel and not following manufacture's guidelines.

Cost for Cardiology to Resolve Critical Incident

- Increase the inventory of TEE probes (6 x \$35,000)
 - Purchase of a TEE automated disinfecter (\$20,000)
 - Increase in SPD staff to reprocess TEE probes (\$50,000)
 - Consumables (\$125 per day)
- Total: \$250,000 (approx.)

Benefit

- Centralize TEE probe reprocessing in SPD
- Provides quality control



Post Audit Follow-Up

- Meet with departments audited to review the findings & discuss corrective actions
- Develop a plan to resolve deficiencies
- Monitor progress of corrective actions
- Work with Infection Prevention & Control to be a resource for user areas
- Develop a plan, conduct & report on findings of future audits



Resources

- CSA Standards
- BC Best Practice Guidelines for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities
- Health Canada/Public Health Agency of Canada Infection Control Guidelines
- Canadian Society of Gastroenterology Nurses and Associates & SGNA Standards
- ORNAC & AORN Standards



Audit Results – St Paul’s

SPH Areas	Audit Rating			SPD Managed
	2010	'09/'08	2007	
• SPD	99.6%	96%	93%	Yes
• GI Clinic	96%	95%	84%	Yes
• ENT Clinic	99%	93%	74%	Yes
• Radiology (U/S)	97.7%	90%	28%	Yes
• OR (flash)	87.5%	70%	56%	No
• Respiratory	92.6%	76%	38%	No



*Comments
or
Questions*



Thank You

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