Balancing Infection Control and Environmental Protection as a Matter of Patient Safety: The Case of Laryngoscope Handles

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The development of general anesthesia made major surgery possible. It did not, however, immediately make surgery commonplace. In the 1840s, over 90% of "clean" surgical wounds became infected, frequently leading to death (Figure 1). Infection prevention and control were essential for the advancement of surgery. The first major decrement in the surgical site infection (SSI) rate occurred between 1880 and 1900, with the development of germ theory and antisepsis. The second major reduction occurred between 1945 and 1970, with the introduction of antibiotics and the development of surgical antibiotic prophylaxis. By 1985, the overall infection rate had decreased to about 5%. While infection control research has continued to focus on antisepsis and antibiotic prophylaxis,[1] the potential incremental impact is small (Figure 1) and may increase both expense and waste. Because of the high cost and potentially devastating consequences of SSI, however, it has been considered worth the investment. A growing body of research demonstrates that a higher yield approach to further reducing SSI rates requires a 2-pronged approach: strengthening host defenses to residual contamination[2] and closer attention to hand hygiene by nonscrubbed personnel to reduce cross-transmission.[3]

The original expectation of antisepsis was that it would render the surgical field sterile, that is, eliminate all pathogenic microorganisms. In fact, that is impossible.[3] The most effective approach is to reduce microbes to the level that they are easily managed by the patient's host defenses. This understanding of antisepsis provides a roadmap for balancing efforts with impact and feasibility. While health care–acquired infections remain a common source of morbidity and mortality and increased health care expenditures, focusing on complete sterility has adverse consequences for ecological health. Daschner, an infection control specialist, first raised concerns about the increasing use of single-use disposable devices.[4] Such devices are valuable when adequate decontamination is not feasible. However, indiscriminate use of single-use disposable devices can increase the environmental footprint of health care through increased resources required for production, transport, and waste management,[5] without having a measurable effect on infection control risk.

Hospital systems are exquisitely sensitive to regulatory oversight and, in particular, may proactively adopt excessive decontamination policies to avoid negative findings during a review.[6] Single-use disposable laryngoscope handles and blades have become increasingly popular, for example, in large part because of recent attention by health care accrediting organizations such as The Joint Commission (TJC). They also may be perceived as increasing patient safety and reducing costs related to decontamination and loss, although these assumptions may not be evidence based. This underscores the hidden issue of environmental pollution stemming from health care, and how well-intentioned efforts to improve antisepsis have heightened the need to balance environmental concerns simultaneously with public health (Figure 2). Indeed, this now represents an expanded view of patient safety. While not the top consideration by physicians working to save a patient's life, or by hospital administrators trying to keep a facility running in regulatory compliance, it is no longer possible to ignore public health impacts. Knowledge of the true costs of such decisions is crucial to optimizing the balance of infection control and environmental impact.

LARYNGOSCOPE DECONTAMINATION

In the absence of appropriate decontamination methods, cross contamination between patients through reusable laryngoscope handles or tongue blades is certainly possible. There are older reports of contamination of reusable tongue blades and handles with organic matter such as proteinaceous material or occult blood,[7] and reports of neonatal intensive care unit infection outbreaks that identified inadequately decontaminated blades (eg, wiping with an alcohol swab) as potential sources of cross infection.[8,9] These reports led to new cleaning guidelines from the Centers for Disease Control and Prevention (CDC) in 2003, requiring tongue blades undergo a minimum of high-level disinfection. There are more recent reports of handle contamination with nonpathogenic bacteria.[10] A contaminated handle was implicated in a reported death in the United Kingdom in 2011.[11] Notably, the hospital did not require any handle cleaning

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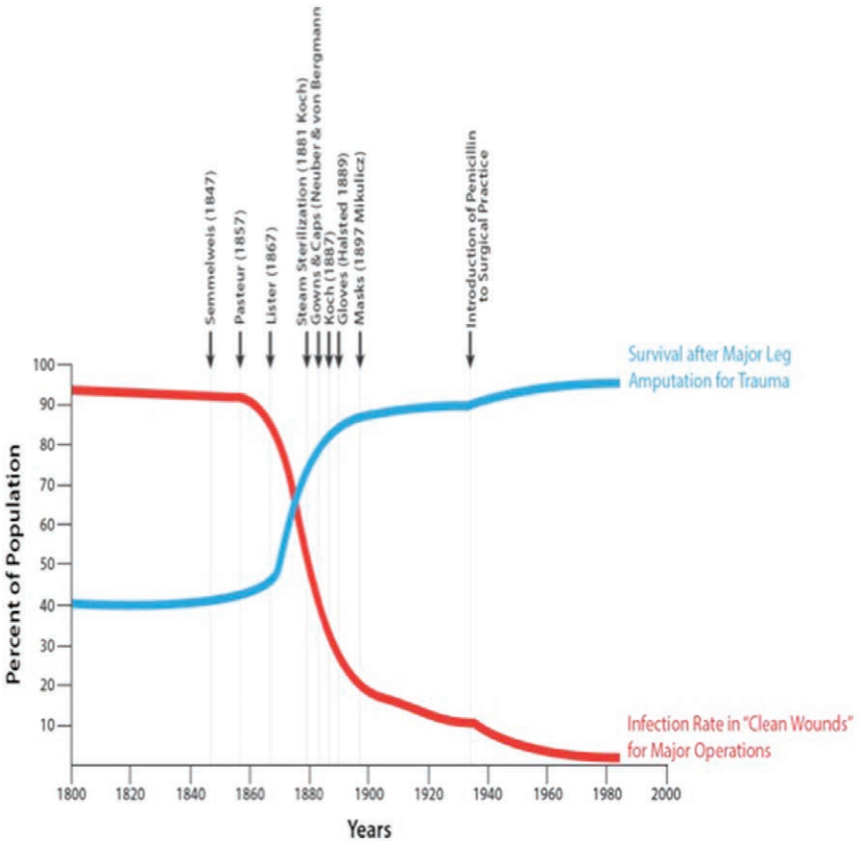

Figure 1. Surgical site infection progress. The first major decrease in infection rate followed antiseptic practices, while the second major decrease followed the introduction of antibiotics. The current rate is <5%, asymptotically approaching zero. Improvements using existing methods achieve proportionally small gains. Used with permission from Alexander.[1]

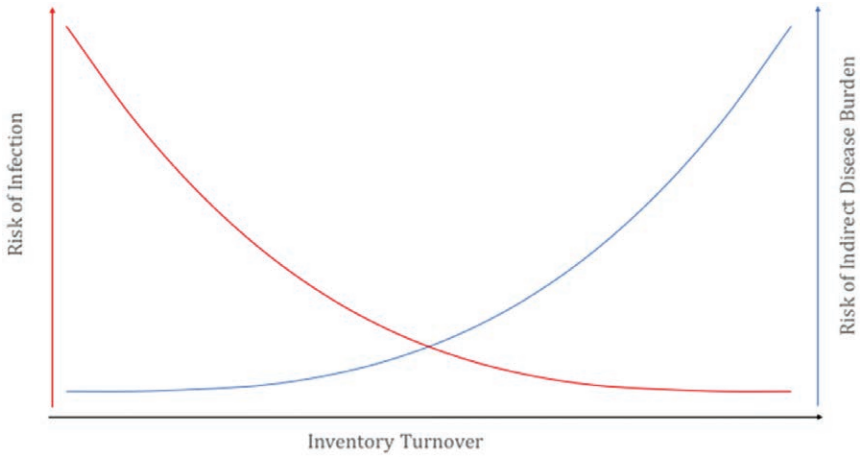

Figure 2. Inventory turnover effects on infection risk and indirect disease burden. This conceptual graph depicts the diminishing returns on infection risk reduction through overcleaning reusable and/or overreliance on single-use disposable devices. At the same time, excessive inventory turnover increases the risk of indirect disease burden.

between uses in that case. More recently, Call et al[12] examined contamination levels after low-level disinfection of the handle. While they found a high incidence of nonpathogenic bacterial contamination, no Vancomycin-resistent enterococci, Methicillin-resistent Staph-aureus, Gram-negative rods, or viruses were detected. In other words, proper low-level disinfection of handles can be achieved in routine use. In a review of cross-infection risk from laryngoscope handles and blades, Negri et al[13] noted that causal relationship between contamination and infection transmission is difficult to establish and, given the overall low quality of studies in the area (largely case reports), it is impossible to quantify risk. Laryngoscope handles treated with low-level disinfection, or tongue blades treated with high-level disinfection, do not appear to be notable contributors to infection transmission in the United States, and thus the merits of higher treatment or single-use disposables need to be weighed against increased costs and pollution-related public health damages.

LARYNGOSCOPE INFECTION RISK CLASSIFICATION CONFUSION

Sterilization is neither feasible nor necessary for all medical devices. A rational basis for cleaning reusable devices based on infection risk was first established by Spaulding in 1968.[14] The system defines 3 levels of decontamination, based on site of use. Critical devices, such as intraabdominal surgical equipment, contact normally sterile tissues and must be sterile at the time of use. Sterilization destroys or eliminates most forms of

microbial life, excluding prions. Semicritical devices, such as tongue blades, contact mucous membranes or nonintact skin and require high-level disinfection. High-level disinfection kills most microorganisms, except certain spores. Noncritical devices, such as blood pressure cuffs, touch intact skin and require intermediate or low-level disinfection. Low-level disinfection kills most vegetative bacteria, some fungi, and some viruses. Several methods of cleaning for each Spaulding class exist and are well described by the CDC.[15] The CDC regulates how medical equipment is classified, and oversight bodies are tasked with enforcing decontamination compliance. Professional societies, such as the American Society of Anesthesiologists (ASA), provide practice guidelines for their members.

Laryngoscope tongue blades are uniformly categorized by the CDC, TJC, and professional guidelines as semicritical in the United States,[15–19] and thus must undergo a minimum of high-level disinfection after each use. Historically, handles have been considered as noncritical, suitable for low-level disinfection by anesthesia staff in the operating room using chemical wet-wipes, except in extraordinary circumstances, such as management of patients with Creuzfeld-Jacob disease or Ebola virus infection. There is lack of consensus on handle classification in the United States, however, and recent attention by TJC has brought this issue to light.

Guidelines of both the American Association of Nurse Anesthetists[19] and the Association of Operating Room Nurses[18] classify the handle as noncritical. ASA guidelines[17] do not distinguish between the handle and blade, but define the laryngoscope as semicritical, thus suggesting that handles require at least high-level decontamination. The CDC[15] and TJC[20] make no clear determination on the handle classification, and instead defer to manufacturer Instructions For Use. Instructions for Use describe how equipment should be used, and provide instructions for various CDC-approved cleaning options, but do not (or rather should not) specify risk classification.[21] This lack of clarity, sometimes resulting in negative findings by oversight bodies, has led some institutions to choose between either shifting laryngoscope handle decontamination to the Central Sterilization and Supply department for higher level decontamination or adopting single-use disposable handles. Such decisions may be made without adequate consideration of cost or pollution impacts.

LARYNGOSCOPE POLLUTION AND COSTS

In this issue in "Life cycle assessment and costing methods for device procurement: comparing reusable and single-use disposable laryngoscopes,"[5] Sherman, Raibley, and Eckelman evaluated environmental emissions and total cost of ownership for alternative management options. They demonstrated that single-use disposable rigid laryngoscope handles and blades result in 16–25 and 6–8 times more greenhouse gas (GHG) emissions, respectively, when compared to alternative reusable cleaning scenarios using average US energy mix. For reusable reprocessing options, GHG emissions were least with high-level disinfection, and most with sterilization. Surprisingly, low-level disinfection resulted in slightly higher GHG emissions than high-level disinfection, though significantly less than sterilization. However, for secondary emissions end points, the chemical wipes rivaled sterilization in several pollutant categories and dramatically exceeded it in ozone-depleting emissions, which are particularly important as they contribute to respiratory disease. This supports the importance of avoiding both routine overcleaning (ie, sterilization) and excessive use of disinfectant wipes.

When making procurement and management decisions, facilities must balance environmental and facility costs. The authors found that rigid laryngoscope total cost of ownership for Yale-New Haven Hospital is 5–18 and 2–7 times cheaper with reusable handles and blades, respectively, than with single-use disposables. Within reusable cleaning options, the cheapest method of reprocessing the handle is with low-level disinfection, and for the tongue blade high-level disinfection (as low level is not acceptable).[5] While costs will vary between institutions, the break-even points suggest that some fiscal opportunities may be generalizable and the costing methods can be tested locally.

The environmental considerations are particularly critical in the context of the US health sector which is one of the largest polluting industries. If the US health sector were a nation itself, it would have ranked 13th in the world for GHG emissions in 2013. GHG and non-GHG emissions, combined, resulted in loss of over 614,000 disability-adjusted life years in public health damages from the health sector that year. This is on the same order of magnitude as damages due to preventable medical errors, and thus pollution prevention in health care is a growing patient safety concern and worthy of our attention.[22,23] Proper classification and management of laryngoscope handle decontamination, just one example, provides an opportunity for cost and pollution minimization without reducing quality of care. Avoidance of both overcleaning and overreliance on disposable equipment could improve the value and quality of care in the broader context of sustainability.

THE PROBLEM WITH INSTRUCTIONS FOR USE

Regardless of cost and pollution assessment, facilities are beholden to oversight body enforcement of CDC regulations. In the case of laryngoscope handles, the CDC defers to manufacturer recommendations, in the Instructions for Use. This deference invites arbitrary designation of higher risk classification by manufacturers due to their incentive to sell more devices. Newly designating handles as semicritical or critical may challenge facilities to simplify their cost-benefit analysis or management alternatives, driving the switch to single-use disposables. Relying on manufacturer recommendations is not in the best interest of public health or health care facilities.

Instructions for Use were never intended to determine infection risk classification, nor should they.[21] Manufacturers should provide cleaning specifications in line with the Spaulding system and CDC regulations. The CDC should base regulations on national professional guidelines, while accrediting organizations assess institution compliance. Risk stratification should be the responsibility of epidemiologists and infection control experts, who develop professional guidelines. Unfortunately, the lack of national professional consensus leaves the CDC deferring to manufacturer Instructions for Use.

WHAT'S NEXT?

Sources of wasteful practices for laryngoscopes are multifactorial, and include unrealistic expectations for infection control strategies, perceived price benefit and convenience of single-use disposables, unclear national guidelines on laryngoscope handle processing, and neglect of the environmental and public health impacts of clinical practice. Anesthesiologists should advocate for regulatory and oversight bodies to clearly define risk classification. The evidence suggests that semicritical classification of the tongue blade and noncritical classification of the handle are sufficient, and consistent with other high-income nations' recommendations. US consensus by infection control and clinical associations on handle risk classification could serve as the foundation for a Citizen's Petition to advocate for CDC regulation update (Title 21; Part 10; subpart B; Section 10.30 of the Code of Federal Regulations) that provides a pathway for individuals or communities to request changes to health policy.[24] Regulatory clarity could help prevent unnecessary waste, costs, and pollution by providing an unbiased source for policy-makers and removing manufacturers from the risk classification process—an area where they have a clear conflict of interest. We should encourage our institutions to adopt life cycle assessment and costing methods, that weigh environmental emissions and facility total cost of ownership, to aid device management decision-making. Such efforts to reduce waste, improve resource efficiency, and minimize use of hazardous or suspected substances will conserve precious health care dollars, as well as prevent excess pollution and secondary disease burden. It is time for anesthesia professionals to take the lead in patient safety through striving to balance infection control practices and pollution prevention as matters of public health.

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