The Clinical and Economic Case for Sterile, Disposable Instruments and Implants

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Healthcare Departments (/healthcare-departments), Operating Room (/healthcare-departments/operating-room)

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Abstract / Synopsis:
Contamination incidents related to cannulated endoscopes has caused more scrutiny of re-sterilization and re-use of orthopedic instruments. This article reviews instrument re-use vs. a trend in foot/ankle surgery toward sterile/disposable sets. We conducted a survey of operating room nurses to consider their current practices and the economics/efficiencies of in-hospital sterilization and disposable orthopedic instruments. Of the 100 respondents, 60 percent had been in the profession for more than

12 years, 20 percent for 8 to 11 years, and 20 percent for four to seven years. When asked how long it took to process and sterilize an instrument set at their facility, 83 percent of respondents said >61 minutes and 10 percent said 31 to 60 minutes. The most worrisome finding was that a majority had seen material residue on cannulated implants or instruments in the OR. Forty-seven percent of respondents estimated the per-case cost of instrument processing to be $600 to $1,000; with 30 percent estimating a lower cost and 23 percent a higher cost. By contrast, single-use disposable instruments can save more than $400 per case by reducing hospital labor and sterilization costs. Disposable instruments can also lower upfront and replacement cost, stand up to the rigors of surgery, help prevent expensive surgical site infections, and reduce liability risks.

Introduction

Recent news headlines reported two deaths and 179 exposures from contaminated surgical instruments used for endoscopic retrograde cholangiopancreatography (ERCP) at a university medical center in California.1 Similar infections also occurred in Washington, Illinois, and Pennsylvania. These events prompted the independent and highly respected ECRI Institute to add “Inadequate reprocessing of endoscopes and surgical instruments” to its Top 10 Patient Safety Concerns in 2014.2 These events also prompted the authors to examine instruments provided for foot and ankle surgery. Of particular interest is the common re-sterilization and re-use of cannulated instruments versus the trend toward sterile, disposable sets.

Cannulated instruments like endoscopes are especially hard to clean, yet Dr. Alex Kallen, an epidemiologist at the Centers for Disease Control and Prevention (CDC)'s Division of Healthcare Quality Promotion, noted that the agency has not found any breaches in recommended cleaning protocols at the affected re-processors or hospitals.3 In May 2015, a hearing held by the Food and Drug Administration (FDA) concluded that the CDC’s subsequent guidance for surveillance of bacterial contamination of reusable instruments could not be considered a best practice.4 Similar conclusions emerged from a recent survey of member of the Association of periOperative Registered Nurses (AORN). A majority of respondents said they had seen material residue on cannulated instruments or implants. Likewise, a majority reported having seen material residue or puddling in a sterilization tray, and 67 percent had seen material residue on a cutting instrument.

Given these findings, the use of disposable surgical instruments for foot and ankle procedures seems to be feasible and prudent. Sterile disposable packs are already the norm for many surgical procedures. This trend is driven by safety concerns, ease of use, lower upfront and replacement cost,

and sterile-pack off-the-shelf convenience.5 This article considers the regulatory actions, current practices, and economics associated with re-sterilization/reuse vs. sterile, disposable instruments.

U.S. Regulatory Actions and Trends

The CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, included evidence-based recommendations on preferred methods for cleaning, disinfecting and sterilizing patient-care devices.6 Unfortunately, recent exposures and infections occurred despite following manufacturer, CDC, and FDA requirements. The guideline noted that many factors affect the efficacy of disinfection and sterilization, including the number and location of microorganisms, innate resistance of microorganisms, concentration and potency of disinfectants, physical and chemical factors, organic and inorganic matter, duration of exposure, and biofilms.

The FDA is currently phasing in a unique device identification (UDI) system for medical devices.7 The UDI system allows individual devices to be tracked through distribution and use. Traceable instruments may well be next. Instrument-tracking systems are already considered a best practice for hospital central service (CS) departments. For foot and ankle procedures, several companies have begun to supply sterile, traceable implant and instrument sets.

Current Practice

To assess the state of current practice, we conducted a survey of sterilization and infection-control practices and costs with AORN members. Of the 100 respondents, 46 percent had earned an RN, 45 percent a BSN, and 9 percent an MSN. Sixty percent had been in the profession for more than 12 years, 20 percent for 8 to 11 years, and 20 percent for four to seven years. Seventy percent worked in a facility with a recycling program for OR consumed disposables. When asked how long it took to clean, process and sterilize an instrument set at their facility, 51 percent of respondents said more than 90 minutes, 32 percent said 61 to 90 minutes, and 10 percent said 31 to 60 minutes. The most disturbing finding was that the majority had seen evidence of inadequate processing or sterilization, 89 percent having seen material residue on cannulated implants or instruments.

Hospital processing requires well-trained and vigilant personnel, annual retraining, and continuous process monitoring, as does any attempt to reduce surgical-site infections (SSIs). So, we also asked about continuing education and feedback regarding infection rates. The majority of respondents to this question (n=46) received one to five hours of continuing medical education (CME) about infection prevention and control in the past year, with the next largest group (n=20) receiving six to 10 hours of CME. Sixty-nine percent of survey respondents received regular feedback about the number of SSIs in their OR. These findings suggest that infection prevention and control are a priority for OR nurses. Less clear is the type of education or monitoring practiced in sterile processing departments. Processing is a complicated, expensive, and repetitive process involving pre-cleaning and containment at point-of-use; soiled transportation; disassembly (if required); decontamination; preparation and packaging (if required); disinfection/sterilization (considering the level of reprocessing required for

items, based on the risk class and manufacturer's instructions); clean transportation; and storage.8 Surgical instruments and foot care equipment are critical devices, according to Spaulding's Classification, and require the highest level of processing. The fact that most of the AORN respondents had seen evidence of inadequate processing and sterilization in the OR remains worrisome. Perhaps human fallibility should be added to the list of factors that affect the efficacy of disinfection and sterilization.

The Economics of Reprocessing Versus Disposables

The average reprocessing cycle from decontamination to sterile storage takes more than 4 hours.8 Decentralized processing, a low set inventory, large case volume, complicated case mix, and trauma or other unscheduled emergency cases can all lengthen this time. The majority of AORN respondents (47 percent) estimated the per-case cost of instrument processing to be $600 to $1,000; 30 percent estimated the cost as lower than that (less than $600) and 23 percent as higher (more than $1,000). For orthopedic cases, facilities have long shifted the cost of large inventories to manufacturers, whose reps deliver implants and procedure sets for each case. Of course, the sets must still be sterilized on site, and manufacturers may simply pass the costs on to their customers. By contrast, single-use disposable instruments save more than $400 per case by reducing hospital labor and sterilization costs.9 Additional inventory savings may come from eliminating lost and obsoleted instruments, which amount to approximately 10 percent of the reusable instruments' value annually.

The costs of reprocessing pale in comparison to the costs of treating a single SSI. We asked our respondents to estimate the cost (including longer length of stay, additional nursing care, antibiotic treatments, possible readmission and further surgery) for a superficial or deep SSI. Sixty-four percent of those who responded said that a superficial infection would likely cost $10,000 to $50,000, and 50 percent said that treating a deep SSI would cost $51,000 to more than $100,000 (Figure 2). Each year there are approximately 300,000 SSIs in American hospitals, imposing a total cost of approximately 10 billion dollars.10

These estimates omit any costs arising from liability or lawsuits. Physician groups, such as the American College of Obstetricians and Gynecologists, are concerned about liability, and would like to see studies demonstrating safety, cost-effectiveness, and quality of reprocessed devices.11 The Association for Professionals in Infection Control and Epidemiology (APIC) warns, “Given the associated unnecessary morbidity and mortality that could be prevented, the suffering that could be eliminated, and the money that could be saved, no healthcare organization can risk ignoring the benefits of effective strategies aimed at preventing hospital-acquired infections.”12 The APIC guide to eliminating orthopedic SSIs, produced in association with AORN, specifically emphasizes the importance of teamwork in the surgical setting. It also notes that contamination of a sterile item is event-related, and the probability of contamination increases over time and with increased handling and longer storage.

The authors have personally experienced re-used instrument sets presented with incomplete and missing components when they reached the operating room (OR). These missing components cause delays in the surgical case and many times result in the need to open additional sterile sets to complete the original set. A missing instrument can totally disrupt OR efficiency. In the AORN survey, 70 percent estimated that pre-case processing of instruments costs greater than $600. A 2005 study of 100 U.S. hospitals placed average OR charges at $62/minute (range $22 to $133/minute).13 In the AORN survey, 83 percent of the respondents indicated the instrument sterilization process takes more than 61 minutes. Given this, a minimum re-sterilization “wait cost” for the OR would be $1,342 ($22 x 61 minutes) with an average minimum cost of $3,782 ($62 x 61 minutes). Instrument availability and reliability are essential to a well-run, cost-effective OR environment.

Sterile Disposable Orthopedic Instruments

Sterile, disposable procedure packs are commonplace for anesthesia, cardiac rhythm, and neuromodulation procedures, but reusable instruments and surgical trays remain the current standard for most orthopedic procedures. Single-use instruments were thought to be too frail to stand up to the heavy demands of orthopedic procedures, where torque set points can range from 0.112 to 11 Nm (more than 100 lb/in). Precision technology that mates surgical stainless steel to engineered polymers challenges that long-held belief. The technology has already proved robust, having been deployed in more than 25 million single-use, torque-limiting instrument sets designed for spine, cardiovascular, and neurological implants.14 These sets qualify for ISO 13485 standards, FDA approval, and CE mark certification. In the context of sterilization and infection control, single-use disposable orthopedic instruments could also tackle the problem of contaminated reusable instruments and associated hospital-acquired infections.

Global market demand for single-use disposable supplies and equipment expands by more than 6 percent annually.15 Lower upfront investment and replacement cost, along with procedure-specific orthopedic designs are certain to contribute to the growth of sterile disposable instrument sales.

Sturdy construction combined with ergonomic design have resulted in high-quality instruments for extremity (foot/ankle and hand/wrist), spine, and trauma surgeries. Turn-key procedure kits are beginning to pair instruments and implants for even greater efficiency (Figure 3). As mentioned previously, off-the-shelf disposable procedure kits offer hundreds of dollars of savings per case by eliminating processing and re-sterilization costs, increasing OR efficiency through decreased turnaround time, helping to prevent expensive SSIs, and reducing liability risks.

Conclusion

Like other medical specialties, a trend is developing in foot and ankle surgery for sterile, traceable implants and instruments. This trend is driven by regulatory, liability, economic, safety and convenience factors. In today's healthcare environment, safety and economic issues dominate. Manufacturing technology has improved enough to make sterile, disposable instruments a safe, economic benefit to hospital ORs. Sterile, disposable orthopedic instruments stand up to the rigors of surgery, save money by eliminating processing and sterilization costs, can help prevent expensive SSIs, and reduce liability risks.

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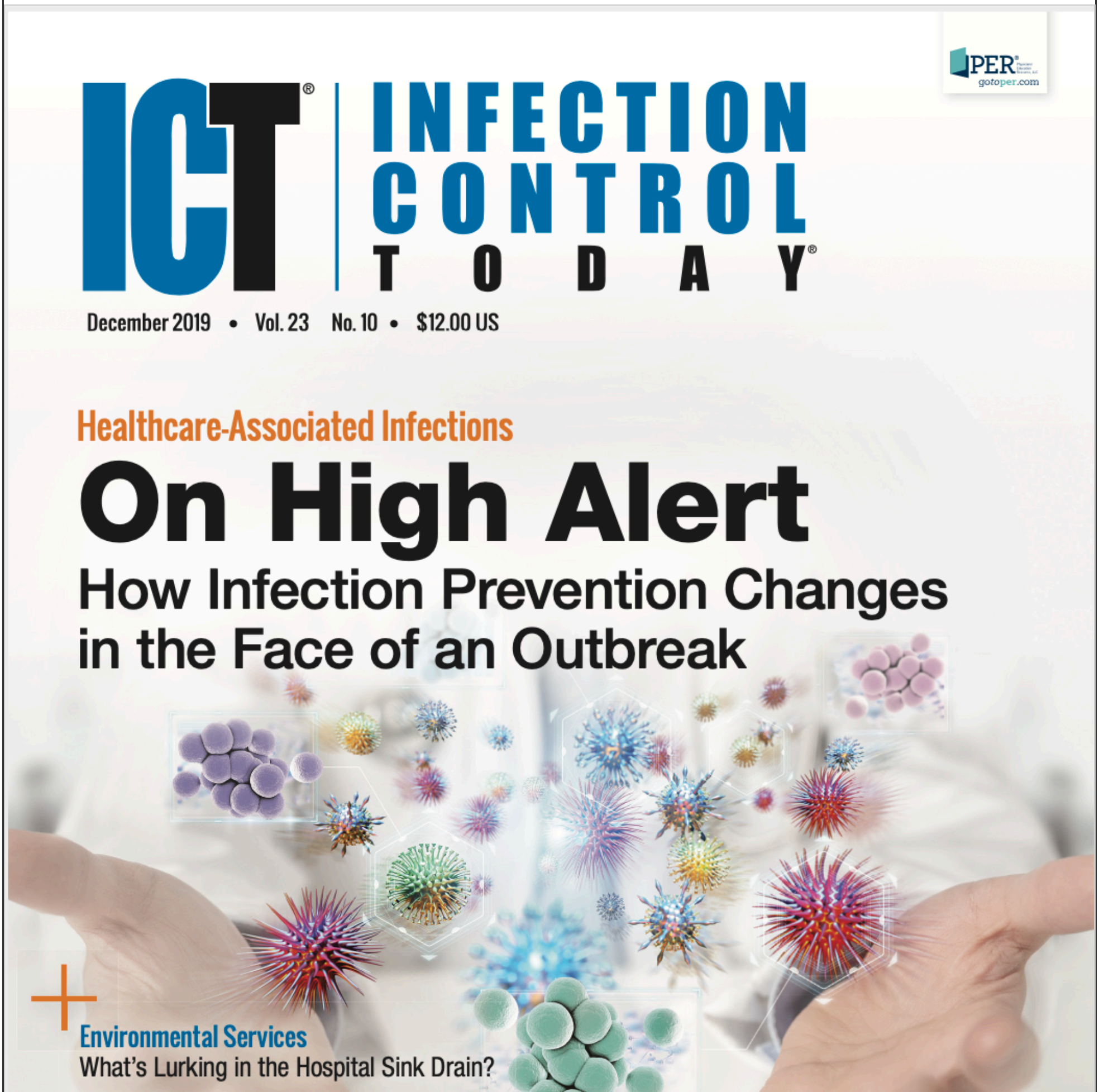

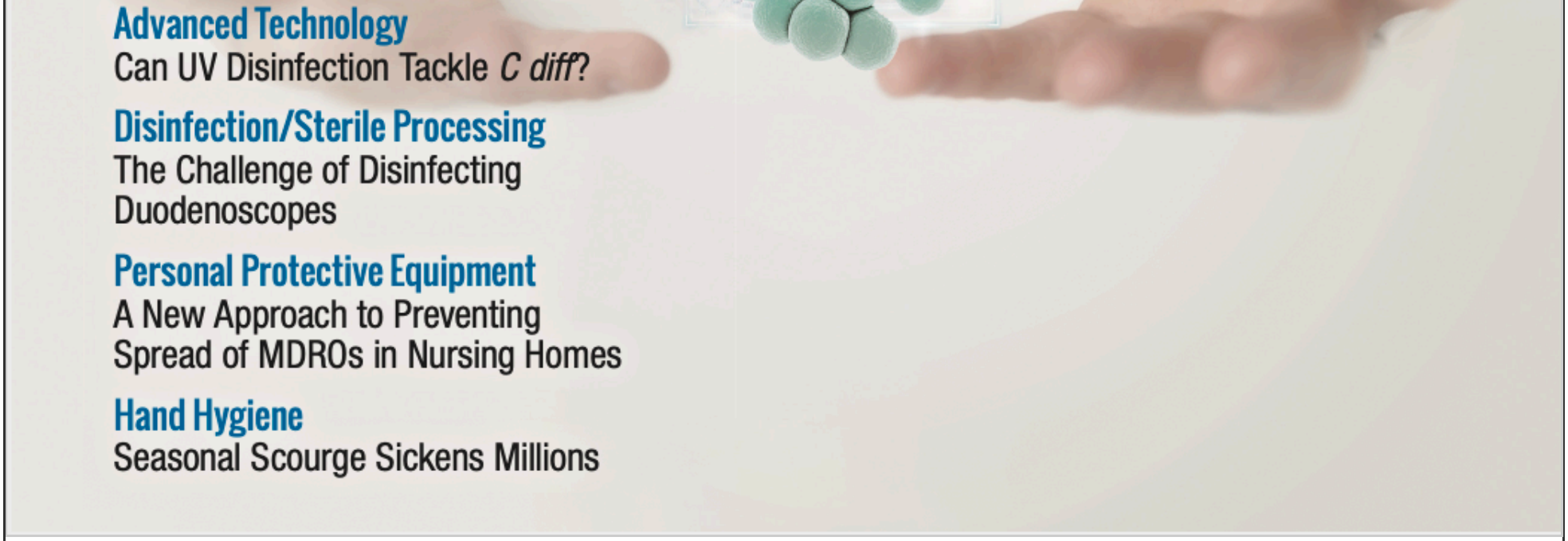

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Dec 10, 2019 Vol 23 No 10

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