Choosing A Reprocessing Method

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WHICH INSTRUMENT REPROCESSING METHOD IS BEST FOR YOUR PATIENT?

The short answer to this question is that there is no single best method. There are many reprocessing methods available to hospitals and to Operating Rooms so any choice will depend on the particular situation at your facility and with your patients. The purpose of this article is to outline the factors to be considered when assessing or comparing reprocessing methods.

Spaulding's Classification

In the mid-1960s Dr. Earl Spaulding developed a framework to guide reprocessing decision-making. The system is based on the patient's risk for infection that various types of instrument or equipment contact can create. The following table summarizes his system.[1]

Critical Contact – The normally sterile parts of the body that are covered by intact skin have no contact with the external environment or with the microorganisms that abound there. If, through inadequate or inappropriate instrument reprocessing, some of those external microorganisms are introduced into this normally sterile tissue, a patient's risk for infection is high. A sterilization procedure, or use of a chemical germicide formulated as a sterilant, is recommended for reprocessing of instruments in order to keep patients safe.

Semi-Critical Contact — While there is still a risk for infection with mucous membrane contact, it is not as high as with trans-parenteral contact. Consequently, a high-level disinfection procedure is recommended for reprocessing semi critical instruments. Although chemical germicides formulated as high-level disinfectants do not kill high numbers of bacterial spores, they are active against all bacterial and viral pathogens and, as a result, they will still keep patients safe.

Non-Critical Contact – In a situation where a patient's intact skin comes in contact with a reusable item (e.g. a blood pressure cuff on the arm), or does not come in direct contact with the item at all (e.g. lying on a bed covered by a fresh sheet), the risk of infection is very low. The safe level of reprocessing is also low. At this point it is important to note that intermediate and low level disinfectants have been designed for use on environmental surfaces and not on invasive medical devices.

Available Methods

Taking Spaulding's system one-step further, the next table categorizes the reprocessing methods currently in use in Canada.

How to choose?

To choose a reprocessing method, the first step is to assess the type of contact the item will make with the patient. Use Spaulding's classification in Table 1.

Table 1

TYPE OF CONTACT	DEFINITION	EXAMPLE	MINIMUM REPROCESSING LEVEL REQUIRED
CRITICAL	Contact with a normally sterile body part	Major Orthopaedic instrument set	Sterilization
SEMI-CRITICAL	Contact with mucous membrane or broken skin	Oral Airway, Flexible Gastroscope	High Level Disinfection
NON-CRITICAL	Contact with intact skin or no direct contact	OR bed, Blood Pressure Cuff	Intermediate or Low Level Disinfection

Continued on Page 35

Custom Procedure Packs (cont.)

Photo by J. Porteous

Custom pack

Brenda Zdunich, the Cardiovascular Specialty Coordinator, really sees the benefit of the patient being dry at the end of the operation. In the past, when taking the vein for the coronary bypasses, the drapes under the legs were saturated and had strike through when we used linen. Now, with the single-use drapes, the patients are dry.

Zdunich also finds that custom packs are efficient for emergencies. The circulating nurse can spend more time with the patient and the anaesthetist, instead of being back with the scrub nurse opening packages. In emergency situations, the room is now ready to go even before the patient even arrives.

Zdunich says she would never go back to linen. The Cardiovascular team looks forward to the day when all they have to open are their gloves!

In summary, since their introduction in 1996 custom packs have been very popular in both the OR and the processing department of the Regina Qu'Appelle Health Region. We now have forty different packs and have expanded from basic packs to more specialized ones. These include abilation packs, laparoscopic nephrectomy packs and paediatric packs. Nurses are happier; surgeons and patients are more comfortable. Some of our nurses have even claimed that they would quit if we ever stopped using custom packs!

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BENEFITS IN REGINA:

PROCESSING

Case cart preparation was reduced to two night staff picking for about two hours.

Lower stress level & frustration

Save 1 hour/day returning incorrectly picked items – annual savings of $3,000 $4,000.

Eliminated 2 positions in Sterile Processing at approximately $48,000 per year

Dollar savings from standardizing to less expensive components – the packs drove the standardization.

Reliable drape supply

NURSING

No strike through

Reduced ICU stay for CABG – annual savings of $728,000.

Patients dry and warmer

Standardized components/draping

Specialty draping to fit needs

Surgeons now cool and comfortable

Saving set up time – 10 to 15 minutes per procedure

Easier teaching of new staff

Latex Free

Quick set up for emergencies

More time can be spent with the patient pre-op

Greater employee satisfaction

Choosing A Reprocessing Method (cont.)

Table 2

TYPE OF CONTACT	MINIMUM REPROCESSING LEVEL REQUIRED	REPROCESSING METHODS CURRENTLY AVAILABLE
CRITICAL	Sterilization	• Steam • Ethylene Oxide • Hydrogen Peroxide Gas Plasma (Sterrad) • Liquid Peracetic Acid (Steris System I) • Ozone (TSO3)
SEMI-CRITICAL	High-Level Disinfection	• Glutaraldehyde • *ortho*-phthalaldehyde (OPA) • Hydrogen Peroxide (apx. 7%) • Hot Water Pasteurization
NON-CRITICAL	Intermediate or Low-Level Disinfection	• Alcohol (70%) • Phenolics • Moist heat • Halogens (Chlorine & Iodine) • Hydrogen Peroxide (apx. 3%) • Quaternary Ammonium Compounds (QUATS)

The second step is to identify the alternatives that will provide the minimum reprocessing level necessary to keep patients safe. Use Table 2.

The third step is to compare the choices within a selected category. Use Table 3 to identify the issues for comparison of the selected reprocessing methods.

EFFICACY

In reviewing any reprocessing method, the first criterion to consider is efficacy. If the method is not effective against the spectrum of microorganisms of concern, patients will not be safe from infection. For example, during the reprocessing of anaesthetic equipment, tuberculosis is always a concern. Equipment must therefore receive high-level disinfection. The processing time for high-level disinfection is based on the time needed to kill *M. tuberculosis var. bovis*. Low-level disinfection procedures are not as potent as high-level disinfection and were not designed to be used on instruments.Following Spaulding's classification will ensure appropriate spectrum efficacy.

Once efficacy is confirmed, a short cycle/contact time is usually preferable. This will allow instrument inventory to be turned around quickly as possible.

The effectiveness of any sterilization or high-level disinfection process must be monitored.[2,3] Some monitoring requirements may be more onerous than others and this will have implications for ease of use.

SAFETY

Once it is determined that the efficacy of a system is appropriate, the next issue to address is safety. Staff using any system must be safe. Ideally, a reprocessing method will pose no occupational health or safety risks. If that is not possible, the risks associated with any process must be mitigated. Include the costs of mitigation when comparing systems or methods. Environmental safety is also a concern and the same considerations apply to it as to staff safety. Ideally, the method should cause no harm but, if it might, the costs of mitigation must be factored in to any comparison.

Confirm device compatibility with the reprocessing method(s) being considered. Contact the device or the reprocessing method

Table 3

CRITERIA	ISSUES FOR COMPARISON
EFFICACY	• Spectrum • Cycle/Contact time • Monitoring protocols
SAFETY	• Staff OH&S • Instrument & equipment compatibility • Environment
BENEFITS & LIMITATIONS	• Ease of use • Cost per use or per item processed • Total processing time

Choosing A Reprocessing Method (cont.)

manufacturer for written guidelines. Reprocessing instructions accompany all new reusable medical devices. Keep a copy on file.

BENEFITS AND LIMITATIONS

Once it has been determined that the processes being considered are both effective and safe, the in-use characteristics become relevant. Depending on the processes, there may be a wide variety of method-specific benefits or limitations to consider. The three listed in Table 3 are common to all reprocessing methods. Add any others that are relevant to your facility and to the specific methods being considered.

CONCLUSION/SUMMARY

The choice of a reprocessing method depends on many factors and there is no one perfect method that suits all situations. The needs of patients, staff and the healthcare facility, as well as the types of products available at any given time, will all influence the decision. And that decision will not be final. Products change as do consumer needs. As a result the reprocessing decision will need to be reviewed, on a regular basis, in order to ensure that it remains current.

For further information on this topic, or if you have any questions, please contact the author at bbolding@medca.jnj.com.

References:

1. Favero, M and Bond, W. Chemical Disinfection of Medical and Surgical Materials. In Block S. ed. *Disinfection, Sterilization and Preservation.* Philadelphia: Lippincott Williams & Wilkins, 2001:895-896.
2. Canadian Standards Association. *Z 314.3-01 Effective Sterilization in Health Facilities by the Steam Process*. CSA International. Toronto: 2001. pp 18-26.
3. Society of Gastroenterology Nurses and Associates, *Guideline for the Use of High-Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* p. 4. From the web www.sgna.org 30 August 2003.

CORL CORRAL (cont.)

and top of the head is very important to preclude any side vents. It is believed that staff members may have become infected with SARS due to improper wearing and handling of masks.

Use of the regulation *N95* masks, with proper fit testing by the Occupational Health department, has become standard for SARS and related viruses. Initially it was thought that surgical masks were sufficient to protect against SARS but that theory has been disproved. Refusal to modify facial hair to accommodate the proper fit of N95 masks presents risk of inadequate protection. In addition, fit testing needs to be redone every year or two. The developments in this field and changing information are not widely understood among team members.

Conclusion

It is of grave concern, in this age of mass media and easy access to information, advanced education and scientific evidence, that a lack of compliance to the fundamental basics of hand washing and the proper wearing of masks still pose an infection prevention risk. It is sometimes said, "The further ahead we are, the further behind we become." Key points for safe health care teams include having current knowledge, sharing the information, following protocols and ensuring your teammates comply. Be a role model for all! Our patients, friends and families may live because of two basics in health care – hand washing and the proper use of masks.

WASH YOUR HANDS!

References:

1. Source: www.handhygiene.org

Infection Prevention Source Web Sites:

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www.health.gov.ab.ca
www.cdc.gov/ncidod/sars
www.cdc.gov/ncidid/hip.ARESIST/mrsawww.cdc.gov/flu/avian