

## Scrub or Toss? Making the Case for Disposable Laryngoscope Blades

Airway-management equipment undeniably assumes a position of prime importance in the EMS arsenal. Of all EMS interventions, appropriate airway management, along with early defibrillation, is most likely to be truly life saving. However, in the course of routine reevaluation of system equipment, Pinellas County (Florida) EMS recently had cause to ask whether or not we were potentially harming both patients and EMS practitioners in the long run with this very same lifesaving equipment.

Pinellas County EMS is a large, all-ALS, public utility model system serving a base population of approximately 900,000 in central Florida. In 2003, almost 1,200 intubations were performed by our 800 paramedics. The system was using reusable laryngoscope blades and handles, with one set of handles and blades (pediatric and adult) issued per ALS unit. The system's equipment committee had periodically been evaluating disposable laryngoscopes and laryngoscope blades, primarily because of infection control considerations. When the committee was ready to recommend adopting a disposable laryngoscope blade system, the county EMS Authority requested a detailed analysis of pros and cons related to moving to disposable equipment.

### How Clean Is Clean?

The Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC) classify medical devices according to the Spaulding classification system as "critical," "semi-critical" and "noncritical." Laryngoscope blades fall into the semi-critical classification. This category includes any medical devices that touch mucous membranes or broken skin.<sup>1-3</sup>

The process for disinfection and sterilization of semi-critical items is designated by the CDC as "high-level" disinfection.<sup>3</sup> High-level disinfection kills all organisms, with the exception of high levels of bacterial spores, and is achieved using a chemical germicide classified by the Food and Drug Administration (FDA) as a "sterilant," or sterilizer. Examples of approved sterilants include Cidex, Sterilox and Sporicidin.<sup>4</sup> The item must be exposed to the sterilant for periods of time ranging from 10-45 minutes, depending upon the chemical used, in order to assure adequate performance.<sup>4</sup> The appropriate use of these chemicals is highly dependent upon careful compliance with manufacturer's recommendations for use, including "debulking" of organic material present on the

equipment via mechanical scrubbing before exposure to the chemical.<sup>3</sup>

Unfortunately, laryngoscope blades have been identified in the literature as potential vectors for cross-contamination and as sources of nosocomial infection.<sup>5,6</sup> Over two million patients per year develop nosocomial infections, resulting in 90,000 deaths annually and significant added healthcare costs, as well as unanticipated burdens on patients and their families.<sup>7</sup> It is not uncommon for laryngoscope blades to routinely be contaminated with gross or occult blood and other infectious body fluids during intubation procedures. The blades also frequently come in contact with disrupted mucosal surfaces, increasing the probability of transmitting infectious material if it is present on the equipment. Blades also tend to have irregular surfaces and crevices that hold on to tissue and other potentially infectious material. A study, reported in 2001, on a series of supposedly clean, sterile pieces of airway equipment within a single hospital found that 77% of laryngoscope blades taken from operating rooms, 86% of those taken from an intensive care recovery area and 100% of those taken from medical or surgical wards stained positive for retained protein material, and indication of possible incomplete cleaning and sterilization.<sup>8</sup> Studies of laryngoscope decontamination and sterilization procedures in hospital in Great Britain and the Netherlands have shown poor compliance with internationally established semi-critical equipment decontamination and disinfection procedures, with causative factors including lack of clear decontamination guidelines and written procedures, cumbersome quality control techniques, and even hazardous-materials classifications of some of the eligible sterilant chemicals.<sup>9,10</sup> In the United States, surveys were sent to 125 large city EMS system medical directors regarding equipment hygiene standards.<sup>11</sup> Only 37% of responding agencies that cleaned and disinfected their own laryngoscope blades used both soap and water and alcohol or a commercial disinfectant (A/DC), while 32% used only A/CD without other cleaning and 4% used soap and water alone. The survey did not address the adequacy or quality control of performance of soap and water washing or disinfecting techniques, so the effective cleaning and high-level decontamination rates are likely even lower.

In Pinellas County, there is no single equipment decontamination and disinfection policy covering all first responder fire departments and Sunstar, the ALS transport agency. All agencies are required to

follow OSHA Bloodborne Pathogens Standards, but these standards do not specify methods of decontamination and disinfection.<sup>12</sup> An informal survey of EMS agencies indicated that CDC and APIC guidelines for semi-critical equipment were not consistently being followed. Challenges to compliance include systems status management of Sunstar units, making access to station or headquarters-based cleaning resources between patients difficult, and call volume, which necessitates frequent serial call dispatching for individual fire and Sunstar units without sufficient time in between for the required procedures. While there had never been a related airway equipment contamination issue identified within the system, it became clear that the status quo was not acceptable.

**Table I: Steps for Cleaning and Disinfecting<sup>3</sup>**

- Assemble appropriate personal protective equipment.
- Prepare cleaning agents with correct dilution, temperature and compatibility with equipment to be cleaned.
- Disassemble instruments with removable parts to ensure all surfaces are exposed to cleaning.
- Thoroughly clean instruments per cleaning agent specifications.
- Rinse instruments thoroughly.
- Dry each item, including lumens and small crevices, to prevent dilution of disinfectant.
- Prepare disinfectant per manufacturer's recommendations and label with name of disinfectant, date of solution expiration and initials of preparer, and place in a covered container.
- Verify correct disinfectant concentration with test strips and document results.
- Disassemble instruments and completely immerse in solution.
- Flush lumens and small crevices with solution.
- Soak for solution manufacturer's recommended period of time.
- Rinse all items at least three separate times with either sterile or potable water (depending on facility policy).
- Dry instruments thoroughly and reassemble; air recommended for drying instrument lumens and crevices.

### **Making the Case**

Although the concept of disposable laryngoscopic equipment makes sense from the perspective of infection control, several previously published studies of disposable laryngoscope blades have suggested potential concerns. Although one study found a particular brand acceptable in the OR

for routine intubations,<sup>13</sup> another found that several brands of plastic disposable blades required the use of greater peak forces than metal nondisposable blades and increased the duration of intubation attempts significantly.<sup>14</sup> Other studies found most disposable blades tested to have lower performance satisfaction scores,<sup>15</sup> along with a lower percentage of glottic opening (POGO) visible scores and a higher incidence of failed intubations.<sup>16</sup> There are also at least anecdotal reports of fragility of the plastic under cold weather conditions and problems with dim lighting. The equipment committee and the Office of the Medical Director had already determined that the clinical characteristics and capabilities of the recommended equipment were acceptable. The main advantages of this particular brand were the metallic composition of the blades, bright fiberoptic lighting, bulbless construction and acceptance by field practitioners who examined the equipment. The remaining factors in the final purchasing determination included logistics, user friendliness, quality management, risk management and, of course, both initial and ongoing cost. The options fell into two basic categories: establish a CDC/APIC-compliant cleaning and disinfection program or change to a disposable system.

The option of implementing a CDC/APIC-compliant program included a host of disadvantages. Logistically, the minimum of equipment stocked on ALS vehicles would have to be at least doubled in order to assure that they would be identically capable on at least two consecutive calls without adequate cleaning time in between. A mechanism for ongoing resupply between calls would be required for Sunstar and other units without routine access to cleaning equipment. Cleaning areas with appropriate ventilation, equipment and personal protective gear would have to be established; this would require a minimum of 20 stations to provide just one location for each agency. Many agencies would realistically require multiple physical locations to minimize travel time to access the equipment. The system has ALS first responder vehicles stationed at over 60 locations, without even considering Sunstar ambulances. Appropriate procedures for cleaning and decontamination and quality control measures would require a significant time commitment from personnel, in some cases causing detrimental alterations in response capability; dedicated staff for the purpose is not practical. The procedures are quite time- and effort-intensive, with vigorous initial scrubbing and rinsing, careful examination of equipment for adequate decontamination prior to disinfection, requirements for monitoring and temperature of solutions, solution effectiveness testing, varying required soaking times according to sterilants used and documentation procedures for all aspects (see *Table I*). Risk management also poses challenges in that the very nature of the procedures as outlined above discourages

compliance. In addition, there is some risk of significant infectious disease exposure during cleaning procedures, and glutaraldehyde, the most common chemical used, can be hazardous if used improperly (see *Table II*).<sup>17</sup> Conservative figures calculated at the time on the basis of uploading just 20 cleaning stations utilizing Cidex and Enzol solutions showed a required investment of about \$15,000. Ongoing costs for the same number of stations would be almost \$8,000 per year, based on the cost of solutions alone (see *Table III*).

A parallel option was to purchase autoclaves for a similar number of cleaning locations. Depending upon size and degree of computerization or automation, autoclaves can be purchased for anywhere from \$600 to more than \$5,000. Additional supplies needed include wrappers, indicator tape, autoclave cleaning supplies and printer paper. While this may be a very reasonable option for smaller departments, the capital expenditure to establish 20 cleaning locations in Pinellas would have exceeded \$15,000. Logistical challenges posed by the limited number of locations would still exist and would also likely increase the required vehicle equipment inventory to assure continued serial patient care capability.

<b>Table II: Signs and Symptoms of Glutaraldehyde Exposure<sup>13</sup></b>
<b>Inhalation:</b> Respiratory tract irritation, asthma or asthma-like symptoms, coughing, chest tightness, sneezing, burning sensations, nosebleed. Worse if the chemical is heated.
<b>Eyes:</b> Burning eyes, conjunctivitis, potentially permanent corneal injury if solution contacts the eye.
<b>Skin:</b> Allergic and/or contact dermatitis, stained hands, hives.
<b>General:</b> Headaches, nausea.
<b>Ingestion:</b> Chemical burns of the GI tract, vomiting, diarrhea, dizziness, syncope.

The option of moving the system to a disposable laryngoscope blade system effectively negated many of the concerns raised by the compliant cleaning and disinfecting program option. The logistical issue of an ALS unit potentially being without required equipment when there were two or more consecutive calls would still, however, need to be addressed. (It should be noted that no critical incidents with lack of appropriate equipment on scene have ever been identified, more than likely because of the routine practice of dispatching

multiple ALS units to every scene.) Clearly, user-friendliness is an advantage of the disposable system, with less effort and time investment required. Procedures would be greatly simplified compared to the disinfection program option; thus, quality control issues would be far less prominent. Risk management concerns related to hazards to workers would also be reduced. The cost of matching the current equipment availability with one new set of disposable pediatric and adult blades and one nondisposable laryngoscope handle for each of 120 ALS units would be approximately \$4,200. Ongoing blade replacement costs based on one blade used for each of 1,200 intubations were also estimated at \$4,200.

Based on financial factors alone, the disposable blade system would provide the opportunity to address not only the cleaning and disinfection issue, but also to improve equipment availability. The additional cost to increase each ALS unit inventory to two sets of adult and pediatric laryngoscope blades and two adult handles (doubling capacity) and to add a pediatric-sized laryngoscope handle was only \$5,400.

### The Decision

Following this methodical problem analysis, the county EMS Authority authorized the system's transition to the disposable equipment option. This option allowed not only for quality improvement of the existing system, but also doubling of laryngoscope handle and blade inventory on all ALS units for less than the cost of uploading and implementing a uniform appropriate cleaning and disinfecting system (approximately \$9,600 versus \$15,000). Ongoing costs were also favorable for this option.

While the financial aspects of this issue will vary depending upon EMS system size, call volume, patient acuity, and the equipment and chemicals selected, the analytical process used by Pinellas County EMS to arrive at the final decision is applicable to many clinical and nonclinical purchasing decisions. In this case, because of the suspected but ill-defined risks to patient well-being in addition to more definable system-related factors, the impact of the final decision may be even more significant than can be obviously appreciated. Pinellas County EMS uploaded the new intubation equipment in September 2004. ■

**Table III: Cost Analysis for Options**

<b>Cleaning and disinfecting</b>	<b>Cost per location<sup>1</sup></b>	<b>Autoclave</b>	<b>Cost per location<sup>2</sup></b>	<b>Disposable system<sup>3</sup></b>	<b>Cost per ALS unit</b>
Solution, test strips, cleaning equipment, PPE	\$745	Autoclave plus disposables	\$750	One full set of pediatric and adult blades, plus one adult and one pediatric handle	\$45
	<b>Variable Costs</b>		<b>Variable Costs</b>		
Estimated ongoing costs per year <sup>4</sup> (disposables) per location	\$400	Estimated ongoing costs per year per location	Varies widely	Replacement blades (based on one blade per intubation)  Replacement bulbs	\$3.50 each blade  \$3 each
Upload of additional full set of nondisposable blades to allow downtime for cleaning	Varies per set	Upload of additional full set of blades to allow downtime for cleaning	Varies per set	Cost of additional capacity of one extra set of blades and one extra adult handle per unit	\$35
Pinellas County upload cost, based on 20 locations and only one set of equipment per vehicle	\$15,000		\$15,000	Pinellas County upload cost based on 120 ALS units and only one full set of blades and handles  Based on two sets of blades, two adult handles and one pediatric handle	\$5,400  \$9,600

1. Does not include construction costs for new space or appropriate ventilation systems for existing space.  
 2. Cost range varies widely. This is a minimum estimate.

3. Prices for Sun-Med, Inc. laryngoscope handles and disposable blades through Trianim per negotiation for Pinellas County EMS. No cost guarantee is implied.  
 4. Based on estimated Pinellas County use and rates of expiration of cleaning/disinfecting solutions.

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**A descriptive study of blood in the mouth following routine oral endotracheal intubation.**

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Oral endotracheal intubation and extubation are two routine procedures performed by anesthesia providers which could lead to breaches of mucosal integrity and slight or moderate bleeding, thereby providing a vector for transmission of a blood-borne disease. This study was designed to determine the incidence of occult or overt blood in the oral and pharyngeal areas during the intubation and extubation periods. A convenience sample of 163 patients from 18 to 70 years of age who underwent an oral endotracheal intubation for general anesthesia were included. Within 15 minutes of endotracheal intubation, the patients were tested at five designated sampling sites for the presence of overt or occult blood. The results demonstrated that blood was present after 34% of the intubations, with 70% of those being positive in the oral/pharyngeal cavity and 52% exhibiting blood on the laryngoscope blade. Upon extubation 72% were positive, with 97% of those being positive at the distal tip of the endotracheal tube. The blood found during both these events was primarily occult. The results suggest that the potential for blood, both overt and occult, to be present in the mouth of patients is significant enough to recommend that all practitioners adhere to the universal barrier precautions to limit their exposure to the transmission of potentially fatal blood-borne viruses.

**Incidence of visible and occult blood on laryngoscope blades and handles.**

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Anesthesia providers must take appropriate precautions to reduce the potential for transmission of infectious agents to the patients under their care. The devastating spread of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) over the past decade has resulted in the development of specific guidelines for the cleaning, disinfection, sterilization, and handling of medical equipment and instruments. Contamination of laryngoscope blades and handles with visible and occult blood frequently occurs during routine airway management. Several studies suggest procedures for cleaning, disinfection, sterilization, or handling of laryngoscope blades and handles are ineffective, or there may be poor compliance with the established protocols. The purpose of this study was to determine the incidence of visible and occult blood on laryngoscope blades and handles that were identified as ready for patient use. Sixty-five laryngoscope blades and handles identified as ready for patient use were observed for visible blood and tested for occult blood. A modified version of the three-stage phenolphthalein blood indicator test was employed to determine the presence of occult blood. None of the blades or handles observed had visible blood. Of the 65 blades tested for occult blood, 13 (20%) tested positive. Of the 65 handles tested for occult blood, 26 (40%) tested positive. More afternoon blades and handles tested positive for occult blood than morning blades and handles ( $P < 0.01$ ). The extent to which contaminated anesthesia equipment plays in nosocomial infection is difficult to determine. The presence of blood is an indicator of potential cross-infection, since biological fluids, such as blood and saliva, are known to transmit infectious diseases. This study confirms the more rigorous decontamination protocols must be instituted to ensure complete removal of blood prior to sterilization, since laryngoscope blades and handles have irregular surfaces with repositories for infectious material.

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**The prevalence of visible and/or occult blood on anesthesia and monitoring equipment.**

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The Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC) have attempted to stop the spread of blood-borne pathogens by issuing several recommendations and regulations. However, unless healthcare workers comply with these standards, they are not effective. In the anesthesia care environment, the anesthetist is responsible for ensuring that the equipment is clean, and disinfected, before use. We studied the prevalence of visible and occult blood on 6 types of anesthesia and monitoring equipment identified as ready to use in 28 operating suites, in 2 facilities. The equipment was inspected for visible blood and then for occult blood using a 3-stage phenolphthalein test. Of the 336 observations, 110 (32.7%) were positive for occult blood with only 6 showing visible blood. The presence of blood on this equipment may be in direct violation of the OSHA Blood-borne Pathogen Standard and the infection control guidelines of the American Association of Nurse Anesthetists. Furthermore, the presence of blood on this equipment may increase the risk for nosocomial and occupational exposure to viral and bacterial pathogens. Recommendations were made to decrease the risks from this contamination by redesigning equipment, increasing the use of disposable equipment, and ensuring compliance with effective infection control practices.

Publication Types:

- Multicenter Study