ADVISORY PANEL

INSIGHTS FROM ALBUQUERQUE

Highlights from the International Association of Healthcare Central Service Materiel Management 2012 annual conference

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The annual International Association of Healthcare Central Service Materiel Management (IAHCSMM) meeting provides a forum for reprocessing professionals to exchange information and learn about developments in the field. Getinge Canada is very pleased to support the development and distribution of this highlights publication from the IAHCSMM meeting. The members of the Medical Device Reprocessing Advisory Panel ’12 (MDRAP’12) selected the topics to cover and provided summaries for this publication.

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Introduction

The meeting of the Medical Device Reprocessing Advisory Panel ’12 (MDRAP’12) was held in conjunction with the annual conference of the International Association of Healthcare Central Service Materiel Management (IAHCSMM) in Albuquerque, New Mexico, April 30 to May 2, 2012. MDRAP members attended selected IAHCSMM sessions andw reported back on the presentations. This newsletter contains their overviews of those sessions.

Medical Device Reprocessing Advisory Panel ’12

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Contents

Session: **Medical device manufacturers' instructions for use: What, where, why and how?**
Presenters: **Chuck Hughes and Matt Beauchaine**
Commentators: **Merlee Steele-Rodway, Gale Schultz, and Dianne Trudeau**

Reprocessing standards

Reusable medical devices are a critical element of modern healthcare, and reprocessing of these devices must be performed according to manufacturers' validated instructions for use (IFU). As scientific advances in diagnostic and therapeutic medicine have led to the development of new and sophisticated reusable medical devices, reprocessing IFU have become very detailed and time consuming for many of these devices. For example, reprocessing IFU for orthopedic instruments are highly individual and complex. It is important for the medical device reprocessing department to have the staff, equipment, space, and time to reprocess new purchases.

> *Great presentation with valuable information that is applicable to the day-to-day reality of reprocessing!*
> *Comments from MDRAP*

Manufacturers' IFU are available from company sales representatives and from quality control and regulatory affairs officers at manufacturers' corporate offices. Alternatively, it is possible to hire a company to perform validation testing and develop and provide IFU.

The Association of periOperative Nurses (AORN), the Canadian Standards Association (CSA), and Health Canada (HC) provide guidance for IFUs that are relevant to reprocessing. The AORN requires written, validated instructions about care of instruments before they can be purchased, and the CSA requires manufacturers to validate recommended reprocessing. The Health Canada template for ISO 17664 requires device-specific IFU. In addition, steam sterilization standard ST79 from the Association for the Advancement of Medical Instrumentation (AAMI) must be followed, with particular attention to extended cycles. Other organizations, such as the Association for Ambulatory Healthcare, the Centers for Medicare & Medical Service, and the Joint Commission, have also identified the need for appropriate, adequate, and achievable reprocessing instructions. Some organizations require manufacturers' IFU to be device specific.

Implications for best practice

Manufacturers' IFU have several practical implications for best practice in the medical device reprocessing department. Department staff must be educated about the manufacturers' IFU. It is also critical to ensure that equipment is functioning properly and that manufacturers' IFU are

- Readily available
- Up to date
- Not in conflict with national standards
- Achievable with current equipment
- Validated, appropriate, and adequate

It is also important to educate the operating room (OR) staff about manufacturers' IFU so that end users understand what is required to reprocess OR instrumentation. National survey organizations expect "compliance with standards, guidelines, and manufacturers' instructions for cleaning, disinfection, and sterilization of instruments, equipment supplies, and implants." The Centers for Medicare & Medicaid Services recently revised their survey, and areas of empha-

sis included the following:

- Compliance with nationally recognized standards and documents
- Formal training in infection control and sterilization
- Compliant cleaning, sterilization, and monitoring procedures
- Established criteria for flash sterilization

Healthcare facilities must stress compliance with IFU in their policies and procedures, keep manufacturers' IFU where they are readily accessible, and keep them up to date. This directive may be challenging to follow for several reasons. Some manufacturers' IFU are outdated, not validated, conflict with other IFU or with national standards, or require resources that are not available at a specific site.

> *'Just follow your normal reprocessing procedures' is not an adequate instruction for reprocessing any reusable medical device.*
>
> *Comments from MDRAP*

Conclusion

Having and following each validated manufacturer's IFU is required for

- Compliance with national standards
- Passing accreditation surveys
- Patient safety
- Peace of mind

References

Association for the Advancement of Medical Instrumentation (AAMI). (2010). ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. Arlington, VA: AAMI.

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Centers for Medicare & Medicaid Services (CMS). (2009). CMS Infection Control Surveyor Worksheet, Exhibit 351.

Accreditation Association for Ambulatory Health Care (AAAHC). (2010). OR Manager Magazine, 26;2.

Session: **So what do you do? The critical role that the central sterile supply department performs in contributing to optimal patient outcomes.**
Presenter: **Wava Truscott**
Commentators: **Gale Schultz and Dianne Trudeau**

Professionalism in reprocessing

A professional can be defined as a person working in an occupation that requires extensive knowledge, skills, and expertise. By this criterion alone, reprocessing staff members are professionals. Reprocessing staff are also essential members of the medical team with a critical responsibility for patient safety. Poorly performed reprocessing tasks can have as much impact on a patient's life as poorly performed surgery.

Mission critical

Reprocessing is a critical function that can determine successful outcomes for patients in intensive care, emergency, trauma, ophthalmology, anesthesiology, respiratory therapy, diagnostics, interventional radiology, interventional cardiology, and the operating room. Inadequate care in reprocessing can have catastrophic consequences for patients (See Critical patients highly susceptible to reprocessing errors).

Critical patients highly susceptible to reprocessing errors

These are some examples of the human impact of reprocessing errors.

- Ottawa, ON, 2011: Six thousand eight hundred patients were notified they may have been exposed to infectious agents as proper cleaning protocols had not always been followed.
- Miami, FL, 2009: Thousands of patients were notified of possible infection because endoscope irrigation tubing had been rinsed but not disinfected.
- Murfreesboro, TN, 2009: Thousands of patients were notified of possible infection because of a misassembled endoscope: a one-way valve had been replaced with a two-way valve.
- Los Angeles, CA, 2006: An endoscope infected 19 heart surgery patients with Escherichia coli within a 2-week period. A leak had been identified and the instrument was to be repaired. However, it was not quarantined and went back into use after being poorly processed and not examined for damage.
- Los Angeles, CA, 2006: Several infants died from bacterial infection contracted in a neonatal intensive care unit due to inconsistent and improper cleaning practices.
- 2003: Forty-two surprise inspections found that fewer than half of the medical device reprocessing departments had adequate sterilization standards.
- Centers for Disease Control, 1996 and 1998: Infection clusters related to bronchoscopes reported to the Centers for Disease Control:
    - Pseudomonas aeruginosa
    - Mycobacterium tuberculosis
    - Mycobacterium intracellulare
    - Mycobacterium avium

Particles and lint

Particles on instruments, including dead biofilms, can cause inflammation, capsule formation, granulomas, adhesions, blood clots, and particulate emboli. Particles on instruments can result from tissue, fat, or blood from poor cleaning; oxidation of gasket seals on containers or devices; rigid containers not cleaned of debris; glove powder; and lint from a variety of sources. Lint can be deposited on clean instruments from linting sterilization wrap; sweaters or fleece vests in the room; devices dried with linting cloth; corrugated cardboard, newspapers, and tissues; and operating room linens. Hair, lint, and debris can also be deposited on clean instruments from reprocessing staff and traffic in the department. The potential for particle deposition on clean instruments reinforces the need for lint-free wrappers, cloths, drapes, and other linens.

Instrument compatibility errors

Different types of sterilization and disinfectants have been shown to be incompatible with some instruments and surfaces. For example, plasma sterilization for ophthalmic instruments degrades brass into copper and zinc that are deposited in the patient's eyes during surgery. This deposition causes corneal decompensation, loss of visual acuity, and irreversible injury. Several cases of blindness have been reported. In addition, corroded crevices in instruments can harbor microorganism biofilms that are protected from disinfection and sterilization.

Inadequate drying

Trapped residual moisture encourages colonization of waterborne pathogens and biofilm formation, can dilute high-level disinfectants, and can cause cycle cancellation in some sterilizers. Proper drying of flexible endoscopes with 70% alcohol and forced air before disinfection or sterilization is critical, as is proper storage.

Implications for best practice

Maintaining best practice in reprocessing depends on staff education about current standards of practice and the value of their work, frequent reinforcement of the 'mission critical' role they play in guarding patient safety, and a continuous improvement approach to change. Change may sometimes be difficult and often unwelcome, but it is absolutely necessary for quality and progress. The best way to approach change is to be part of it, rather than to resist it.

Categories of change

Corrective change is required to correct compliance errors against established guidelines, manufacturers' instructions for use, best practices, and facility policies.

Progressive change is required to implement new technologies and discoveries, including new devices; new cleaning agents, disinfectants, and sterilization units; new wa ys to work with the operating room; new knowledge and learning opportunities, and new government policies.

> *Excellent approach to explaining how poorly performed tasks can alter lives and families forever and to ensuring that we know that our role is critical to patients.*
>
> *Comments from MDRAP*

Conclusion

Each staff member in the medical device reprocessing department is a healthcare professional with a serious responsibility for patient safety and a valuable contribution to make to the healthcare team

Session: **Are you leading or just taking a walk?**
Presenter: **Bob Marrs**
Commentator: **Merlee Steele-Rodway and Dianne Trudeau**

Effective leadership requires several important personal qualities, especially honesty and integrity, intelligence, vision, and the ability to listen well. Effective leadership is not something that just happens. You create it intentionally.

> *An excellent and inspiring presentation. I am glad I attended.*
> *Comments from MDRAP*

EAGLES

The acronym EAGLES encapsulates essential conditions to support you in leading your team.

E: Environment

For staff to accept your leadership, it is important to create an environment of caring, learning, and professionalism in the reprocessing department. And the critical first step in influencing others is leading by example. If you want staff to care about their work, learn how to improve, and become competent and responsible professionals, you must demonstrate these qualities to them.

A: Attitude

Attitude is a matter of choice, and your attitude affects your entire department. A good and positive attitude is critical to ensuring the department follows standards and best practices. In many cases, you do not control events, but you do completely control the way you react to these events. The attitudes you demonstrate to staff determine, at least partly, how they model their response to changing circumstances. Belief in the importance of the department's work, enthusiasm for doing the best job possible, and commitment to patient safety—all of these are only possible with a positive attitude.

G: Goals

Achievement does not happen without goals. Effective leadership requires that you have a vision for your department, your role as leader, and a development program for staff and that you set goals to support achievement of your vision. In addition to setting goals such as responsibility and accountability, certification, and best practice in reprocessing, it is important to remember more general goals, such as work-life balance and family, as these are part of an environment of caring.

L: Learning

Effective leaders must be knowledgeable in their fields. Spending an extra hour daily learning about your field ensures that you develop and maintain a high level of expertise. Devoting a small amount of time to learning on a regular basis means you will become an expert in only a few years.

E: Encouragement

Staff must know that they are encouraged and supported in making positive changes. Not only must staff feel acknowledged and rewarded for making positive changes but also this support must be communicated to the department. In this way, encouragement and positive change gain momentum.

S: Start today

True leaders have followers. Developing strong and effective leadership requires no additional budget allocation, committees, or meetings. It begins with you, and specifically with your attitude, goals, and care for your staff. There is no need for delay and every reason to start leading effectively today.

Session: **Rising to excellence: Incorporating central sterile supply department best practices into each work area**
Presenters: **Elizabeth Vane and Natalie Lind**
Commentators: **Lorna Coutoulas and Anne Marie Rancourt**

"If you do what you've always done, you'll get what you always got."'
Mark Twain
Comments from MDRAP

Importance of best practice

Maintaining best practices in all work areas is an important goal for managers of central sterile supply departments. Following best practice helps to maintain work quality, meet customer expectations, and provide the best possible patient safety. Consistent implementation of best practice requires a pride in one's work, the will to change, and knowledge of best practices. In addition, an activity, technique, or procedure that has been successful in another situation or that has consistently shown results superior to those achieved by other means can provide an example for your organization.

Why best practice may not be followed

In a given department, one or more reasons may exist for not following best practice. Lack of support from administration and lack of perceived value of best practice to the facility are important obstacles to change. Other reasons include lack of awareness of changes to best practice in a particular area, inertia and the habit of doing things in particular way, a perceived lack of time to learn about changes in best practice and implement them, lack of skill in managing change, and inadequate budget to make the necessary changes.

"An activity or procedure that has been successful in another situation … might be the best way to do something in one's own organization."

International Association of Healthcare Central Service Materiel Management Central Service Leadership Manual, 2010
Comments from MDRAP

Implementing best practice

The knowledge required to implement best practices can be developed through training, reviewing relevant legislation and industry standards, and staying up to date with current scientific information. Useful information can be found in publications such as Infection Control Today; web sites of different organizations, including the Association for the Advancement of Medical Instrumentation; publications from government agencies responsible for industry standards, such as the Occupational Safety and Health Administration and the Environmental Protection Agency; and vendor documents.

Once best practice in each work area has been identified, it is important to perform a review or audit of current procedures, checking for compliance with best practice. Only then is it possible to develop a short- and long-term plan to correct deficiencies, and a plan to stay up to date with changes in best practice as they happen.

Once implementation of best practice has been initiated, it is important to ensure that it remains a departmental priority. For example, a sample departmental vision for maintaining best practice might read as follows: "The [insert name] hospital central sterile supply department will follow regulations, standards, and industry best practices in all aspects of the reprocessing of medical devices."

Conclusion

Challenges in achieving and maintaining best practice in reprocessing include doing the work quickly and correctly, while keeping both staff and patients safe. Finally, it is critical to stay current with changes in best practice over time and to implement them.

The Canadian situation

The Canadian Standards Association (CSA) has published and reviewed documents on medical device reprocessing for over 20 years. In addition, the Canadian government requires audits of reprocessing departments and procedures every 3 years for healthcare facilities to receive and maintain accreditation. This requirement now makes meeting Canadian standards a prescriptive process. The healthcare facility undergoing accreditation must demonstrate that policies and procedures in medical devices reprocessing are both in place and implemented, and that the organization reviews them annually. This important condition ensures conformity to best practice in medical device reprocessing in Canada.

Session: **Preventative versus reactive maintenance: A case study**
Presenter: **Rick Costello**
Commentators: **Lorna Coutoulas, Anne Marie Rancourt, and Gale Schultz**

Measuring an action ensures that it will be performed.
Comments from MDRAP

Preventive maintenance

Preventive maintenance includes several concepts:

- A routine schedule based on time intervals or usage criteria
- Identification of problems and potential problems
- Incorporation of a quality feedback system
- A strong education component
- Documentation and measurement

The value of preventive maintenance lies in proactive problem-solving, instrument audits, and reduction of new instrument purchases. The problem-solving process includes investigation, solution, education, and tracking.

Case study: Five-hospital system in Indiana

A preventive maintenance program for instrument trays included identification of high-use trays; high-problem areas, including surgeon complaints; a time- or use-based rotation system; and a quality feedback system, including documentation of maintenance findings and repairs, to adjust instrument maintenance strategies. Other components included instrument selection, care and handling, testing and inspecting, and repair and replacement. A quality preventive maintenance system ensured both preventive and corrective actions. A surgical instrument quality assurance program instrument board inspection checked that:

- All Pakistani instruments were removed
- No instruments had cracks
- Needle holders had no excessive wear
- Scissors were sharp
- Overall condition, function, and appearance of instruments was adequate

The preventive maintenance program reduced costs by 40%, enabling the purchase of 20% more trays.

Implications for best practice

Prevention is the optimal approach to healthcare-acquired infections, as up to 70% of these infections may be preventable. It is important to use an International Standards Organization approach, with education as a critical component of a quality system. This includes general education on instrument care and handling, specific education addressing major issues, and education about solutions to quality complaints. The cost of errors can be high. For example, patients or staff can be severely burned, and foreign objects can remain in the patient. A strong quality system for instrumentation provides good customer service and positive patient outcomes.

Tray rotation

A study of 50 hospitals found 9 major preventive maintenance programs. Some hospitals used preventive maintenance for tray service. The average number of times instruments were used across all services was 48, with 50% of the hospitals using cardiovascular instruments ≤25 times.

Dirty instrumentation can cause intra-abdominal infection. Taking apart medical devices is critical before cleaning and sterilizing them to protect

patients. For example, rongeurs and laparascopic instruments that are cleaned without taking them apart are often full of crusted bioburden.

Conclusion

Preventive maintenance increases patient safety, reduces purchases of new instruments, and cuts costs.

Session: **Steam quality and testing**
Presenter: **Walt Deacon**
Commentator: **Anne Marie Rancourt and Merlee Steele-Rodway**

ST79: new guidance

The second edition of the Comprehensive guide to steam sterilization and sterility assurance in health care facilities contains revisions to section 3.3.4, Steam for sterile processing. These revisions address steam quality, purity, and quantity, with quantitative provisions regarding steam quality.

> *Poor steam quality is an important cause of sterilization process failures.*
> *Comments from MDRAP*

Preventive maintenance

Preventative maintenance and regular monitoring of sterilizers is critical to quality assurance. Testing should be performed at the steam connection to the sterilizer upon installation of the sterilizer, relocation of the sterilizer, and after any change to the steam distribution lines or boiler supply water.

Steam quality

The three critical variables of steam quality are dryness, level of noncondensable gases, and superheat. As in the previous edition, ST79:2010 specifies that steam dryness should be between 97 and 100% (Table). Wet steam can contribute to wet packs at the end of the sterilization cycle

Dryness of Steam: Percentages

Percentage Vapour	Percentage Liquid	Percent by Weight	Percent by Volume
100	0	100	100.000
97	3	97	99.997
95	5	95	99.995
90	10	90	99.989
80	20	80	99.975
50	50	50	99.901

Noncondensable gases, such as air, entrained in the steam supply can hinder steam penetration into loads. ST79 specifies the acceptable level of noncondensable gases as <3.5% volume per volume condensate.

Superheated or “dry” steam is defined as steam existing at a temperature greater than the boiling point temperature corresponding to its pressure (saturation temperature).

Steam purity

ST79 contains a caution against the use of amines to condition steam lines, because of the risk of staining packaged items.

Steam quantity

Constant steam pressure meeting the sterilizer manufacturer’s minimum pressure recommendation must be available to properly operate sterilizers. Steam supply systems should there-

fore consistently be designed and built to meet this demand.

Implications for best practice

Poor steam quality is an important cause of sterilization process failures. Effective steam sterilization requires a supply of saturated steam of the appropriate quality, purity, and quantity to the sterilizer.

References

Association for the Advancement of Medical Instrumentation (AAMI). (2010). ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. Arlington, VA: AAMI.

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