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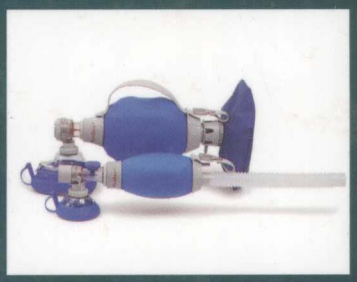

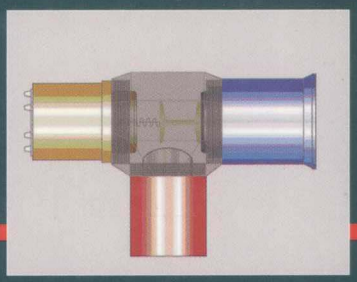

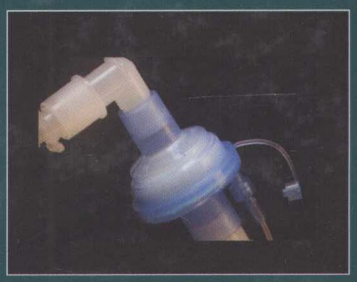

The MGH Textbook of ANESTHETIC EQUIPMENT

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The MGH Textbook of Anesthetic Equipment

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Preface

Medical technology has changed at a rapid pace over the past 30 years and continues to evolve quickly as new devices and techniques change and facilitate the way we practice anesthesiology. For example, a mere 15 years ago, ultrasound was a luxury in anesthesia. Today portable ultrasound has become a de facto standard of care for central venous catheter placement and for regional anesthesia. There are numerous examples of the profusion of such 'ancillary' anesthesia equipment, with completely new classes of equipment appearing almost overnight. On the other hand, some aspects of technology – such as the anesthesia machine – seem to be fairly constant. However, a closer examination reveals that this is not really correct as modern equipment only appears to function like its predecessors. Learning to operate, diagnose and troubleshoot all of this equipment competes aggressively with the patient- and disease-oriented components of anesthesiology practice.

Our goal in writing this book was to help clinicians better understand the underlying principles behind the equipment they use on a daily basis. In this firstst edition, we cover all of the equipment used in the operating room from the anesthesia machine to airway devices, physiologic monitors, and equipment used for point-of-care testing. We also included chapters on anesthesia information management systems, alarms, challenges encountered working outside of the operating room, and equipment for use in unusual environments such as a field hospital.

We begin this book with a chapter on simulation in anesthesia. This was deliberate – complexity in anesthesia practice has increased to the point where simulation must play a larger role in the education of future anesthesiologists, including education about the use of equipment and management of equipment in failure mode. It is increasingly problematic to learn how to use equipment 'on the fly' with actual patients.

Recognizing that technology evolves rapidly, we sought to illustrate fundamental principles succinctly, rather than provide a completely comprehensive review of each available device within every category. This book represents the collective wisdom of almost one hundred experts in the fields of anesthesiology, biomedical engineering, and technology. We are grateful to all of our contributors whose efforts, insight, and expertise made this book the most accessible and up-to-date work of its kind.

We would like to thank a number of individuals without whom this book would not have come to fruition. They include Dr Elisabeth H. Sandberg, Dr Katharine M. Nicodemus, Dr David C. Ehrenfeld, and Dr Zina Matlyuk-Urman. Additionally, we would like to thank our families and colleagues for their tireless support, and the generations of trainees, from whom we have learned as much as we have taught, for their inspiration. Special thanks to the Elsevier editorial team, especially Natasha Andjelkovic and Bradley McIlwain.

We hope you find this book useful and wish you well in your journey through the world of clinical anesthetic equipment.

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Chapter 1

Anesthesia Equipment and Patient Safety

Arna Banerjee, L. Jane Easdown, and Matthew B. Weinger

CHAPTER OUTLINE

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The Nature of Errors 3
Use Error Versus Device Failure 5
Current Methods for Training New Users of Anesthesia Equipment 5
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Anesthesia Safety: Is It a Model or a Myth?

Anesthesia has been touted as being one of the safest specialties in medicine. In 1999, the Institute of Medicine (IOM) published a report on medical errors in U.S. hospitals, which noted that anesthesiology had made substantial improvements in patient safety.[1] One impetus for reducing medical errors in the 1970s and the 1980s was the soaring cost of medical malpractice. Anesthesiologists responded by establishing national practice standards for patient monitoring, deliberately analyzing adverse events, improving the safety of anesthesia machines, fostering the widespread adoption of new technologies (e.g., pulse oximetry), improving provider training in crisis event management, and creating an independent foundation whose sole purpose was to advance anesthesia patient safety (the Anesthesia Patient Safety Foundation or APSF). Deaths in anesthesia have decreased from 2 deaths per 10,000 anesthetic procedures in the 1980s to about 1 death per 200,000 to 300,000 in 2000.[2] These numbers have been validated by surveys conducted in the Netherlands, France, and Australia.[3-5] A 2003 report from the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) found 1369 complications from anesthesia in 1,933,085 patients at risk of 0.71 per 1,000 discharges.[6] This rate compares favorably to other rates of hospital complications as shown in Table 1–1.[6] Not all anesthesiologists believe that anesthesiology is as safe as these data suggest—even in young, healthy patients. For instance, in 2002, Lagasse published an extensive review of the literature in which he concluded that anesthesiology mortality was still in the range of 1 in 10,000.[7] Similar contention has been made by other authors.[8] It can be very difficult to separate errors or mishaps in anesthesia from surgical mishaps or patient disease. In studies reviewed by Lagasse, the definitions for death in which anesthesia was "associated," "related," "contributory," or "preventable" varied widely as did the time windows for defining the perioperative period (24 hours to 30 days). Many of these studies had small numbers and involved single healthcare sites. An alternative way of understanding patient safety in anesthesia is to study "opportunities for error." This more probabilistic approach focuses on events and their likelihood of causing patient harm. A key advantage of an event, rather than injury focus, is that data can be collected prospectively and the analysis is less likely to be affected by hindsight or outcome bias. For example, Weinger and colleagues introduced the concept of "nonroutine events" (or NRE) and showed that NRE, which represent any deviation in optimal care, occurred in 25% to 35% of all anesthetics in three different academic medical centers.[8] Moreover, an NRE data collection system captured seven times more patient injuries than a traditional anesthesia quality assurance reporting system.[9] They concluded that anesthesiology is complex and errors still occur, resulting in poor patient outcomes.

Role of Equipment in Anesthesia Safety

In 1978 Cooper et al applied the critical incident technique first described by Flanagan to understand anesthesia incidents. A critical incident was defined as: a human error or equipment failure that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of stay to death.[10] In this study, 139 anesthesiologists were interviewed and 1089 preventable incidents were reported. Seventy incidents were deemed a critical event with a substantial negative outcome. They reported that 30% of critical incidents reported by clinicians were related to equipment problems. Nineteen percent were reported instantly, while 11% were reported retrospectively. Twenty-eight percent of these demonstrated inadequate knowledge or familiarity with specific equipment or use of a relatively new technique or device.

Table 1–1 Patient Safety Indicators: Comparison Between Medical and Surgical Subspecialties[6]

Patient Safety Indicators	No. of Events	Risk Pool	Rate per 1000 Discharges at Risk	Match Rate %
Accidental puncture or laceration	11,810	5628 112	3.32	75
Birth trauma, injury to neonate	4740	720 021	6.53	96
Complications of anesthesia	1369	1933 085	0.71	74
Decubitus ulcer	41,440	1932 676	21.51	56
Foreign body left during procedure	536	6572 845	0.09	69
Iatrogenic pneumothorax	3919	5861 689	0.67	66
Obstetric trauma, cesarean birth	1138	191 227	6.97	99
Obstetric trauma, vaginal birth with instrumentation	12,518	51,225	224.21	95
Obstetric trauma, vaginal birth without instrumentation	51,223	591 752	86.61	99
Postoperative hemorrhage or hematoma	3494	1695 495	2.06	69
Postoperative hip fracture	1068	1397 898	0.77	51
Postoperative physiological and metabolic derangement	799	801 702	1	44
Postoperative pulmonary embolism or deep vein thrombosis	15,704	1689 662	9.34	61
Postoperative respiratory failure	2275	633 855	3.58	37
Postoperative sepsis	2592	229 853	11.25	33
Postoperative wound dehiscence	843	411 099	2.05	55
Selected infection resulting from medical care	11,449	5752 102	1.99	63
Transfusion reaction	30	6572 845	0.004	80

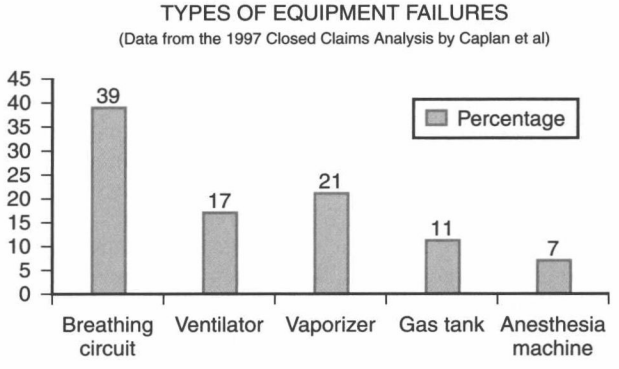

Figure 1–1 Adverse anesthetic outcomes from equipment failures.[11]

The American Society of Anesthesiologists (ASA) Closed Claims Project (CCP) was initiated in 1985 to collect information about anesthesia-related adverse outcomes. A total of 8496 closed insurance claims have been collected and analyzed. An analysis in 1997 found that only 2% of the claims were related to equipment issues (Figure 1–1). Death or brain damage occurred in 76% of these cases. Misuse of equipment was judged to have occurred in 75% of the cases and true equipment failure in 24%. Overall, 78% of claims were deemed preventable by appropriate use of monitoring.[11] Subsequent studies have called into question the validity of this finding since the reviewers were not blinded to case outcome.

Subsequent studies in anesthesia showing similar results are summarized in (Table 1–2).

Similar studies have been conducted in other countries. The Australian Incident Monitoring Study issued results on 2000 critical incidents in 1993. One hundred and seventy-seven (9%) were due to equipment problems and of these 107 (60%) were due to failures of the anesthesia gas delivery system.[13] The National Reporting and Learning System database from the United Kingdom reported similar results. Of 12,606 incidents reported to the National Patient Safety Agency, 13% were related to equipment failures. Of those incidents, 81% caused little or no harm, 18% produced moderate harm, and only 1.2% resulted in severe harm or death.[14]

As of May 2009, the ASA Closed Claims Database had 71 claims of a total 2945 claims from 1995 to 2003 due to problems with anesthesiology equipment. Eighteen of these claims were for gas delivery equipment. These included one anesthesia machine problem (unspecified), five vaporizer problems, three ventilator problems, and four breathing circuit problems. There were another five claims involving supplemental oxygen equipment or other devices attached to the patient's endotracheal tube. There were an additional two claims involving malfunctioning Ambu bags. Most equipment problem claims resulted in temporary or nondisabling injuries (66%). There were 8 (11%) permanent and disabling injuries and 16 (23%) deaths. Payment was made in 52 (73%) of these claims, with a median payment (in 2007 inflation adjusted dollars) of $137,525 (range $2720 to $2,825,750).[15] Over time, gas delivery problems appear to be decreasing as a proportion of total claims. These types of incidents represented 3% of all claims in the 1970s, 2% in the 1980s, and 1% in the period 1990 to 2003.[16]

In Canada, medical device problems reported to the Health Protection Branch were studied to determine the problems associated with anesthesia devices.[17] While only 2.3% of new

Table 1–2 **Studies Examining the Incidence of Human Error in Anesthesia Mishaps**[12]

Authors	Year	Type of Study Design	No. of Cases	% Equipment-Related
Cooper JB et al	1978	Retrospective critical incident reporting	359	14% as a result of failure
Craig and Wilson	1981	Retrospective critical incident reporting	81	12% related to failure
Cooper JB et al	1984	Retrospective critical incident reporting	1089	11% as a result of failure
		Also instant reporting	239	19%
Keenan and Boyan	1985	All anesthesia-related cardiac arrests	27	
Utting JE	1987	Deaths or cerebral injury cases reported to medical defense unit of UK	1501	28% of technique errors
Kumar V et al	1988	Voluntary QA reporting	129	19% related to failure
Cheney FW et al	1989	ASA closed claims study analysis	869 lawsuits	?
Chopra V et al	1992	Voluntary QA reporting	549	21% related to failure
Caplan RA et al	1997	ASA closed claims study of gas delivery equipment claims	72	24%
Weinger et al	2007	Prospective videotaped anesthetics	407	45% as judged by at least two expert reviewers of the actual videotape; usability or failure was considered to be a contributory factor in a nonroutine anesthesia event

devices were classified as anesthesia devices, these devices produced 8.6% of problem reports and 37.5% of alerts. The percentages of recalls and problem reports were also higher in the anesthesia (10.2%) than in other (4.9%) devices.

Why Is It Important to Know Your Equipment If the Mortality Has Decreased Tenfold in the Last Decade?

Although the most recent gas delivery system closed claim was for an event in 2003, equipment failures have been reported in the literature after that and even in 2008. New equipment continues to be introduced and errors reported. If the goal of the APSF, "no patient will be harmed during anesthesia," is to be realized, then any error occurring due to equipment misuse or malfunction is unacceptable. Safety can plateau or even diminish without constant effort at improvement. Included in Table 1–3 are recent examples in the literature of equipment problems.

The Nature of Errors

Although anesthesia is deemed safe, there are still reports of poor patient outcomes due to equipment failure or misuse. Detailed literature exists on the types of errors and mistakes that occur during the perioperative period and the complex human and organizational factors which lead to it.[10, 22-23] The practice of anesthesiology incorporates many sophisticated types of medical equipment both to deliver therapy and to monitor the effects of anesthesia and surgery on patient physiology. Safe anesthesia requires a comprehensive understanding of equipment both for routine cases and during clinical crisis. The following chapters provide key knowledge about commonly used anesthesia equipment; the goal is to prevent misuse, reduce use errors, facilitate failure detection and recovery, and enable clinicians to help manufacturers to design even better equipment in the future.

The complexity of anesthesia has been compared with that of managing nuclear power plants, military campaigns, or airline flight operations. In fact, the induction and emergence phases of general anesthesia can be compared with the "take off and landing" of an aircraft.

Errors involving disasters in power plants (Chernobyl) or factories (Bhopal) have been examined in great detail.[24] Although a single event or person may have been initially implicated in each of these disasters, careful analysis has consistently revealed an array of complex organizational problems and system factors interacted over time to produce the accident. Anesthesiology critical events show similar patterns. However, healthcare errors typically involve only one patient and if the outcome is poor, rarely garner public attention.

Most investigations of patient safety in anesthesia have attributed human error as being responsible for 70% to 80% of critical events. However, this is not a useful statistic. Even most outright equipment failures are inevitably due to human errors—failures of design, installation, maintenance, etc. Moreover, as described above, the clinician who ultimately pushes the wrong button is but one factor in a complex chain of events that can lead to an adverse event. Reason suggested that: "Individual unsafe acts are hard to predict but organizational and contextual factors that give rise to them are both diagnosable and manageable.[22]"

Errors by individuals do occur and can be characterized further according to Reason. There are slips and lapses that result from inattention during routine management. Mistakes, rule-based or knowledge-based, imply deviation from a plan. An example of a rule-based mistake would be the failure of an anesthesiologist to provide a proper rapid sequence induction to secure a patient's airway leading to aspiration of stomach contents. Rule-based mistakes may result in misapplication of a rule or not understanding the full rationale for its use. Knowledge-based mistakes occur when an event or experience is outside the experience of the provider. This causes the diagnosis and management to be complicated by poor mental

Table 1–3 **Recent Examples in the Literature of Equipment Failure**

Title	Synopsis	Date	Reference Citation
A surprising twist: an unusual failure of a keyed filling device specific for a volatile inhaled anesthetic Michael F. Keresztury, MD	Two cases were described where keyed filling devices for sevoflurane were inadvertently screwed onto isoflurane bottles. The mishaps were possible because the collars on sevoflurane and isoflurane bottles are mirror images of each other. The particular keyed filling device was designed with a flexible outer sleeve and could be screwed onto the wrong bottle while slightly gouging its soft plastic collar. The keyed filling adapters for sevoflurane and isoflurane could each be manipulated to fit the other's bottle. A manufacturer (Southmedic, Inc., Barrie, Canada) has modified their keyed filling adapters to prevent this unusual circumstance from recurring.	2006	18
An insidious failure of an oxygen analyzer Bryan Harris, MD and Matthew B. Weinger, MD, MS	The authors reported a case of oxygen analyzer malfunction that was diagnosed by the failure of the patient to adequately breathe oxygen as a measure of end-tidal oxygen concentration. Those involved with the care of the patient did not notice a warning icon, compliant with international standards, at the time.	2006	19
Aestiva ventilation mode selector switch failures Dietrich Gravenstein, MD; Harshdeep Wilkhu, MD; Edwin B. Liem, MD; Stuart Tilman, MD; Samsun Lampotang, PhD	Three cases of previously unreported failures of the Bag-Ventilator Switch in Aestiva/5 anesthesia machines (GE Healthcare/Datex-Ohmeda, Madison, Wis.) were described by the authors. Each failure mode produced a large breathing-circuit leak. Examination of the switches revealed a cracked toggle actuator, residue build-up, and cracked selector switch housing as causes for the failures. When a leak with no visible cause develops, consider advancing the mode selector switch fully to its mechanical limit or consider that the toggle actuator or its anchoring mechanism may have failed.	2007	20
APSF newsletter: dear sirs, misplaced valve poses potential hazard (Vanderbilt University Med Ctr)	A problem is in the AGSS (active gas scavenging system) option which produces, when the evacuation hose becomes occluded, sustained airway pressures (PEEP) of up to 40 cm. This condition was exacerbated by high fresh gas flows during mechanical ventilation. The AGSS is designed to have an opening in the bottom of a plastic receiver, providing relief of both positive and negative excess pressures. In what appears to be an assembly error, a negative pressure relief valve (similar to a circle system one-way valve) was installed in this opening (see photos below 1 and 2). This provided relief of excess negative pressure (too much evacuation suction), but no positive pressure relief. This valve is used appropriately in the passive system, but the passive system also has a positive pressure relief in the upper portion of the receiver unit.  Bottom view of the active scavenging reservoir without valve (correct configuration).  Bottom view of the active scavenging reservoir with valve in place (incorrect configuration).		21

modeling and false hypotheses. In this situation the practitioner is prone to have fixation or "cognitive lockup" going down the wrong diagnostic pathway or fixating on one cause to the denial to all other clues. Violations imply a deviation from a standard and must be managed in a social context. An example would be the complete disregard for doing a complete machine check in the morning before starting a case.

Conditions that predispose front-line personnel to make operational errors are called latent failure modes and lead to latent errors. Most hazardous systems are well designed to prevent single point failures; it is the occurrence of multiple unlikely events that culminate in a critical event. Prevention of latent errors (failures of design that lead to the occurrence of errors) is where we need to focus through better communication and teamwork, better design and maintenance of equipment, and planning for coordination of patient care.

Table 1–4 Common Equipment Errors

Breathing circuit disconnections
Breathing circuit leaks or defective valves
Breathing circuit misconnection
Breathing circuit control error (e.g., failure to adjust APL valve)
Inadvertent gas low control errors
Gas supply problems
Vaporizer control errors (under-dose/over-dose)
Intravenous drug dose errors (including infusion and syringe pumps)
Intravenous drug/fluid delivery system problems
Ventilator missetting or malfunction
Misuse of monitors
Laryngoscope malfunction
Scavenging system problems
Other (e.g., soda lime exhaustion, sensor failure, blood warmer malfunction, etc.)

Use Error Versus Device Failure

A use error is an "act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user.[25]" Use errors can be subject to budgetary constraints, regulatory demands, and limits of technology. It may become necessary to compromise complexity for simplicity for use in complex environments. Monitoring devices may have an array of alarms to increase vigilance but unfortunately, many alarms are confusing and distracting. Equipment designers often do not interface with users and proper feedback mechanisms often do not exist. A report by the International Electrotechnical Committee (IEC), a body that regulates and standardizes electrical and electronic devices, made the following comment:

"Medical practice is increasingly using medical devices for observation and treatment of patients. Use errors caused by inadequate medical device usability have become an increasing cause for concern. Many of the medical devices developed without applying a usability engineering process are nonintuitive, and difficult to learn and to use. As healthcare evolves, less skilled users, including patients themselves, are now using medical devices, and medical devices are becoming more complicated.[25]"

What Sorts of Problems Can Occur Directly as a Result of Equipment Failure?

Equipment malfunction may be due to poor equipment design, poor user interface, or poorly designed displays or alarms. Sometimes equipment used in the operating room is used in an other environment—ICU or home care—and is inappropriate for the educational level or pace of use. Included is a table of the most common equipment errors (Table 1–4).

Current Methods for Training New Users of Anesthesia Equipment

The Food and Drug Administration (FDA) regulates the manufacture, distribution, importation, and use of medical devices in the United States. The FDA regulates the "labeling" of all medical devices. Labeling includes specific indications for use, all on-device markings, and all instructions for use (including user manuals and quick reference guides). While modern medical devices intended for patients' use often include well-designed training materials, this is much less common for devices intended for clinicians. In fact, with the recent exception of very high risk devices (e.g., carotid stenting), the FDA does not mandate clinician training before device use.

Conventionally, new anesthesia equipment is introduced through an "in-service" session. An in-service is an educational session during which the company demonstrates the equipment to intended users. These efforts are usually voluntary, superficial, and inadequate because they do not allow the individuals to practice with the device nor do they include an assessment of user understanding or competency. Moreover, in-services typically occur only once with installation and are not repeated for personnel who are away from work or who join the facility thereafter. Device manufacturers have manuals for use but 48% of anesthesiologists do not read the manual and 60% do not follow a manufacturer's checklist before using new equipment.[26]

Unfortunately, there are no laws or regulations regarding responsibility for assuring equipment use competency. There is one federal statue, the Safe Medical Devices Act of 1990, but this is directed toward the manufacturer and not the hospital or practitioner. Responsibility is diffusely disbursed among clinicians, facilities, and industry. The APSF has recently advocated mandatory training and certification before introduction of new critical care equipment into patient care.

Is Conventional Training Enough?

Dalley et al showed that after a standard introduction to complex and unfamiliar anesthesia equipment, clinicians were unable to self-assess their competence to use that equipment. They concluded that providers were likely to make multiple errors, which interacting with latent design faults may produce critical incidents.[27] Similar findings were seen by Larson et al.[28] Their study was performed during a nationally attended anesthesia meeting held at a large academic medical center. Anesthesia providers were observed performing anesthesia machine checkouts on an anesthesia machine with five preset faults. Regardless of experience, most anesthesia providers were unable to uncover a majority of the machine faults (Table 1–5).

In another recent study, eight simulated scenarios were developed, which included equipment failures or misuse.[29] Second to fourth year residents completed the scenarios. A four item scoring checklist for each scenario was employed to evaluate completed items. Performance increased with experience but no perfect scores were obtained as shown in Table 1–6.

Management of some types of machine problems may require annual review to assure continued competency. A simulation-based training environment may be helpful to develop and maintain these skills.

How Should We Introduce New Equipment into the Operating Room and Train Anesthesia Personnel?

An APSF Board of Director's Workshop was convened in 2007 to discuss the attitudes, evidence, comparisons, and recommendations for training on the use of complicated new equipment.[26] Seventy-two participants from medicine, nursing, technical, administrative, regulatory, insurance, governmental, aviation, and safety industries participated (Table 1–7).

Table 1–5 Detection of Equipment Failure by Anesthesia Providers

Years of Experience	Number of Faults Detected
0-2 yr	3.7 faults
2-7 yr	3.6 faults
7 yr	2.3 faults

Larson E, Nuttall G, Ogren B, et al. A prospective study on anesthesia machine fault identification. Anesthesia Analgesia 2007;104(1):154.[28]

Table 1–6 Detection of Equipment Failure by Anesthesia Residents - by Year of Training

Residents (n = 43)	Score	Range (Maximum Possible Score of 32)
CA – 1 (n = 13)	21.8 ± 3.9	14–26
CA – 2 (n = 14)	23.86 ± 2.0	21–26
CA – 3 (n = 16)	24.7 ± 3.1	19–30

Waldrop W, Murray D, Kras J. Simulation training for anesthesia equipment failure. Anesthesiology 2007;107:A1110.[29]

Table 1–7 Goals, Findings, and Recommendations of the APSF Workshop

Goals and Findings of the APSF Workshop
▸ THE PROBLEMS AND SHORTCOMINGS OF CONVENTIONAL TRAINING
Conventional "in-service" programs are thought to be superficial and inadequate. They usually do not require advanced preparation, are not mandated, do not allow individual practice, and do not test for learning or application skills. They are frequently abandoned for lack of time. These programs typically occur only once when new equipment is installed and do not account for personnel who are away from work or new personnel.[30]
▸ LIMITATIONS AND IMPEDIMENTS OF MANDATORY TRAINING
There are no published trials of mandated vs nonmandated training. Most believe that it would greatly benefit the specialty, but there is a need to establish baseline practices and to convince the staff that this is necessary and valuable. The most difficult obstacle is to figure out how to mandate the program to so many different categories of clinician
▸ DESCRIBE NEW APPROACHES TO TRAINING THAT MIGHT BE MORE SUCCESSFUL
Focus on new technology. Development of an in-house training program would be beneficial (train users and then have them train others, thus demonstrating understanding, and create superusers as resource personnel). Simulation and hands-on training show greater promise.
▸ CONSIDER ANALOGOUS END POINTS AND SUCCESSES FROM AVIATION MODEL
Aviation safety is regulated by the airline industry. As pilots die of their own deficiencies, they too support the efforts of regulating training. Mandatory retraining is derived from actual complications encountered in the previous year. If possible e-learning is also used in the aviation industry.
▸ EXPLORE THE REGULATORY AND THE MEDICOLEGAL AND REGULATORY PRESSURES DRIVING SUCH EFFORTS
Most believe that the Joint Commission would be the most appropriate regulatory body to oversee training for advanced medical devices. This training should be further tied in to the credentialing process and not be optional.
▸ PROMOTE DISCUSSION AND TARGET EFFORTS AT IMPLEMENTATION
Most believe that we should require mandatory training on all new equipment, but keep it focused on the critical aspects. To change culture and increase competency, a sense of accountability and responsibility needs to be instilled in the practitioners. We need to partner with other bodies, such as NPSF, Joint Commission, NQF, IHI, CMS, and insurance companies, to implement this training.
APSF Recommendations
Although existing literature does not describe frequent adverse anesthesia events owing to the anesthesia professional's lack of understanding of equipment, the APSF believes that the logic is compelling to require confirmation of competency before using unfamiliar and/or complex anesthesia equipment that can directly affect patient safety. In this regard, the APSF believes that each facility should develop a required, formal process to ensure that anesthesia professionals have received appropriate training and/or demonstrated competence in the use of such medical devices.
Manufacturers should refine and initially offer this training. This required process for administering training and/or demonstrating competence should be efficient, timely, and pertinent in addressing new critical features and relevant failure modes. The most effective manner to successfully accomplish this training and testing is not known and requires deliberate investigation.

SIMULATION AS A METHOD TO TRAIN FOR EQUIPMENT COMPETENCY

Simulation is used in most industries that handle hazardous materials, involve risk of injury, and face uncommon critical situations or in which operational errors have high costs. Thus simulation training and testing is ubiquitous in nuclear power, process control, aviation, military, and maritime industries. *Simulation* can be defined as a situation or environment created to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain an understanding of systems and human factors. The first medical simulation mannequin, Sim One, was developed in 1960 by Dr. Stephen Abrahamson at the University of Southern California. It was not until the 1980s that computer-controlled mannequins were created for anesthesiology training at two separate university centers: at the University of Florida at Gainesville by Drs. Nik Gravenstein and Mike Good and at Stanford University by Dr. David Gaba. These early innovators spawned a robust industry that now has international implications across most medical, nursing, and ancillary care disciplines. The advantages of simulation for medical training are obvious. It is possible to train in a totally safe environment where mistakes are not costly to real patients, to observe and evaluate performance, to create a reliable curriculum and to train teams in emergency management, communication skills, and especially the use of new equipment (Figure 1–2). The simulation lab can become an operating room (OR), intensive care unit (ICU), bed on a floor, or an emergency department (ED) bay (Figure 1–3). With the appropriate props, all clinical scenarios can be simulated. Although there are not yet rigorous studies showing that simulation training leads to better patient outcomes, anecdotal evidence and face validity have moved the field forward. Students enjoy experiential learning and there is good evidence that simulation learning is more profound than passive learning (e.g., lectures) (Figure 1–4). The biggest impediment to simulation is that it is very costly to build, outfit, staff, and maintain simulation facilities. Beyond training, simulation can be used to evaluate skills and behaviors, credential personnel, and evaluate equipment. Simulation is now a part of the Israeli national board examination for all anesthesiologists.[30]

Figure 1–2 Team debriefing a simulation event.

The ABA has introduced simulation as a method to demonstrate maintenance of certification (MOCA) and the ASA has begun to endorse simulation centers for delivery of high quality simulation training (Figure 1–4).[31] It seems inevitable that full-scale simulation will be an integral part of all anesthesiologists' training, certification, and MOCA in the near future.

USE OF SIMULATION FOR DEVICE DESIGN AND USABILITY TESTING

Simulation for device design and usability testing is a more recent development. A few prospective trials have demonstrated the value of simulation in medical device design and evaluation. Such usability studies are carried out to ensure safe use of anesthesiology equipment in the simulated clinical environment.[32] Kushniruk et al have made use of simulation to test out the effectiveness of new healthcare information systems and medication ordering systems.[33] In another study, a new infusion pump was tested in simulation by 13 nurses during three scenarios. As a result of observations made during the simulation, changes were made to the hardware and software program, making it safer for patient use.[34] The FDA has asked that companies seeking premarket clearance for clinical use of their products add to their application proof that the device can be used safely by typical users working under the normal range of conditions. Most manufacturers do usability studies in their own centers and then in clinical trials. Not all

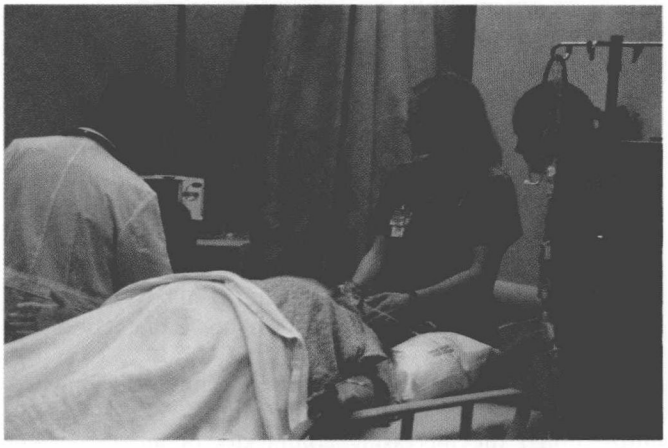

Figure 1–3 Residents responding to a critical event in a simulation.

Figure 1–4 Multidisciplinary team training.

clinical scenarios can arise during this testing, however. Using simulation to test devices under stressful conditions is very useful and centers such as the Center for Medical Simulation in Boston have worked with device manufacturers on just such studies.[31]

Dalley et al introduced a new anesthesiology delivery system with a new circuit design, fresh gas flow delivery, and ventilator control to 15 anesthesiology residents.[27] In a randomized, controlled, prospective study they investigated the value of the addition of a simulator session compared with a traditional in-service one. Each group was tested in a second simulation involving an emergency situation. The group who had used the new anesthesia machine in a simulation scenario solved the emergency problem in less time and made fewer errors. Both groups made serious mistakes despite assessing themselves as competent in using the new machine.

Simulation was also used to evaluate the prototype of a new system for administering anesthesiology medications.[35] The new system included special trays of medications with prefilled syringes, which were color- and bar-coded. Before administering the drug, the barcode would be read and the system audibly enunciated the name of the drug. Ten anesthesiologists performed simulated clinical scenarios with each system and then were asked to rate the new system for its acceptability, practicality, ease of use, propensity for error, and overall safety. Medication set up time was shorter with the new system. Three drug omissions occurred with the traditional system. With the new system, one event was prevented; the wrong drug was picked up for use but the auditory clue caused the provider to realize the error. The anesthetists believed the system was safe and clinically useful.

Simulation has also been used to study the use of anesthesiology monitoring. Lampotang et al demonstrated that the use of pulse oximetry and capnography shortened the time to detection and treatment of hypoxemia in a clinical scenario.[36] This study is not ethical to do in human subjects since this type of monitoring is mandatory in the clinical setting. Overall there are many reasons why simulation can be useful to test medical devices but the most important one is that it does not impact patient safety.

In 2006 the APSF Committee on Technology launched an Anesthesia Workstation Training Initiative.[37] The committee noted the increasing complexity of anesthesiology equipment and the paucity of literature on how best to train providers for safe and effective use. Technology training has been mandated by a few institutions in the United States and Europe. Olympio et al at Wake Forest University conducted a pilot project to train providers before introduction of a new and more complex electronic anesthesia workstation. Over a 2-month period, the learners had to complete four training components: attend a lecture, a hands-on workshop, a 30-minute simulation, and take a competency examination. Of 195 eligible participants, 54% completed the training. Most or many participants said that the hands-on and simulation components were the most valuable and endorsed more of these kinds of training experiences (especially if conducted close to the clinical areas). However, only 14% of faculty completed this training. Of note, while required by the department chair, residents and nurse anesthetists, the training was voluntary for faculty. This is unfortunate since faculty members are the ones who are called on should an equipment event occur. All authors emphasize the need for continual in-service for new techniques and devices and a real appreciation for the inherent hazards of working with the unfamiliar.

Equipment safety in a complex system involving both humans and machines, human error is always a factor. What can manufacturers and clinicians use to improve equipment safety? A task checklist is one way to ensure systematic review of key portions of a task. Checklists can support teamwork and are authority neutral. The Food and Drug Administration and the ASA first endorsed a checklist for anesthesiology machine checkout in 1986. The FDA machine checklist has been revised and abbreviated but is still recommended.[38] In another study, a checklist was developed for preoperative preparation for administering general anesthesia for a cesarean delivery.[39] Twenty experienced anesthesiologists in a high-fidelity simulator prepared for induction both using and not using this checklist. On average, without the list, the participants missed one third of the items, but no items were missed when using the checklist. The simulation study made modifications to the checklist to make it easier to use in the clinical setting.

The ASA Committee on Standards and Practice parameters recently recommended that all practitioners receive training and demonstrate competence before use of any anesthesia workstation. They also recommended the use, the completion and documentation of a pre-use checkout before an anesthesia provider uses an anesthesia workstation on patients. The APSF has advocated that training be mandatory and implemented at the local level.

SIMULATION AS A QUALITY IMPROVEMENT TOOL

Simulation can be used to examine errors made in the clinical setting. During simulation scenarios, other problems may arise which are not anticipated. As reported by DeAnda,[40] during a simulation session many other events can occur which are not expected. Analysis of these events can help to determine human errors or problems with equipment. Simulation has been used to observe the use of standard operating procedures (SOP).[41]Although the use of SOP is often evaluated by survey, one group of anesthesiologists was studied performing an SOP, rapid sequence induction, using simulation. They demonstrated more automatic functions than they described in the survey. The authors felt that using both a questionnaire and simulation could lead to better evaluation and improvement of SOP. Anderson et al studied the effect of using a disposable laryngoscope, which had been mandated for use by the United Kingdom Department of Health, to prevent prion infection.[42] They demonstrated in simulation that the recommended disposable laryngoscope was more difficult to use than reusable ones, a problem not anticipated when the mandate was put into effect.

Conclusion

Anesthesiology is generally very safe, but poor patient outcomes still occur because of device failures and use errors. These are most commonly associated with equipment design flaws. An excellent understanding of all equipment (but especially new devices) is essential for safe patient care. The ASA and the APSF have advocated standardized, mandatory training and certification before the clinical use of new equipment

in the anesthesiology workstation. Simulation is an excellent tool for studying new devices and to train providers in its safe and effective use.

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Chapter 2

Medical Gases: Properties, Supply, and Removal

Jesse M. Ehrenfeld and Michael Oleyar

CHAPTER OUTLINE

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In the United States, the supply and sale of medical gases and medical gas delivery systems are regulated by the Food and Drug Administration (FDA). Most other industrialized nations also regulate gases used for medicinal purposes—including Canada (by Health and Welfare Canada), the United Kingdom (by the Medicines and Healthcare products Regulatory Agency), and the European Union.[1] Requirements for the manufacturing, labeling, filling, transportation, storage, handling, and maintenance of cylinders and containers for the storage of medical gases have been published by the U.S. Department of Transportation. The Department of Labor and the Occupational Safety and Health Administration (OSHA) regulates matters affecting safety and health of employees in all industries, including employee safety when dealing with waste anesthetic gases.[2] Other safety measures, either voluntary or regulated, are published by The National Fire Protection Association (NFPA),[3] the Compressed Gas Association (CGA), Canadian Standards Association (CSA), and the International Standards Organization (ISO).

While regulatory measures are designed to ensure the safe and consistent manufacturing and use of medical gases, occasional accidents have been reported during their delivery.[4] Unfortunately, these incidents have the potential to harm both patients and health care providers alike, especially anesthesiologists. Therefore proper precautions should be taken and backup systems must be put into place to minimize the impact of an adverse event. While regulatory measures play a large part in ensuring the safety supply of medical gases, perhaps even more important is the vigilant anesthesia provider, who should always be mindful of medical gases and their safe delivery.

Physical principles of medical gases must be considered by anesthesia providers as each gas has its own unique properties, which can affect storage, delivery, and use. Medical gases may be found throughout the hospital, especially in anesthetizing locations such as operating rooms. Anesthesia providers must be aware of the sources of medical grade gas to ensure an adequate supply when delivering to patients. The three most common medical grade gases (oxygen, nitrous oxide, and air) are typically supplied via a large central source. Alternatively, these and other gases may be supplied via gas cylinders, most often "E" size cylinders mounted on the anesthesia machine. A waste anesthetic gas (WAG) scavenging system and a medical suction system for surgical and anesthetic use are also provided centrally.

Physical Principles of Medical Gases

Common Gas Laws

Medical gases may be stored either as liquefied gases (oxygen, nitrous oxide, carbon dioxide) or compressed gases (oxygen, air). The state in which a gas may be stored is dependent on the physical properties, and the relationship between pressure, volume, and temperature. These relationships are described by the Common Gas Laws (Table 2–1), also see chapter 27. Although the SI unit of pressure is the pascal (see Appendix I), anesthesiologists often measure and report pressure as kilopascals (kPa),