# Medical Suction and Fluid Waste Management: Patient and Workplace Safety Considerations for Health Care Organizations

A White Paper by Joint Commission International







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## **Executive Summary**

Medical suction and the management of collected fluids are essential and ubiquitous activities for care of patients across the care continuum. As medical suction and fluid management technology have rapidly evolved and become available using a wide variety of devices, minor and serious adverse events have occurred without raising a global alert about the risk to patients. Human error, transmission of infection, excessive negative pressure, and equipment failure are the most common causes of adverse events.

This burgeoning technology also produces a huge amount of fluids and solid medical waste, posing a significant risk in the form of biohazards to patients, waste handlers, and the environment. Emerging and reemerging global infectious diseases present an urgent and compelling reason for safe waste management on a global scale.

This white paper provides a high-level review of the current state of medical vacuum suction and fluid waste management systems. It also includes clear recommendations on managing fluid waste and evidence-based purchasing and managing the vacuum suction system, including a suggested checklist for reference. It is recommended that practice guidelines and strict maintenance requirements are established for safe and effective use of this important technology to improve patient and workplace safety in health care organizations around the globe.

## INTRODUCTION

The approach to managing respiratory secretion and fluid waste in patient care has evolved, thanks to the technological advancement in harnessing the power of a vacuum. Since the early 20th century, electrically powered vacuum suction devices have facilitated and improved efficiency of medical vacuum suctioning. Today, medical suction systems and related technologies are integral to patient care, and their scope of use has expanded greatly. Medical suction is used not only to clear airways and drain fluids during surgery, but also to resuscitate critically ill patients, recycle blood from the surgical field, assist in difficult deliveries of newborns, facilitate wound healing, and clear waste gasses and smoke from operating rooms. Such technologies have become much more portable, expanding their use beyond hospitals to extended care locations such as chronic care facilities, outpatient clinics, physician offices, emergency transportation vehicles, and patient homes.

## *Risks related to medical suction and fluid handling*

With any burgeoning medical technology comes the risk of unintended patient harm. As the use of vacuum suction technology has rapidly expanded, adverse events have been noted. For example, multiple serious adverse events associated with vacuum suction devices were reported between 2005 and 2009 to the National Patient Safety Agency in the United Kingdom.<sup>1</sup> In the United States (US), similar reports have been submitted sporadically to the Federal Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database for two decades without a significant safety alert. In 2012, serious adverse events occurred in the US, including a death when a high-volume/ high-flow vacuum suction device was connected to drain a pleural space, which would have required a low-volume/lowflow vacuum device.<sup>2</sup> The FDA concluded that the events were due to human error and emphasized the importance of ensuring that all users are properly trained and aware of all risks before using the device, and the devices were recalled. This is just one example of the many possible patient safety risks associated with medical suction devices. Additional risks include mucous membrane injury, bleeding, and infection.

Of significant importance is the fact that suction canisters comprise 25% of all regulated medical waste in hospitals.<sup>3</sup> According to the World Health Organization (WHO), improperly managed medical waste can put patients, staff, and community members at risk of infection, toxicity, and environmental damage or contamination.<sup>4</sup>

## Purpose of this white paper

Recognizing a threat to patient safety and health care professionals' significant lack of information about this ubiquitous patient care system, this white paper provides a high-level overview of medical suction and fluid waste management systems in health care settings, focusing on potential risks and known adverse events. This paper aims to close some gaps in knowledge and practice. It also offers recommendations to stakeholders in the health care system to ensure safe clinical practice and waste management. The goal is to enhance patient and health care safety.

## Sources of information for this white paper

The materials for this paper were collected from a variety of sources, including the following:

- A comprehensive review of Joint Commission International (JCI) standards related to this topic
- A review of literature, standards, codes, guidelines, and regulations on medical vacuum suction as well as device manufacturers' manuals
- Interviews with facility professionals, physicians, nurses, respiratory therapists, and infection preventionists at acute care hospitals in multiple regions of the world
- The Manufacturer and User Facility Device Experience

(MAUDE) of the FDA, which houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters (health care professionals, patients, and consumers)

- Internet searches for "fluid waste management," "fluid disposal," "medical waste," "vacuum suction + injury," "vacuum suction + serious injury," "vacuum suction + malfunction," "vacuum injury," and "vacuum suction + bleeding"
- Hands-on trials and testing of multiple components of the medical vacuum systems at hospitals in several countries, including the US

**Note:** *Waste anesthetic gas disposal and wound vacuum systems were not included in this review.* 

## BACKGROUND: MEDICAL SUCTION AND FLUID WASTE MANAGEMENT

Health care providers today rely on various methods and technologies to remove fluids, gasses, and other harmful materials from patients. The medical use of the vacuum was a natural evolution of knowledge regarding vacuums and their practical application as vacuum pumps in the 17th and 18th century. In 1916, Dr. C. Edmund Kells, a dentist in Louisiana, published his design of an electrically powered suction pump. He reported that "[a small electric motor] developed a vacuum of 12 inches or more."<sup>5</sup> Over the last several decades, multiple variations on the classic medical suction system have emerged, including free-standing portable models, hand-held or battery-powered suction pumps, dedicated digital pleural drainage devices, and more, many of which include multiple safety features to prevent contamination, spillage, and backflow.

## Medical suction

A *vacuum* for the suction system is generated either by a centrally located vacuum generator (or a pump) or by a free-standing device. The source of the negative pressure is connected to multiple devices to achieve the therapeutic function: a *vacuum regulator, suction tube, canister,* and *suction catheter* in a daisy chain. Once vacuum suction is generated, the only device that can control the negative pressure upstream to the patient is the vacuum regulator; therefore, it is the most critical component to optimize the power of a vacuum and ensure safety. The optimal vacuum pressure is selected by occluding the vacuum port on the regulator (or the suction tube as an alternative) to set the optimal pressure.<sup>6</sup>

## Collection and handling of fluid waste

The canister is where the suctioned waste is collected and stored until the waste is disposed of properly. Note that a wall-mounted system draining waste directly to the existing sanitary sewer does not require a canister. Canisters are either reusable or disposable, and disposable liners can also be inserted in the canisters. A solidifying agent is typically added to the canister after it is full or pre-installed inside the canister or liner before use. This is an important risk prevention step, because leaks or spillage during storage or disposal are hazardous to patients, workers, and the environment. Biofilters, which can be included in collection systems, can be either antibacterial or both antibacterial and antiviral. While antibacterial filters typically have efficiency exceeding 99.99%, contamination of equipment downstream from the patient can still occur, as aerosols are generated during various procedures. Overflow protection devices can stop suction and prevent overfilling of the canister and prevent the backflow of waste by shutting off the vacuum. The suction tube connects the canister to the suction catheter, which is the working end of the system that reaches the patient.

## International regulations related to medical vacuum suction and fluid waste management

In the 1990s, The International Standardization Organization (ISO)<sup>7</sup> and the National Fire Protection Association (NFPA)<sup>8</sup> published standards for the vacuum pressure, flow rate, and mechanical equipment for health care facilities. See Table 1 on page 6. Additionally, Joint Commission International (JCI) publishes comprehensive accreditation standards to help health care organizations around the world address their most pressing issues in patient safety and advance their goals for continuous quality improvement.<sup>9</sup> These standards can be applied across the continuum of patient care where medical technologies, hazardous materials, and waste could pose safety and infection risks to patients and health care workers. The JCI standards address many issues related to the daily activities of medical suction and fluid waste management, including the following:

- Leadership decision-making in purchasing and using medical equipment
- Staff education, training, and evaluation
- Communication of information among caregivers
- Prevention and control of infections
- Management of infectious disease outbreaks
- Medical equipment inspection, testing, and maintenance
- Safety in the workplace and patient care environment

	Table 1. Pertor	mance Require	ements for Electric ISO 10079-1	cally Powered St	iction Equipme	nt	
Equipment Vacuum Level (-)*	High-vacuum high-flow rate	Medium- vacuum**	Low-vacuum high-flow rate	Low-vacuum low-flow rate	Intended for thoracic drainage (adult) ***	Intended for pharyngeal suction	
kPa	≥ 60	20 ~ 60	≤ 20	≤ 20	≤ 10****	Evacuate 200 ml of simulated vomitus in not more than 10	
mmHg	≥ 450	150 ~ 450	≤ 150	≤ 150	≤ 75		
cmHg	≥ 45	15 ~ 45	≤ 15	≤ 15	≤ 7.5		
Free air flow rate (liters/minute)	≥ 20		≥ 20	< 20	≥ 15	seconds	

\*Target vacuum level to develop within 10 seconds

\*\*Medium vacuum level for breast pumps should not exceed 33 kPa

\*\*\*Not applicable when connected to a closed drainage system or used for broncho-pleural fistula

\*\*\*\* For most situations the vacuum level should not exceed 7 kPa

## Adverse events associated with medical suction and fluid waste

Reporting adverse events associated with suction devices is not required in many countries. In Europe, the European Commission established a medical devices guidance, known as MEDDEV (or Medical Device Vigilance System), but it does not offer a database open to public access. The European Union Network for Patient Safety and Quality of Care solicits voluntary reporting for educational purposes, but has not developed a guideline or database for such information. In the United Kingdom, the National Health Service had issued the "signals", meaning serious adverse events, arising from various "difficulties" involving vacuum suction devices.1 In the US, the FDA's reporting system, MAUDE, is a database, open to public access, for device-related death or serious injury reported by the manufacturers, importers, and user facilities. Reporting less serious injuries is voluntary for health care professionals, patients, and consumers. Workplace accidents and injuries associated with suction devices are not tracked by the Occupational Safety and Health Administration (OSHA) in the US or other organizations internationally.

There are five general causes for adverse events associated with medical suction and the management and disposal of fluid waste: 1) human error, 2) negative pressure, 3) infection related to device use, 4) infection related to fluid waste, and 5) ineffective suction or mechanical/electrical dysfunction.

#### 1. Human error

Safety does not reside in a person, device, or department, but emerges from the interactions of components of the system. Institute of Medicine (IOM). 2000. To Err Is Human: Building a Safer Health System<sup>10</sup> The underlying causes for the adverse events in the United Kingdom were lack of training and poor checking procedures coupled with equipment failure.<sup>1,11</sup> The FDA determined that the primary cause of the serious adverse events in 2012 (referenced earlier in this white paper) was human error.<sup>2</sup> Other serious adverse events reported to the MAUDE include similar human errors.

Human errors with medical suction and collection equipment can be caused by several factors:

- *Lack of user education, training, and competence.* These three core elements are the foundation for the skills and knowledge needed to properly operate all patient care equipment and deliver safe care. Insufficient communication of clear information can also be related to a lack of training or competence.
- Negligence. In its To Err is Human report, the Institute of Medicine defined negligence as a "failure to meet standards reasonably expected of the average [physician]."<sup>10</sup> Caregivers who lack knowledge of optimal pressure prior to suctioning or selecting optimal pressure for the patient are negligent by this definition. More than a quarter of adverse events for hospitalized patients are caused by negligence.<sup>12</sup>
- Unsafe design/manufacturing. Most discussions on human error associated with medical devices tend to place the blame on caregivers or end users. However, equipment manufacturers must also be sure to include all necessary safety features and sufficient instruction and information to allow for safe operation.

Joint Commission International accreditation standards for hospitals, specifically the Staff Qualifications and Education (SQE) standards, SQE.3 and SQE.8, address in detail the process of hiring, educating, and training qualified clinical staff, as well as ongoing evaluation and in-service education and training, to maintain or advance staff skills and knowledge and to ensure that they match patient needs. These standards also stress the importance of pre-employment evaluation, probationary periods for high-risk service positions, and the development and maintenance of accurate job descriptions.

Another reason that could cause human error is the multiple units of measurement used for reporting vacuum pressure internationally: kPa, inches H20, cm H20, mbar, and MPa. When one manufacturer developed a checklist after the 2012 adverse event, the first item on the list was to verify the units of measure in "mmHg" and to keep checking it through subsequent handovers.<sup>13</sup> One of JCI's International Patient Safety Goals (IPSG.2.2) frames a safe handover process between caregivers, including "critical content" that must be transferred between health care practitioners and patient care areas during transitions in care. Optimal vacuum pressure would certainly be an example of such critical information to be shared.

#### 2. Negative pressure

Anatomical and physiological complications during vacuum suctioning can be divided into three types: 1) damage to human tissue as a direct result of the pressure differential generated by the suction system—a reverse barotrauma; 2) less frequent, but no less significant, physiological side effects on pulmonary and cardiac functions during airway clearance manifested as either hypoxia or cardiac arrhythmia; and 3) infectious complications. See Table 2 below.

Airway Suction. After a publication demonstrating the complications of airway suction by Plum et al. in 1956<sup>14</sup>, multiple scientific publications started reporting adverse events associated with vacuum suctioning of the airway.<sup>15,16,17,18</sup> The adverse events were predominantly trauma to the upper airway caused by negative pressure with or without suctioning. Higher negative pressure, deep suction, continuous suction, and frequent and prolonged suction caused more severe injury.<sup>19</sup> Serious complications ranging from oxygen deprivation to death have been reported.<sup>20</sup> Most reports in MAUDE, aside from the serious adverse events that occurred in 2012 and discussed earlier, involved self-limited bleeding episodes. The safe ranges of vacuum pressure to avoid trauma are poorly defined. The effective vacuum pressure is influenced by the nature of the fluid or secretion, especially the viscosity. The optimal vacuum pressure recommended by various professional organizations varies depending on the location and the age of the patient in the case of airway suction.<sup>6,21,22</sup> See Table 3 on page 8.

Another risk associated with the vacuum is the flow rate. An optimal flow rate is essential for effective and efficient suction<sup>7</sup> but unnecessarily high flow rate could add to the untoward effect of negative pressure.

*Pleural Drainage.* Adverse events occur when the chest tube is in the wrong location or an abnormally high negative pressure is applied. Because very low negative pressures are required for thoracic suction, a more accurate

Table 2. Complications of Airway Suction							
	Airway Trauma	Cardiac Dysfunction	Physiologic Deterioration	Infection			
Confirmed or Probable	Edema Hyperemia Mucosal ulceration Ciliary epithelial loss Squamous metaplasia Fibrosis Bleeding Atelectasis Right upper lobe collapse <sup>50</sup> Emphysema Pneumothorax	Tachycardia Arrhythmia	Hypoxia Hypotension Hypertension Alveolar derecruitment Bronchoconstriction Increased intracranial pressure	Respiratory tract infections Increased microbial colonization of airway			
Possible	Electrical shock, ignition of	of gas, and explosion					

pressure-limiting device is necessary. The passive suction by gravity is being gradually replaced by low-pressure suction or suction devices equipped with digital sensors for measuring air leak and regulating pleural pressure. These new devices are reported to be safe and to reduce the duration of chest tube placement, especially for air leaks.<sup>23,24</sup>

*Surgical Field Drainage.* Vacuum suction is integral to modern surgical procedures and anesthesia. Even though serious adverse events attributed to vacuum suction during surgery are rare, extreme caution is necessary to avoid close contact with vital organs or blood vessels.<sup>11</sup> For example, an adverse event occurred when a vacuum-assisted heart positioner device set at 250mmHg was associated with the development of holes in the heart (cause undetermined)<sup>25</sup> and a heart valve became entangled with the suction tip.<sup>26</sup>

A high-volume/high-flow rate vacuum is installed or available in all modern operating rooms. Anesthesiologists usually need maximum pressure, indicating high-volume and highflow rate vacuum, for endotracheal intubation and extubation. ISO standards require suction equipment marked as "high vacuum/high flow" to develop a vacuum level of at least 60 kPa within 10 seconds and a free air flow rate into the collection container (without suction tubing fitted) of not less than 20 liters per minute.<sup>7</sup> Currently, there are no coordinated guidelines on vacuum suction in the operating theater from the Association of periOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), or other professional organizations representing surgeons. The traditional method of adjusting suction pressure in anesthesiology involved selecting a suction pressure that supports the weight of the suction tube held waist high.<sup>27</sup> The pressure selected by this arbitrary method varied between 95 and 180 mmHg.

#### 3. Infection related to device use

Many attendants failed to recognize the hazards of bacterial contamination and kept nasal and tracheal catheters in the same container. In some cases, catheters that had been dropped onto dusty surfaces were reinserted into trachea. Personal hygiene—that is, washing hands thoroughly betweensuctioning procedures—was often neglected by attendants. Plum and Dunning<sup>14</sup>

Infection is frequently mentioned as a complication of suction-induced trauma to the upper airway in multiple articles.<sup>15,16,17,18,19</sup> The hypotheses in these reports are that suctioning traumatizes the mucous membranes of the airway and then introduces potential pathogens to the damaged airway which subsequently becomes infected. There is no published report of longitudinal research unequivocally demonstrating the cause-and-effect relationship between suctioning, suction-induced mucosal injury, and infection, despite abundant literature. However, there are multiple epidemiologic investigations linking suctioning, suction apparatus and health-care-associated infections.<sup>28,29,30,31</sup>

Furthermore, the individual components of medical suction and fluid collection systems are frequently contaminated and may become the source of infection.<sup>32,33,34</sup> The overall risk of infection due to collected fluids is high if each component of

	Suction Pressure (- mmHg)	Duration (seconds)	Frequency	Continuous vs. Intermittent	Depth
Nasotracheal	Neonates: 80 ~100 Infants: 80 ~100 Children: 100 ~ 120 Adults: 100 ~ 150	Less than 15	Only as needed	Intermittent	Shallow
Endotracheal	Neonates: 88 ~ 100 Adults: less than 150	Less than 15	Only as needed	Intermittent	Shallow
Pleural Drainage	Less than 75 (7 ~ 10 kPa)				
Anesthesia Suction	No published standards				
Surgical Field Suction	No published standards				

the system is not well managed, maintained, and thoroughly disinfected or sterilized after each use. One case example illustrates that an outbreak of infection in the intensive care unit (ICU) was attributed to the reuse of suction catheters.<sup>30</sup>

Interviews with infection preventionists in multiple countries for this paper and review of the literature confirm inconsistent practices and lack of overarching guidelines for cleaning and disinfecting suction apparatus, 34,35,36 except for the catheter tip, which is universally a single-use device. Of note, the vacuum inlets were seldom disinfected, although some facilities used a backflow method with a diluted hypochlorite solution. The vacuum regulators were rarely subjected to an investigation during endemic Acinetobacter infections in the ICUs. They were never sterilized, even though the external surface of the vacuum regulator can frequently be contaminated<sup>32</sup> and the contamination may penetrate the internal structure as well.<sup>34</sup> Disposable regulators are available, and at least one major manufacturer of the regulators published detailed specifications for sterilization when backflow or contamination occurs. Few of the interviewed infection preventionists were involved in maintaining the suction system.

The suction and collection equipment, except for the suction catheter, fall under non-critical items per the Spaulding classification conceived in the early 1960s. The Spaulding classification preceded the emergence of most multidrug-resistant organisms, prions, certain viruses (for example, norovirus), and *Clostridium difficile*; thus, there is a need to "modernize" the classification and publish an overarching standard of practice for suction and collection equipment.

The JCI standard on Prevention and Control of Infections, PCI.7, provides a comprehensive guide to process improvement for meticulous cleaning, disinfection, sterilization, and storage of medical/surgical equipment and devices. PCI.7.1 focuses on the appropriate use of single-use devices to prevent device-associated infections.

#### 4. Infection related to fluid waste

The WHO estimates that 15% of all medical waste generated by health care providers is hazardous; of that 15%, 10% is infectious, and the rest is radioactive waste or cyto- or genotoxic chemicals and sharps. According to the WHO, infectious waste should always be assumed to potentially contain a variety of pathogenic microorganisms, and as many as 26 types of infections can be transmitted from infectious waste through a puncture, abrasion, a cut in the skin or mucous membranes, or by inhalation and ingestion.<sup>4</sup>

Fluid waste generated from medical suction is classified as medical waste; it can be either infectious waste or hazardous

waste or both. Safe handling is critical throughout the collection and disposal process. The best practice is to collect waste at the point where it is generated in the patient care environment. Fluid waste from vacuum suctioning has been associated with health care-associated infections, but published reports on health care workers acquiring infections—especially blood-borne infections caused by hepatitis and human immunodeficiency virus—from suctioned waste could not be found in the literature.

In Asia, overarching regulations for medical waste management are not evident.37,38 In the European Union, the EU Commission has defined the "properties of waste which render it hazardous" and provided some guidance (Preparing a Waste Management Plan—A Methodological Guidance). However, it is up to its member states and each facility to review the applicable regulations of the region and comply.<sup>39</sup> In the US, untreated fluid waste generated from health care facilities is considered "regulated medical waste" and falls under the oversight of the Environmental Protection Agency (EPA), OSHA, and local authorities. The Centers for Disease Control and Prevention's (CDC) Guidelines for Environmental Infection Control in Health-Care Facilities provides simple guidance on regulated medical waste.<sup>40</sup> The WHO published Safe Management of Wastes from Healthcare Activities (a Blue Book) in 2014.4 This guideline provides detailed information and direction to start or upgrade an action plan and legislation on medical waste management.

The JCI Prevention and Control of Infections (PCI) standard, PCI.7.2, requires the proper disposal of body fluids, blood, blood components, and materials contaminated with body fluids. The Facility Management and Safety (FMS) standard, FMS.5, provides a list of hazardous materials and waste, and delineates safe inventory and disposal processes.

Reusable fluid collection systems require the complete disposal of waste from the canister after each use. Fluid disposal should always occur in a non-patient care area. This process of disposal runs the risk of employee exposure to the droplets or aerosols, even if allowed by regional regulations. Full personal protective equipment is required, including eye protection. Adding solidifying agents and using disposable liners can reduce risks in waste disposal. Reusable canisters must also be thoroughly cleaned and disinfected after disposing of the waste. High-level disinfection or sterilization is advised when using reusable canisters for infected patients.<sup>34</sup> Reusable systems also require appropriate storage and maintenance for long-term use.

Disposable fluid collection systems often include supplemental safety features such as antibacterial/antiviral filters, smoke filters, backflow prevention, and pre-installed solidifying agents. As in the case of reusable systems with added solidifying agents, solidifying the waste reduces the possibility of exposure or contamination. Once completely solidified, the waste in the container can be disposed of as either regulated or non-regulated medical waste, per local regulations or ordinances. While disposable systems may reduce the risk of spillage and cross-contamination at the point of care, additional precautions should be taken to ensure that disposable systems are disposed of properly, according to all internal policies and local or regional regulations.

#### 5. Ineffective suction or mechanical dysfunction

Vacuum pressure is a double-edged sword. While higher-than-optimal pressure is detrimental to human tissue, low pressure does not clear secretions, blood, or debris efficiently and effectively. Multiple types of electrical desktop suction equipment tested in different regions of the world did not meet the two ISO standards, that is, the time to develop intended vacuum pressure within 10 seconds, and, for equipment for pharyngeal suction, 200 ml of simulated vomitus evacuated in no more than 10 seconds.<sup>6</sup> On rare occasions, the pressure could not be adjusted on the vacuum regulators connected to the wall inlet because the dials for attenuation did not function. Again, most of the staff using the vacuum suction were not aware that the pressure had to be adjusted by occluding the vacuum inlet on the regulator or the suction tubing.<sup>6</sup>

There are reports in MAUDE of malfunctioning suction equipment, including vacuum regulators, portable suction devices, and an incident of a poorly fitting canister lid which caused a loss of suction power during a cardiopulmonary arrest. These examples illustrate the importance of monitoring and maintaining the efficiency and effectiveness of the entire suction system regularly. Many hospitals turn on cardiac defibrillators at least daily to ensure they are functioning properly and document the results, but the same cannot be said of the suction devices. Most acute care hospitals in the US regularly conduct a scheduled inspection of their vacuum systems according to the NFPA codes. Vacuum regulators, however, are not necessarily included.

The JCI standard on Facility Management and Safety, FMS.8, requires the hospital to establish and implement "a program for inspecting, testing, and maintaining medical equipment and documenting the results." Standard FMS.9 is about the effectiveness and efficiency of the utility systems including medical gases and air flow. These standards require an overarching safety and quality control program including an ongoing preventive maintenance and timely response to any recall.

### RECOMMENDATIONS

The following recommendations are based on the observations and discussions presented in this paper. These recommendations are not intended to replace available guidelines or recommendations from the manufacturers or professional organizations. They are an attempt to close the gaps that have not yet been addressed in those guidelines and standards.

## For Caregivers

#### Airway and surgical suction

As we have learned, endotracheal suctioning is not a riskfree procedure, and caregivers should be aware of possible hazards and complications and take necessary precautions to ensure patient safety. The individuals who perform airway suction should be qualified through necessary training and

#### Sidebar 1. Potential Harm to Health Care Workers

Data on the incidence of workplace accidents or injuries related to medical suction or fluid collection devices are not readily available. Safe design to prevent electric shock, a rare event, is being incorporated into the new generation of free-standing models. Explosion and fire risks are listed in ISO standards and NFPA codes, even though no reports were found in MAUDE.

The suction system and the fluid collection system can also be a source of increased noise in the operating room, which can adversely affect patient safety. Noise affects staff's ability to concentrate, makes it difficult to detect alarms, and can increase the risk of miscommunication. It is a nuisance, health hazard, and distraction during a procedure or surgery. ISO offers several different standards between 60 decibels and 70 decibels based on the vacuum pressure and flow rate of the equipment. Some portable models have reduced the noise level to 50 decibels. The difference between 50 decibels and 70 decibels is equivalent to a quiet living room at home versus a household lawnmower in action.

The mechanical breakdown of system components, especially, for example, the imploding canisters reported in MAUDE, can pose a serious threat to both patients and caregivers. In one documented incident, a canister imploded in the operating theater during working hours, but no injury occurred. These reports did not, however, address environmental contamination.

Furthermore, some surgical procedures can generate surgical smoke, which consists of carcinogenic and neurotoxic compounds; this smoke could be an additional workplace hazard to staff.

Multiple JCI standards address workplace safety. Specifically, the Facility Management and Safety standard FMS.4 requires an organization to plan and implement a program for a safe physical facility; additionally, standard FMS.7 discusses prevention and other abatement strategies in response to fires. demonstrate skills to correctly assess the need for suctioning, perform the procedure, and adequately evaluate the patient before, during, and after the procedure.

Surgical procedures (for example, cauterization) can sometimes generate surgical smoke, which consists of carcinogenic and neurotoxic compounds. A smoke evacuator, disposable liner with pre-installed smoke protection filter, high filtration masks, and proper operating room ventilation are recommended to address this potential workplace hazard.

See the Airway Suction Checklist below for more specific recommendations to address this critical area of risk to patient safety.

#### **AIRWAY SUCTION CHECKLIST**

#### Before suctioning

- 1. Check indication for suction. Is there a need for suctioning?
- 2. Check if the vacuum (suction) regulator is functioning properly.
- Occlude vacuum, preferably at the regulator, to set the optimal pressure for the planned procedure and age of the patient<sup>6</sup> (see Tables 2 and 3 on pages 7 and 8).
- 4. Check that all necessary equipment is ready.
- 5. Check that all personal protective equipment is ready.
- 6. Assess the following needs:
  - ✓ Supplemental oxygen
  - ✓ Adjusting fraction of inspired oxygen (FiO<sub>2</sub>)
  - ✓ Adjusting positive end-expiratory pressure (PEEP)
  - ✓ Monitoring cardiac rhythm
  - ✓ Communicating with clinician(s)
  - The depth of the airway that needs to be suctioned
    The default is shallow. Calculate and measure the depth prior to suctioning.
    - Mark if necessary.
  - ✓ Duration of suction
  - Precisely determined in seconds
  - ✓ Continuous vs. intermittent
  - The default is intermittent
  - ✓ Frequency of suction
  - Only when necessary. Avoid a scheduled suction.
  - ✓ Perform hand hygiene, and don sterile gloves.

#### **During suctioning**

- ✓ Stop suctioning immediately by turning off the vacuum (suction) regulator if blood is noted in the secretion and/ or abnormal findings are noted (see below). Do not clamp suction tube or tip.
- ✓ Monitor oxygen level or saturation.
- ✓ Monitor cardiac rhythm.
- ✓ Monitor blood pressure

#### After suctioning

- 1. Monitor for bleeding from the airway.
- 2. Monitor oxygen level or saturation.
- 3. Monitor cardiac rhythm.
- 4. Monitor blood pressure.
- 5. Communicate with clinicians if any abnormal change(s) occur.
- 6. Document the procedure.
- 7. Communicate with facility, bioengineering, and risk
- management for any adverse event or malfunction of suction devices.

Often, caregivers are also involved in the direct handling and disposal of fluid waste; caregivers should refer to the section on "Environmental Services and other support staff" for detailed recommendations on this topic.

## For Infection Preventionists

#### Surveillance and outbreak investigation

A facility-specific investigation and solution should include the suction device/apparatus when there are persistent endemic infections (such as ventilator-associated pneumonia or catheter line-associated bloodstream infection) or outbreaks in ICUs or burn treatment areas. Considering the recent report on internally contaminated vacuum regulators,<sup>34</sup> these components should also be included in the investigation of an infection from an unknown source.

JCI Prevention and Control of Infections (PCI) standard PCI.5 requires health care facilities to include outbreak investigation within the comprehensive infection program, and standards PCI.6 and PCI.6.1 define the process of tracking and trending healthcare-associated infections as well as infections arising in the surrounding communities.

#### Cleaning, disinfection, and sterilization

Cleaning, disinfection and sterilization practice regarding the suction device/apparatus needs to be standardized. In the absence of global guidelines, the following practice is suggested based on emerging findings of contaminated devices and potential risk of infections discussed in this paper and literature.<sup>34,41,42,43</sup>

- Vacuum inlet. Consider a backflow with an approved disinfectant when contaminated. Consider a surveillance and regularly scheduled backflow in high-risk areas such as the ICU, operating theater, and endoscope disinfection area.
- Vacuum regulator. To prevent contamination, ensure the safety features (biofilters, overflow shut-off mechanism) are installed upstream. Clean and disinfect daily or more often in the high risk-areas such as the ICU, operating theater, and endoscope cleaning area. Sterilization of the vacuum regulator depends on the manufacturers' specification.
- Suction tubing, when used, needs to be discarded daily. Consider changing more frequently after suctioning blood or vomitus.
- Reusable canisters (including glass containers), after disposing of the waste, must be cleaned and disinfected. High-level disinfection or sterilization is advised when these canisters are used for infected patients.

- Disposable canisters or single-use liners should be disposed of per internal policy and regional regulations.
- The suction catheter is always a single-use item.
- Suction tips (for example, Yankauer suction tips) are usually used for 24 hours. Consider changing more frequently, especially after suctioning blood or vomitus.
- Portable suction devices must be cleaned and surfacedisinfected daily, but more often when contaminated.
- Consider validating cleaning and disinfection processes. Validation could include a simple checklist, observation, fluorescent markers, culture, or adenosine triphosphate (ATP) testing.

## Safety features for infection prevention

Antibacterial filters (biofilters) and hydrophobic filters or other shutoff mechanisms are essential to prevent contamination and overflow (or backflow) of suctioned fluids from canisters. Antiviral filters are also available.

## For Environmental Services and Other Support Staff

### Fluid waste

Fluid waste can be disposed of in several different ways:44,45

- 1. Packaging the fluid waste and containers into biohazard bags and disposing of them as such. In addition to the risk of spillage, the containers cannot be reused, and other costs could be added. Biohazard medical waste should be collected by a qualified and certified disposal expert and processed for decontamination (autoclaving or chemical decontamination) before it is sent to the final destination (usually a landfill).
- 2. Draining down the sanitary sewer. This is a common practice in multiple regions where reusable glass bottles are used for collecting waste. Disposal of fluids should always occur in a non-patient care area. This process runs the risk of employee exposure to the droplets or aerosols, even if allowed by regional regulations. Full personal protective equipment is required, including eye protection.
- 3. Adding a solidifying agent. This process adds extra cost but reduces the possibility of exposure or contamination. Some canisters or liners are sold with solidifying agents pre-installed. Once completely solidified, the waste in the container can be disposed of as either regulated or nonregulated medical waste per the local regulation or ordinance.

Disposable liners can decrease the chance of exposure to contaminated waste associated with the manual disposal of waste and cleaning/disinfection of the reusable container. The liner and the lid are removed in a single step at the point of care, minimizing the risk of spillage and cross contamination. The waste may be downgraded to regular waste if antimicrobial agents are mixed with a solidifying agent. This practice needs to be evaluated in the light of the international movements to reduce the environmental and agricultural use of antimicrobial agents to prevent the emergence of multidrug-resistant organisms.

4. Direct disposal to the existing sewer system. Suctioned materials can be drained directly to a sanitary sewer, bypassing the canister if allowed by the regional regulations or laws and if the draining system is already in place. New drainage pipes or an intermediary container can be retrofitted.

## Sidebar 2. Waste Management During Infectious Disease Outbreaks

**Ebola virus.** The WHO states that sanitary sewers may be used for the safe disposal of waste, such as feces, urine, or vomit, from patients with Ebola. Most of the suctioned fluid waste can be included.<sup>46</sup> Ebola virus as a Category A infectious substance is also regulated by the US Department of Transportation (DOT) and must be packaged and transported in accordance with the US DOT Hazardous Materials Regulations (HMR, 49 CFR, Parts 171-180). The handling of the suction devices was merged with the management of other contaminated equipment. OSHA and CDC published guidelines<sup>47</sup> to protect environmental workers at risk of acquiring infection from infectious waste, including waste containers with visible contamination from blood, bodily fluids, or other potentially infectious or unknown material.

*Middle East Respiratory Syndrome – Coronavirus (MERS-CoV).* Unlike Ebola, there are no detailed guidelines for MERS-CoV. The CDC recommends medical waste management should be performed in accordance with "routine procedures." During the recent epidemic in South Korea, hospitals autoclaved the suction canisters and did not reuse them. No infection among the health care workers was attributed to the waste collection process.

JCI introduced a new standard, Prevention and Control of Infections (PCI) standard PCI.8.2, in 2017, which requires hospitals to develop, implement, and test an emergency preparedness plan to respond to global communicable diseases in the light of recent pandemic infections (SARS and influenza) and highly fatal regional infections (Ebola and MERS-CoV). Coupled with other standards (PCI.7.2 for safe disposal of body fluids, blood, and blood components; FMS.5 for safe management of hazardous materials; and others), these standards help health care facilities to design an umbrella policy or protocol for fluid waste management during an epidemic or pandemic.

### Personal competency and knowledge

Education and training on safe handling of infectious and hazardous waste are critical to prevent cross contamination and healthcare-associated infection. This education and training should cover the following topics:

- Personal protective equipment including eye protection
- Prevention of cross contamination
- Hand hygiene
- Safe collection and handling of body fluids
- Safe practice for fluid disposal and storage
- Knowledge of central versus portable suction system
- Knowledge of reusable canisters, liners, solidifying agents, and other suction items
- Workflow between soiled and clean areas
- Proper disposal of contaminated equipment
- Properly managing a spill

## For Facility and Engineering Staff

If the facility is equipped with a central vacuum pump, a free-standing or portable suction device needs to be available for all patient care areas in case of pump malfunction. The backup portable device assigned to the emergency department or operating theater or attached to an emergency cart needs to be monitored for appropriate function and the results documented.<sup>48</sup>

The entire suction system needs to be regularly monitored, and any malfunctions should be addressed immediately.<sup>49</sup> To avoid confusion, it is recommended to post a conversion chart for different vacuum scales in key areas and on the vacuum regulators if the facility uses more than one vacuum scale. The NFPA codes on medical gas and vacuum<sup>8</sup> provide standards for installing and maintaining the system.

## For Purchasing

#### Evidence-based purchasing

Evidence-based purchasing plays a key role in managing patient safety risks related to the use of medical equipment across a health care organization. JCI standards on Governance, Leadership, and Direction (GLD), GLD.7.1 and GLD.7.2, underscore the importance of safety and quality as factors in the decision-making process when purchasing critical patient care equipment. These standards require hospital leadership to make "decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions," including medical equipment choices. The hospital leadership is to seek and use "data and information on the safety of the supply chain to protect patients and staff from unstable, contaminated, defective, and counterfeit supplies." Hospital leaders are urged to understand and identify "the significant risk points in supply chains," especially for critical patient care equipment.

A central vacuum pump system may be suitable for a new facility project or major renovation in terms of the scale and cost involved. NFPA codes on hospital medical gas and vacuum systems and ISO standards provide the current standards and codes.<sup>7,8</sup> Safety, efficacy, efficiency, and environmental hazards must be the primary considerations when purchasing portable suction equipment and waste disposal mechanisms. Key components to be considered include the following:

- Conformance of the equipment with the international standards for efficacy needs to be assessed, considering the potentially serious adverse events arising from suboptimal function.
- Knowledge on the differences between reusable and non-reusable fluid collection systems should be shared among the stakeholders, including the topics discussed in the previous section.
- Infection prevention features. Form follows function, and some models are designed to make it easier to clean and disinfect by positioning controls flush with the external surface of the equipment. Pre-installed antimicrobial filter (biofilter) and a shut-off valve to prevent overflow (or backflow) are essential safety features (see above).
- Noise level management to minimize distraction and potential miscommunication during procedures.
- Safety from electric shock. Certain models have a safety feature against static electric shock as well.
- Weight. Health care worker injury from handling a heavy equipment is one of the most frequent work-related disabilities.
- Cost. The decision on purchasing reusable versus single-use or disposable systems must carefully analyze risks and benefits. The tangible array of cost factors includes the effect on staff workflow associated with collecting, transporting, cleaning/disinfecting reusable canisters or bottles; cost of container/liner; and expenses for disinfecting/sterilizing reusable apparatus. The non-tangible elements, which could require more detailed analysis, include the savings from the reduction in worker exposure to and infection from cross contamination.
- Fluid waste management is a major factor in purchasing

decisions, especially for facilities performing a high volume of surgery or similar procedures.<sup>45</sup> The decision process may include a failure mode and effects analysis (FMEA) for risk, optimization for the facility, and thorough review of local law and regulations on waste disposal.

### CONCLUSION

Medical suction and fluid collection activities are ubiquitous in health care organizations. As the technology advances and the complexity of procedures increases, the potential risks to patients, workers, and the environment are many, ranging from environmental contamination to infections to injuries to and other impacts on patients and workers.

While there remains a compelling need to collect and analyze more comprehensive international data on adverse events related to these activities and to develop global guidelines for safety, this paper provides some practical, evidence-based recommendations and checklists for staff in health care organizations around the world—leadership, clinicians, infection preventionists, purchasing staff, facilities managers and engineers, and environmental services staff—to better manage risks proactively when using medical suction equipment and collecting and disposing of medical waste.

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