Reprocessing Standards

Steve Winter (SVA)

Background: Effective instrument cleaning is the critical prerequisite for disinfection and sterilization, and a key battleground in the fight against hospital acquired infections.

As the understanding of surgical instrument contamination has evolved, so to have the definitions and methods used to determine cleanliness. This evolution has been informed by several large-scale quantitative studies conducted in Europe, which led to the updated ISO 15883-5 Standard for demonstrating cleaning efficacy. Limited research has been carried out in Australia that assesses the efficacy of current cleaning practices within operational sterilizing departments.

Objective: The objective of this study was to quantitatively analyze the residual protein contamination on surgical instruments reprocessed through Australian central sterilizing departments.

Procedure / Methods:

A total of 785 clinically soiled instruments were analysed following exposure to cleaning in automated washer disinfectors across more than 60 hospitals. Residual protein was extracted from surgical instruments via elusion with sodium dodecyl sulphate, and samples were subjected to a biochemical assay and protein quantification using UV-VIS spectrophotometry. Samples were collected from a wide variety of instrument families, including Ophthalmic, Neurological, Spinal, Orthopaedic, Cardiac, Oral Health & General. The study was conducted using an ISO-recognized and validated quantitative methodology, allowing comparison of the results with international benchmarks.

Results / Discussion: The rate of failure (defined as residual protein contamination above 6.4µg/cm2) was less than 5%. The results suggest that the maximum limits for residual contamination on surgical instruments as specified by ISO15883-5 are readily achievable within Australian sterilizing departments. In all but one occasion, instances of elevated protein residues were attributed to factors preceding treatment within the washer disinfector. These factors included prolonged dwell time, application or omission of certain types of pre-treatment, incorrect disassembly or poor loading practices. Comparison with international benchmarks showed that the cleaning performance within Australian sterilizing departments is high, however opportunities for continual improvement remain.

Key Learning Outcomes: The study highlights the improved end-point visibility provided by quantitative analysis and most notably, efficient protein extraction. A comparison with previous cleaning efficacy assessment methods (such as swabbing) emphasises the need to adopt current best practice techniques. The study identified several challenges for industry consideration, particularly the difficulty in final protein concentration expression where instrument surface area is not provided by the manufacturer and is difficult to determine. The results show that the importance of user training and process controls within sterilizing departments cannot be overstated. Manual processes and human factors had the largest impact on the outcome of surgical instrument cleaning activities.

Conclusion: Cleaning efficacy assessments which use clinically soiled instruments that are exposed to the sterilization departments routine protocols, and all processes from point-of-use, provide valuable data in the fight against hospital acquired infections.