The Future of Low-Temperature Sterilization Technology

Safety, Economics, and the Environment
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Overview of the Issues

Preventing patient exposure to disease-causing microbial organisms on instruments utilized during their care is of great importance in fulfilling the basic Hippocratic ideal: do no harm. As a result, sterilization is an important technological component in the success of all surgical procedures. The field of medical sterilization has become increasingly complex, however, due to advances in medical instruments and devices. This complexity has raised serious safety, economic, and environmental concerns about traditional low-temperature sterilization technologies. Important to this discussion is the expected role emerging technologies will play in medical sterilization in the near future.

Sterilization may be defined as a process that renders medical devices and surgical instruments devoid of all life forms, including fungi, viruses, active bacteria, and heat- and chemical-resistant bacterial spores. Disinfection—often used erroneously as an interchangeable term for sterilization—is a process that is designed to kill actively growing and vegetative microbial organisms; spores will commonly survive this process. Importantly, disinfection is not a substitute for sterilization. Instruments that are used invasively generally require sterilization, not just disinfection.

Medical sterilization technology has remained essentially unchanged over the last 40 years or more. Traditional methods used to sterilize medical devices and surgical instruments can be categorized by the temperature at which they are effective. Those that use high heat and/or humidity include dry heat and steam techniques. Low-temperature methods include liquid chemical germicides and ethylene oxide (EtO) gas. Dry heat and steam are commonly used to sterilize liquids, linens, wood-containing items, metals, and heat-stable plastics. Liquid chemical germicides are used in certain specialty applications due to questions of sterilization efficacy.

For the majority of heat- and moisture-sensitive medical devices and surgical instruments, EtO has been the most useful sterilization technology available. This is particularly true for those sensitive materials that have been utilized over the last 40 years, as EtO is an effective sterilant in relatively less harsh environments than dry heat or steam. It can be stated with relative assurance that the widespread use of low-temperature EtO sterilization has contributed significantly to the revolution in medical device and surgical instrumentation development—delicate, sophisticated instruments do not fare well in the environments of intense heat and high humidity required for sterilization with other methods.

While EtO and other traditional sterilization technologies have been shown to be efficacious for medical sterilization applications, they are not without significant safety problems. For example, liquid chemical germicides, while functional at low temperatures, have no established method to ensure a sterile result. The use of EtO raises significant
concerns of compromised employee health and safety as a result of exposure to the gas during the sterilization process. Even at extraordinarily low levels of exposure allowed for employees, the gas has been linked to cancer, fetal abnormalities, and chronic medical problems. In addition, the carrier gases currently used in most EtO sterilizers to render the system relatively safe (i.e., not overly explosive or flammable) no longer can be produced legally due to overt environmental concerns. Replacement carrier gases are costly and do not alleviate any of the safety problems for employees that are associated with EtO. Finally, for patient safety reasons, extended cycle times are required to eliminate toxic gas residue, which effectively limits the number of times a device or instrument can be used to no more than once per day. This limitation demands that hospitals carry excess inventory, which can create problems for effective budget management.

In the last five years, low-temperature sterilization technologies, particularly EtO, have come under increased scrutiny. Issues of employee and patient safety, economics, and environmental mandates have all coalesced in creating a crisis with increasing momentum: the well-accepted method to achieve low-temperature sterilization, EtO, fails to address these problems. The questions then arise: What will replace EtO? What sterilization method can ensure patient safety? How can delicate and expensive surgical and medical instruments be sterilized without damage? These are difficult questions to address as they require a fundamental change in the way in which sterilization has been considered for more than 40 years.

Recently, several new sterilization technologies have been cleared for marketing by the United States Food and Drug Administration (FDA). These technologies represent the first attempts to meet the strict criteria for efficacy and safety of medical sterilizers set forth by the FDA. The anticipated role these emerging sterilization technologies will play in the future of sterile medical processing is expected to be significant as traditional sterilization technologies are retired or relegated to disuse.

With more than 100 years of sterilization knowledge, the medical community generally agrees on the components necessary for an ideal sterilization technology. These include demonstrated efficacy against all potential disease-producing microbial life forms, rapid sterilization cycle times, cost-effective operation, established safety for both patients and staff, inexpensive installation and maintenance, non-corrosiveness and compatibility with instruments and devices, and environmental safety. Traditional low-temperature sterilization technology fails to address a number of these issues and may no longer be appropriate for healthcare institutions. With the introduction of novel low-temperature sterilization technologies that have been specifically designed to address safety, economic, and environmental concerns, it may now be possible to better protect healthcare employees, patients, and the environment in a cost-effective manner. A thorough understanding of the relationship among safety, economic, and environmental issues is essential to appropriately evaluate the options available in medical sterilization today and into the 21st century.
For much of human existence, the underlying cause of microbe-induced disease was unknown. Common explanations promulgated by folklore and early practitioners of medicine included angry gods, bad air, various spells, and the odd demon or two—all apparently capricious in both the choice of who suffered and who recovered.

Beginning in the early 1800s, however, the battle against the unseen microbial world began to shift with the application of the scientific method to the practice of medicine. By the mid-19th century, the fundamental disciplines of biomedical research—physiology, anatomy, and biochemistry—had been established.

During this period of dramatic change, the practice of surgery evolved rapidly, due mainly to the advent of anesthesia (ether and chloroform) that made possible significant advances in surgical technique. Surgeons now had the means to perform more invasive operations that lasted for extended periods of time. Simply surviving a surgical procedure, however, was not sufficient to ensure recovery—there was one significant hurdle left to overcome.

Microbial contamination of surgical wounds became a significant source of both postoperative morbidity and mortality; the gains made with better surgical procedures were often more than offset by massive infections in the days and weeks following surgery. Throughout this time, the underlying source of these life-threatening complications remained poorly understood, if at all.

With the development of the germ theory of disease, first promulgated by Agostino Bassi, an Italian biologist, in 1836, and later extended by Louis Pasteur with the demonstration that microorganisms were responsible for producing disease in silkworms, the stage was set for a more thorough understanding of the nature of postoperative complications due to microbial contamination. With extrapolation of these early studies to humans in 1863, again by Pasteur, both the cause and effect of surgical wound contamination by microbial organisms were gradually recognized.

Developing methods to achieve asepsis, or the lack of microbial contamination of a surgical wound, became the goal of a number of medical scientists and surgeons during this time. By 1865, Joseph Lister, a British surgeon, began using carbolic acid (phenol) as a surgical disinfectant. His work, and that of Robert Koch, a German bacteriologist, and others, brought aseptic techniques into widespread surgical practice by the early 1870s.

**The Development of Sterilization Techniques**

The identification of the microbial basis of infectious disease provided a rational basis to improve the success rates of developing surgical techniques and procedures. Early attempts to prevent infection in contaminated wounds used chemicals such as sodium
hypochlorite, other chlorine-containing solutions, strong acids and bases, and alcohols. Some chemicals were more effective than others—some even achieved a moderate degree of asepsis. All, however, were notable for their toxicity to the patient. This series of trial-and-error studies culminated with the publication, in 1881, of a classic monograph by Koch of the relative abilities of more than 70 different chemicals to kill the spores of the bacteria that caused anthrax. This identification of chemicals capable of destroying spores was an important advance in the evolution of sterilization and disinfection.

Limited use for medical applications of sterilization by heat and steam began by the early 1880s. Interestingly, the steam pressure cooker, an early version of the autoclave, had been invented in 1681 and used solely for culinary purposes until Charles Chamberland, a colleague of Pasteur’s, began to use it 200 years later for sterilization in the laboratory. The first commercial steam sterilization system intended for use on medical products was developed in 1889.

Until the introduction of EtO sterilization in the late 1950s, dry heat and steam were the only methods available to routinely sterilize surgical instruments. With EtO, increasingly sophisticated and delicate instruments could be sterilized at low temperatures, reducing the damage to these instruments that would otherwise result if more aggressive forms of sterilization were used.

Together, dry heat, steam, liquid chemical germicides, and EtO represent the range of traditional medical sterilization technologies. Each technique functions differently to eliminate microbial life from medical devices and surgical instruments. Each has its advantages and disadvantages. Low-temperature sterilization—liquid chemical germicides and EtO—has come under increased scrutiny over the last 10 years due to significant problems with employee, patient, and environmental safety. These problems have, however, created opportunities to implement novel methods to achieve both safe and complete sterilization in the healthcare setting. While it is essential that effective, low-temperature sterilization methods remain available for the ever-increasing number of heat- and moisture-sensitive medical devices and surgical instruments, traditional methods to meet these expectations are no longer viable within today’s healthcare environment.
Medical Sterilization: Definitions and Guidelines

As a procedure, sterilization uses either physical or chemical methods to destroy all microbial life, including viruses and bacterial spores.\(^4\)

In contrast, disinfection is a process that eliminates virtually all forms of microbial life except bacterial spores, a difficult-to-kill form of certain pathogenic bacteria that often can resist harsh environments such as heat and chemical disinfectants.\(^5\) Less lethal than sterilization, disinfection lacks the level of safety provided by sterilization, and failure to properly disinfect an instrument can be the source of potential infections by disease-causing bacterial spores.

Cleaning is the process of removing organic matter—in which microorganisms may find favorable conditions for continued life and growth—from an instrument or device that has been in contact with a patient or the environment. It is usually accomplished by washing with a cleanser and hot water. No matter how extensive, instrument cleaning is not a substitute for either sterilization or disinfection—but it should always be performed prior to either procedure to ensure efficacy.

Guidelines for Device Classification

The Centers for Disease Control and Prevention recommends that medical devices, surgical instruments, and environmental surfaces be divided into three general categories to determine whether sterilization or disinfection is appropriate.\(^4,6,7\)

- **Critical devices.** These are items that are introduced into the body or are attached to devices that are in direct contact with the patient’s internal tissues, such as scalpels and cardiac catheters, and laparoscopes. The Association of Operating Room Nurses (AORN) recommends that critical devices be sterilized, not disinfected.\(^8\)

- **Semicritical devices.** These are items that come into direct contact with intact mucous membranes, and include such devices as endotracheal tubes, cystoscopes, and proctoscopes. While many hospitals accept intermediate-level disinfection for semicritical devices, other hospitals prefer disposable instruments in this category.

- **Noncritical devices.** These items only require low-level disinfection, as they only come in contact with intact skin, if they touch the patient at all. Examples include humidifiers, bedside tables, and similar equipment.

Professional societies and government agencies have promulgated recommendations and guidelines in an attempt to ensure adequate decontamination of medical and surgical instruments and devices, yet in practice, hospitals determine which protocols to employ,
and sterilization and/or disinfection practices may differ significantly among institutions.

**Guidelines for Sterilization Validation**

There is no such thing as “partial sterility” or “degree of sterility.” Items are either sterile or nonsterile. Sterilization technologies can be deemed effective only when methods exist to ascertain the success or lack of success of each sterilization cycle. Absolute sterility assurance would require laboratory testing to detect the presence of single microorganisms, viruses, and bacterial spores—a goal that no test method can actually achieve. Instead, guidelines have been developed for assessing degrees of microbial contamination.

In the United States, the widely accepted Association for the Advancement of Medical Instrumentation (AAMI) guidelines recommend that steam and EtO equipment (representing the majority of healthcare sterilizers) demonstrate at least a $10^{-6}$ sterility assurance level (SAL), i.e., that the probability of a defined bioburden (selected bacterial spores on a particular object or volume of liquid) surviving after exposure to the sterilization process is no greater than one chance in one million. The AAMI guidelines dictate that the organism used in the biological challenge should be as resistant as possible to the sterilization process being monitored, and recommend specific bacteria for use as biological indicators.

The AAMI guidelines also discuss the “overkill method” of assuring sterility. In this method, sterilization conditions are established that will kill highly resistant bacterial spores, followed by an additional safety factor of sterilization time or intensity appropriate to the sterilization method that is added to the cycle. The conditions required for “overkill” are thus far more severe than those established for inactivation of the most resistant organisms.

In the evaluation of new sterilization technology, the FDA has established a number of validation tests designed to demonstrate an acceptable level of efficacy and safety before new sterilizer technologies are approved. Sterilizers that use technology available prior to 1976 are grandfathered under the Medical Device Amendments of 1976, allowing their continued marketing. Sterilizer technologies developed since that time, however, must show evidence of extensive sterility validation testing to gain FDA clearance to market.

Among the important efficacy requirements for FDA marketing clearance are:

- **Spectrum of activity.** The manufacturer must demonstrate that the sterilizer is effective against a wide range of clinically important microbial organisms.

- **Efficacy against most resistant strains.** Efficacy validation must be performed using organisms (usually bacterial spores) that have been shown to be the most resistant to the new technology.

- **Appropriate SAL level.** The manufacturer must demonstrate that the instrument is capable of killing a defined bioburden in one-half the usual cycle time.
• **Biological indicators.** A validated and reliable biological indicator must be developed (liquid chemical germicides still do not have this requirement) and cleared for marketing.

• **Critical process parameter study.** A study is required, with appropriate statistical analyses, which establishes that sterility will be consistently achieved when critical process parameters operate within a defined range. This assures the operator that as long as there is no operational error or equipment failure, sterility is achieved.
Although the vast majority of microorganisms do not pose a risk to humans, a few do cause illness, including serious disease and death. Avenues of research in the field of sterilization have focused on the development of technologies that can ensure the absence of microbial life forms on medical and surgical instruments, thus preventing the transmission of potentially life-threatening organisms to the patient.

Medical sterilization technologies can be broadly placed into two categories: high-temperature and/or high-humidity or low-temperature and/or low-humidity. The following represents a brief overview of the primary technologies used in healthcare institutions today to sterilize medical devices and surgical instruments.

**High-Temperature and/or High-Humidity Technologies**

**Dry Heat**

Dry heat sterilization is a general term for a number of different technologies having in common only that water is not added to the sterilization chamber. In fact, dry heat can be viewed as any sterilization process where the amount of moisture is less than 100% (i.e., below 100% relative humidity). Dry heat sterilization often is considered the system of choice for sterilizing heat-stable items and surgical instruments that may be damaged by moisture or are of a design that moisture fails to penetrate. Examples of such materials commonly used in the healthcare setting include powders and certain liquids.

Materials to be sterilized are placed in an oven-like chamber and are subjected to temperatures that range from 160–180°C (320–356°F) for 60–180 minutes (not including the heat-up and cool-down cycle times, which can be significant).

Dry heat sterilization technology has several advantages over other general-use methods. It is less destructive to many materials than steam, which can be corrosive to metal objects and damaging to certain glass surfaces. Unlike EtO sterilizers, dry heat systems do not leave toxic gas residuals on sterilized items following the completion of a sterilization cycle—an important consideration for both staff and patients. Furthermore, since the items to be sterilized are directly exposed to the heat, wrapping of the materials often is not necessary. Finally, dry heat sterilizers and protocols are relatively straightforward with minimal danger to staff if they are maintained well and operated correctly.

Dry heat sterilization also has a number of significant disadvantages. For example, the heating and cooling times of dry heat sterilizers often are lengthy (2–5 hours) because air is a poor conductor of heat. The killing rate of bacteria and bacterial spores also is slow with dry heat technology, so that the time required...
to effectively sterilize instruments is relatively long. Finally, dry heat sterilization requires high temperatures; many materials are unable to withstand these temperatures because of thermal decomposition that leads to damage or destruction of the instrument or device, requiring premature replacement.

Steam

Steam sterilization (often referred to as autoclaving) is a traditional and dependable method of sterilization for many applications in healthcare. Steam sterilization is performed under high pressure at temperatures that range from 121–140°C (250–284°F), which is lower than temperatures required for dry heat sterilization. Sterilization times range from 5–45 minutes, depending on the items to be sterilized.

Many solids and some aqueous liquids (e.g., saline) can be sterilized by steam techniques. For solids, proper packaging is important in order to allow the steam to contact all surfaces and condense while simultaneously allowing for the removal of air—failure to completely sterilize an item due to entrapped air or impervious surfaces is common. When water condenses on the surface of an instrument, the latent heat that is released brings the temperature of the object rapidly to temperatures that ensure sterilization.

The main advantages of steam include the relatively short processing times and the lack of toxic residues following sterilization. The main disadvantages of steam are the relatively high temperatures necessary for sterilization and the inability to sterilize products that are either moisture-sensitive or moisture-impermeable. In addition, a number of important variables—temperature, time, steam saturation, steam purity, and steam availability (within the object to be sterilized)—can adversely affect the efficacy of the sterilization process. Finally, employees are at risk for burns due to the high temperatures involved with the process.

Low-Temperature and/or Low-Humidity Technologies

Liquid Chemical Germicides

Liquid chemical germicides (LCGs) are commonly used agents in the healthcare setting. While dry heat, steam, and EtO sterilization methods are used for the majority of healthcare sterilization applications, LCGs do find appropriate, albeit limited uses with a small number of delicate medical devices, including endoscopes.

A few LCGs—glutaraldehyde, hydrogen peroxide, formaldehyde, chlorine dioxide, and peracetic acid—have been approved by the FDA for use as sterilants, but most LCGs are disinfectants, not sterilants. Chemical sterilants have few advantages other than convenience. The disadvantages generally outweigh the benefits when a rigorous analysis is performed. For example, each of the approved sterilants also can be used as a disinfectant, depending on how long the device is exposed to the LCG, thus raising the possibility of inadvertent substitution of less effective disinfection protocols (concentration of sterilant, soaking time, proper cleaning, etc.) when sterilization was intended. Thus, the potential for untrained or busy personnel to disinfect, rather than sterilize, an instrument is high.
This is particularly troublesome in light of the fact that LCGs do not have established methods to monitor sterilization success.

Patient and employee safety issues with LCGs also are worth considering. For example, direct contact with glutaraldehyde can be very irritating to the skin, causing chemical dermatitis or exacerbating an existing case of eczema. Breathing glutaraldehyde vapors can irritate the nose and mouth as well as induce coughing and bronchospasm even in previously unexposed individuals.

**Ethylene Oxide**

Ethylene oxide is a small, simple organic molecule that has, in many ways, revolutionized the medical and surgical product markets over the last 40 years. Compared with dry heat and steam sterilization technologies, the conditions under which EtO is used lead to relatively little damage to delicate and complex surgical instruments.

For healthcare applications, EtO can be used either in a pure form or, more commonly, as a mixture with a “carrier” gas. The carrier gas is usually chlorofluoromethane—a chlorofluorocarbon (CFC)—in a 12% EtO, 88% CFC ratio. The “12/88” blend is used more commonly than pure EtO in healthcare facilities because it reduces the flammability and explosiveness of EtO. In addition, systems that use blended gases have lower overall capital acquisition costs than those that use unblended gases.

The chief advantages of EtO sterilization of healthcare products are the low temperatures typically employed (25–75°C or 77–167°F) and the wide range of EtO-compatible medical and surgical instruments and devices. Microorganisms (including spore-forming bacteria, fungi, and viruses) are effectively destroyed by chemical reactions with the EtO molecules—both cellular components and genetic material are destroyed or altered beyond the ability to function following exposure to EtO.

Ethylene oxide is not without problems, however, some of which are difficult to overcome. For example, EtO is a very toxic gas with potentially significant risks to both employees and patients (see: Issues of Safety with Traditional Low-Temperature Sterilization Technology, page 12). In addition, most EtO systems use the 12/88 mixture to decrease the flammability and explosiveness of EtO, but the production of CFCs in the United States ceased at the end of 1995 for environmental reasons (issues pertaining to the use of CFCs will be discussed in a later section).
Progress in medical care often is driven by advances in technology. In the field of sterilization, advances in medical and surgical devices are placing new demands on sterilization procedures and personnel. In addition, issues of patient and employee safety, costs associated with traditional technologies, and environmental hazards are creating pressure for new technologies.

New Demands

The primary goal of medical sterilization is to prevent infections during medical and surgical procedures. The complexity of the process that surrounds this goal, however, often obscures the role sterilization must play in protecting patients’ health. As noted previously, disinfection is not a substitute for sterilization. Sterilization is the ideal procedure for all medical devices and surgical instruments used for invasive procedures that place a patient at risk of infection. As a result, diligence in the choice of sterilization methods provides the greatest margin of safety for every patient that receives care.

A significant problem for infection control specialists arises from the frequent introduction into medical practice of sophisticated, hard-to-sterilize instruments. While these devices play an important role in the treatment of disease, it is important that they also do not contribute to disease. A thorough evaluation and examination of the sterilization requirements for each new, invasive item purchased by the institution is important to maintain control over the spread of increasingly dangerous and difficult-to-treat microbial diseases.

Minimally invasive surgery has initiated a revolution in the manner in which surgery is performed. Originally, minimally invasive surgical techniques were almost exclusively used by gynecologic and orthopedic surgeons. Since the late 1980s, minimally invasive surgery has gained rapid acceptance in the general surgical environment as an alternative to traditional, and more expensive, surgical techniques. The driving force behind the growth of minimally invasive surgery has been a juxtaposition of technology and economics. In the mid- to late-1980s, endoscopes became sufficiently advanced to allow surgeons to perform such operations as gall bladder and appendix removal, and to perform a wide variety of diagnostic and therapeutic procedures with minimally invasive techniques. Hospitals also were under great pressure during this time to reduce the average length of stay of all patients; those who did not need to recover from the large incisions associated with many forms of traditional surgery could be discharged more rapidly.

In most endoscopic procedures, the instruments (either flexible or rigid) come into contact with mucous membranes or are placed into sterile areas of the body. As such, endoscopes are considered semicritical or critical devices. Depending on the intended use,
endoscopes must be either disinfected or sterilized prior to their next use. Though sterilization rather than disinfection of endoscopes would be ideal, in practice many endoscopes are only disinfected. In a recent survey of more than 100 hospitals in North Carolina, 57% performed “high level” disinfection (with 2% glutaraldehyde) while only 17% sterilized their endoscopes with EtO. The major technical barrier to adequate sterilization of endoscopes is inherent in their design. Endoscopes are complicated devices that contain numerous channels and crevices that are poorly accessed by sterilizing chemicals and gases. In addition, sterilization by traditional methods—dry heat, steam, EtO, and liquid chemical germicides—can damage or destroy the delicate mirrors and cables commonly found in endoscopes.

There are numerous descriptions in the literature of serious, and sometimes fatal, infections believed to be associated with improper endoscope decontamination. The major technical barrier to adequate sterilization of endoscopes is inherent in their design. Endoscopes are complicated devices that contain numerous channels and crevices that are poorly accessed by sterilizing chemicals and gases. In addition, sterilization by traditional methods—dry heat, steam, EtO, and liquid chemical germicides—can damage or destroy the delicate mirrors and cables commonly found in endoscopes.

There are a number of incentives to choose disinfection over sterilization for these complicated instruments, the most significant perhaps being economic. Sterilization with EtO often requires a turnaround time of 12 hours or more. This slow turnaround time effectively removes a particular instrument from surgical use for the rest of the day. Limiting the availability of these expensive devices because of slow sterilization cycle times adds to the cost of providing patient care. With the cost of equipment inventories placing increasing pressures on hospitals, the use of rapid disinfection instead of sterilization, though potentially subjecting patients to increased risk, is a choice that is increasingly made.

Choices in sterilization technology acquisition must account for the ever-increasing complexity of emerging surgical and medical instrumentation. The level of sophistication in invasive instruments often outpaces the ability of traditional sterilization technologies to meet the requirements of both sterilization and instrument protection. Damaging an item while sterilizing it, however, is not a reasonable choice. New technologies that come closer to accomplishing the goal of sterilization of a wide range of medical devices and surgical instruments should be evaluated to address this problem.

**Health and Safety Issues**

In hospitals today, ethylene oxide is considered the sterilization technology of choice for heat- and moisture-sensitive medical devices and surgical instruments. The other traditional sterilization technologies—dry heat, steam, and liquid chemical germicides—are used more for specialty applications. As a result, the significant issue of safety is focused on EtO as a stand-alone technology rather than on the other, less-utilized methods.

The healthcare institution is charged with ensuring, to the best of its ability, the safety of its patients, visitors, and employees. In an ever-litigious society, much effort goes into reducing the potential for liability, thus protecting the institution from avoidable and costly litigation.

**Occupational Health Risks**

In the healthcare setting, there are numerous and often unseen hazards that may be encountered by employees on a daily basis. In hospitals
a reas that perform sterilization, occupational hazards include exposure to high-temperature sterilizers, liquid chemical sterilants, and especially ethylene oxide, a very toxic gas.

In the most recent United States government study on the effects of ethylene oxide exposure, an estimated 90,000 hospital workers were exposed annually, either directly or indirectly, to EtO. Although acute exposure to high levels of EtO is rare in the healthcare setting, low-level exposure is more common. The long-term effects of low-level exposure are only just beginning to be fully understood and appreciated. Acute and chronic exposure to EtO can cause respiratory tract irritation, central nervous system disorders, gastrointestinal problems, and chemical burns. In addition, occupational exposure to EtO has been linked to changes in the structure of human chromosomes, an increased risk of cancer, and an increased rate of spontaneous abortions and birth defects.

The significant potential for harm to hospital personnel prompted the Occupational Safety and Health Administration (OSHA) in 1984 to place tight restrictions on occupational exposure: 1 part per million (ppm) over an 8-hour time period. This directive, updated in 1988, is monitored through EtO detectors (EtO is odorless to humans up to a threshold of 100 ppm—a dangerous level) and medical monitoring of employees. Importantly, a number of studies have demonstrated biochemical and biologic effects on healthcare workers at or below the limits for EtO exposure. As noted by Schulte and colleagues:

"The results indicate that workplace levels which meet the current OSHA standard do not protect against certain biologic changes associated with ethylene oxide exposure."

The respected International Agency for Research on Cancer has recommended that EtO be reclassified from a Class IIA (probable human carcinogen) to a Class IA (recognized human carcinogen). As noted by Siegel and Bunn:

"Hospitals are under increased scrutiny for all hazardous exposures under OSHA’s ‘general duty’ clause....In the standard [Occupational Exposure to Ethylene Oxide, 1984, OSHA], OSHA acknowledges the potential risks to health posed by ethylene oxide exposure. This acknowledgment of risk provides a legal basis for lawsuits."

Clearly, the risks to employees as a result of the use of EtO as a sterilant can be significant. Every institution that continues to use a technology with such well-documented short- and long-term harmful effects runs the risk of substantial financial burden in compensation to those who can demonstrate personal damage. Some of the tests for genetic damage are relatively simple to perform, and are accessible to any employee who may request them. The continued exposure of employees to EtO can thus damage an institution in two ways: by harming its valued employees and, possibly, its financial well-being.

Patient Health and Safety

The acute toxicity associated with low-level exposure of patients to EtO was first recognized in the 1970s. Patients suffered chemical burns,
inflammatory reactions, and even death due to improper aeration procedures. National guidelines for aeration were defined in the late 1970s, aimed at reducing the risk of EtO residual-associated patient injuries. Recent reports, however, have underscored the fact that despite strict regulations regarding EtO aeration cycles, patient injuries still occur.

Anaphylaxis, an allergic reaction that can be fatal, has been reported in patients undergoing renal dialysis with EtO-sterilized hemodialysis equipment. In addition, EtO-sterilized tissues commonly used in orthopedic surgery have been implicated in postoperative adverse reactions. While reports in the literature would indicate that EtO-associated adverse reactions are uncommon, the actual rate of injury may be much higher, as pointed out by McGreevy Steelman:

Because of the seriousness of the issue and concerns about accreditation and public image, hospitals may be unwilling to publish manuscripts indicating noncompliance…. [P]erioperative nurse managers… indicated that patients who came into contact with improperly aerated instruments were not followed to see if injuries were sustained. This poses a very serious concern for the quality of care in operating rooms.

As the role of EtO residue in nosocomial disease becomes better understood, risk management in this area will be increasingly important. With the long sterilization processing times associated with EtO—sometimes approaching 24 hours—the temptation to speed up the process increases. In these cases, sterility cannot be guaranteed. Each time an instrument or device whose sterility is in doubt is used on a patient, the possibility exists of an adverse event occurring. The evaluation of traditional sterilization technologies and the newer methods that have fewer opportunities to cause patient harm can help to address the issue of providing better patient care without the risk of serious adverse events. The decreased potential for inadvertent patient harm can have a positive bearing on the financial well-being of the institution and the general level of care in the hospital.

Environmental Issues

High-temperature and/or high-humidity sterilization methods pose little environmental danger if they are kept in proper working order. Liquid chemical germicides, while exhibiting environmental toxicities much greater than dry heat or steam, nevertheless are considered reasonably safe due to adequate disposal mechanisms. Ethylene oxide, however, is toxic to all living things even at extremely low concentrations; because of this, it was considered as a potential chemical warfare agent during World War I. It is precisely this property of EtO that makes it an excellent sterilant, and a dangerous chemical to all who may inadvertently come in contact with it. In order to achieve a degree of safety for hospital staff during a sterilization cycle, EtO must be released directly into the atmosphere through a complicated series of pipes and vents to ensure no possibility of a leak. This process is under increasing attack due to its toxicity to all forms of life, just as CFC emissions were attacked due to their effect on the atmospheric ozone layer.

The Environmental Protection Agency (EPA) recently has proposed a set of national
regulations under the Clean Air Act to curb the release of EtO into the atmosphere by large-scale industrial sterilizer sites. While there is cause for concern by healthcare institutions regarding these new regulations, the EPA currently considers the discharge levels of EtO by individual hospitals too low to be affected by the proposed abatement regulations. Once full implementation of the strict discharge regulations occurs at the large-scale industrial sterilization units, however, healthcare institutions could be targeted for enforcement since they are not excluded from the regulations, only considered too small at this particular time to be worthy of regulatory oversight.

Of more concern to hospitals is the likelihood that state and local regulatory agencies, using EPA regulations as a model, will require EtO gas abatement. In states such as California, Michigan, New York, Texas, Wisconsin, and local areas such as the Puget Sound Basin of Washington state, regulatory agencies generally have required a 95–99.9% reduction in all EtO emissions. Any large metropolitan area not in compliance with the EPA’s limits on environmental pollution can reasonably expect to be placed under similar restrictions within the next several years.

Scientists have recently confirmed that the CFCs used with EtO sterilizers are contributing to the destruction of the ozone layer in the upper atmosphere. In an unusual display of scientific, political, and economic unity, the United States and the European Community (EC) signed the Montreal Protocol in 1987, which banned the manufacture (and, ultimately, the use) of CFCs by the end of 1995 in the United States, and by 2003 in EC countries. Hydrochlorofluorocarbons (HCFCs), a replacement for CFCs used with EtO sterilizers that are claimed to be less harmful to the ozone layer, also are subject to the international agreement. Although the EC originally proposed the year 2015 for the completion of a phase-out of all substances other than CFCs that deplete the ozone layer, including HCFCs, the governing body of the EC has in fact recently voted for stricter controls with a view toward phasing out production by the year 2003.

Once CFCs and HCFCs are unavailable, some hospitals may retrofit their EtO sterilizers to use 100% EtO—an expensive option that does not address worker and patient safety issues and only partially addresses the environmental concerns. In fact, as the number of institutions using EtO declines, and those that remain begin to utilize 100% systems, the EPA may find it much easier to closely monitor those hospitals that made the choice to continue to use EtO. In addition, because 100% EtO systems will use more EtO each year, federally imposed storage safety requirements for the larger quantities of the flammable gas will place a further economic and space burden on hospitals.

Other hospitals may opt to retrofit their sterilizers to accept a different carrier gas, such as carbon dioxide (CO₂) in a mixture of 90% CO₂ and 10% EtO (“90/10” systems). Aside from the cost of the retrofit—which includes the installation of new cylinders that can handle higher pressure gas—additional tanks of carbon dioxide will have to be stored and handled. Moreover, the sterilant would still be EtO and the concerns about employee, patient, and environmental safety would remain.
Economic Issues

Taxes and Regulation of Carrier Gases

To curb CFC use prior to the production cut-off date at the end of 1995, the United States Congress levied a punitive excise tax on CFC use in 1989 that escalated annually to a high in 1995 of $5.35 per pound. The trade publication OR Manager reports that, as a result, a typical 300-bed hospital using an estimated 5,280 pounds of CFCs per year would have paid $28,000 in taxes in 1995, compared with $8,800 for the same level of usage in 1993. If the United States follows the lead of the EC, the date of 2030 for HCFC phase-out in the United States mandated by the Clean Air Act may be revised, and healthcare facilities could soon be facing a similar tax for HCFC usage.

Monitoring Costs

The degree of medical monitoring required by OSHA of employees potentially exposed to EtO is extensive, and includes medical and work history, an annual physical examination with particular attention paid to organ systems known to be affected by EtO exposure, and a complete blood work-up. The costs associated with this medical monitoring can be significant. In fact, in 1985, they were estimated to exceed $70 million per year. Since medical surveillance is a mandated function that must be performed if an institution uses EtO gas sterilization, these costs must be considered as direct costs associated with EtO sterilization equipment. Medical monitoring of employees exposed to EtO is not the only monitoring cost associated with EtO technology. OSHA regulations require environmental monitoring before, during, and after each sterilization run. Environmental monitoring, which must be available to employees at all sites of potential EtO exposure, can be one of a number of types of tests including personal dosimetry (monitoring) and direct-reading continuous analysis of the area where EtO is used. Considering methods to comply with OSHA’s mandate, Gschwandtner and colleagues reported that there was probably no single best method for monitoring personal exposure to ethylene oxide in all situations. They recommended that a combination of procedures should be used for effective monitoring of the environment.

These EtO monitoring costs, including insurance premiums that have been estimated at $4,000 per year or more per EtO sterilizer, and those associated with general and emergency training of staff, can add a significant financial burden to the department responsible for sterilization and to the healthcare institution as a whole.

Instrument Processing and Inventory Management

Hospitals are under increasing pressure to control the costs of performing surgery, which include staffing and maintaining the operating suite, central supply, surgical pathology, and recovery. This pressure comes not only from within, but also from emerging non-traditional venues such as off-site surgical locations. These sites can compete for the surgical dollar in a number of ways important
to this discussion, including the ability to concentrate selectively on high-volume, low-cost surgical practices.

In an effort to reduce surgical costs, institutions are beginning to look more closely at the time required to complete sterilization cycles of surgical instruments. As already mentioned, EtO sterilization can take 12–24 hours to complete, due mainly to the extended aeration cycle required to eliminate residual EtO on the instruments. In a recent Health Devices report, it was noted that, compared with EtO sterilization systems, an emerging sterilization technology demonstrated:

\[ \text{...[a] throughput...about five times higher...than in the larger EtO sterilizer (if aeration time is included). The larger throughput translates to faster instrument turnaround and potentially places less demand on instrument inventory.}^{58} \]

As noted in this report, less demand on instrument inventory can be expected to translate into lower inventory carrying costs, with a commensurate decrease in inventory budgets. The reduction of expensive surgical instrument budgets is one goal many institutions now have in a global program to lower operating room costs and increase competitiveness for managed care contracts.

**Sterilization vs. Disinfection**

Utilizing disinfection inappropriately as a substitute for sterilization without written policy and procedure guidelines, training, and other safeguards can pose a significant financial risk in the event of litigation. Even with guidelines, successful high-level disinfection depends on trained staff, sterility assurance monitoring, and other difficult-to-control variables.

Presumably, hospitals would gladly sterilize instruments instead of merely disinfecting them, so long as a new technique was fast, effective, and at least as harmless to instruments as EtO or steam. In addition, any new sterilization technology must not be hazardous to employees, patients, or the environment. Finally, ideal technology for fiscally constrained healthcare institutions should have a significantly shorter cycle time and cost substantially less to purchase, install, and operate than existing sterilization technology.
Newer Low-Temperature Sterilization Technologies

The inherent toxicity and danger of traditional sterilization processes argue for the development and adoption of better sterilization technologies. Any new technology should be safe for employees and patients throughout the sterilization process and the subsequent use of the sterilized instruments and equipment. Ideally, the sterilant should be effective at low temperatures and packaged in such a way that spills and leaks would be virtually impossible, eliminating the need for protective garments, badges, and monitoring equipment. Janssen and Schneider have suggested several additional attributes of an ideal sterilization technology for hospital use, including: 

- **High efficacy**—must be shown to be bactericidal, sporicidal, fungicidal, and virucidal
- **Cost**—must have reasonable equipment, operating, and installation costs
- **Rapid activity**—resulting in short cycle times to reduce instrument carrying costs
- **Strong penetrability**—to ensure sterilization of device lumens as well as packaging materials
- **Materials compatibility**—the sterilization process should be non-damaging to devices and packaging materials and should not alter the appearance of instruments
- **Nontoxic**—must be safe for workers, patients, and the environment
- **Adaptability**—should require little or no site modification for installation at point of use
- **Organic material resistance**—should be able to withstand reasonable challenge (bioburden) without loss of efficacy
- **Monitoring capability**—should be easy and accurate, with approved chemical and biological indicators

Several new technologies have been developed to more effectively address these safety, efficacy, installation, operation, and environmental goals, to varying degrees of success.

**Vapor Phase Hydrogen Peroxide**

Liquid hydrogen peroxide solutions have been used to disinfect instruments for many years. Vapor phase hydrogen peroxide sterilization began in the food industry and reached the healthcare market in the mid-1980s.

Two approaches for the use of vapor phase hydrogen peroxide in medical settings have been developed. The first uses a deep vacuum to pull liquid hydrogen peroxide (30%) from...
a cartridge through a heated vaporizer and into the sterilization chamber. This process operates at temperatures of 55–60°C. The second method uses a flow-through approach, in which the vaporized hydrogen peroxide is brought into the sterilization chamber by a carrier gas.

Although vapor phase hydrogen peroxide systems meet several of the criteria for an ideal sterilization technology, they cannot be used with highly absorptive materials such as cellulose materials, nylon, and certain types of rubber. Moreover, polypropylene/polyester packaging has been shown to retain hydrogen peroxide residues, necessitating post-sterilization aeration. Because of exposure concerns with the 30% hydrogen peroxide during loading of the cartridges, operators must wear protective garb and installation requires special venting and emission monitoring considerations.

The ozone-based system has the advantage of nontoxic by-products, low operational temperatures (25°C) and a relatively short (compared with EtO) cycle time of 1–3 hours.

Although the cycle time is relatively fast and does not require prolonged aeration, ozone sterilization is unsuitable for moisture-sensitive instruments. Moreover, some packaging materials, certain types of rubber, and many plastics may be damaged by exposure to the highly reactive gas. Also, the gas must be generated on-site at the time of the reaction from oxygen stored in large containers, adding to the complexity of the operation. Finally, concerns about penetrability into materials also exist.

**Liquid Chemical Sterilants**

A liquid peracetic acid (peroxyacetic acid) sterilizer was introduced for commercial use in the late 1980s. The technology uses 0.2% peracetic acid (an oxidizing agent) in which the instruments are immersed for approximately 30 minutes. Although fast, the system can only sterilize immersible items and requires the use of filter-sterilized water and sterile air since the items to be sterilized are not wrapped or otherwise protected while in the immersion chamber.

Liquid chemical sterilizers using peracetic acid have two main advantages over traditional chemical sterilizer technologies: no overtly toxic end-products (peracetic acid breaks down into acetic acid [vinegar] and oxygen) and a short cycle time.

Ozone

Ozone, used for many years to disinfect drinking water, is created by producing an electrical discharge in the presence of oxygen or air. Ozone is a naturally occurring, highly reactive form of oxygen that is very unstable. Ozone quickly converts back to stable oxygen.

The medical sterilizer combines ozone with humid air which is passed through the sterilization chamber. Sterilization cycles take up to two hours to complete. At the completion of a cycle, the sterilizer is purged by the flow of regular oxygen or air and residual ozone is catalytically converted back to oxygen.
The disadvantages of current liquid peracetic acid systems include limited capacity (current models can only sterilize one large endoscope at a time) and no available biological indicator.\textsuperscript{20} As discussed earlier, because a biological indicator is not available to monitor liquid chemical sterilizers, there is considerable debate as to whether items are truly sterilized or only disinfected.\textsuperscript{77} In addition, exposure to liquid peracetic acid has been linked to skin and eye irritation as well as occupational asthma, nausea, and headache.\textsuperscript{78} Liquid sterilants also must be monitored daily to ensure that they have not become contaminated or diluted.

**Gas Plasma Systems**

Scientists refer to gaseous plasma, not to be confused with blood plasma, as the fourth state of matter, different from solids, liquids, and gases. Plasmas are cloud-like collections of ions, free electrons, and neutral atomic and molecular species that occur naturally in outer space. One of the more prominent plasmas in nature is the \textit{aurora borealis}, or “northern lights.” An everyday example of a gas plasma is a neon light—its glow is the result of electrical energy applied to a reactive gas.

Forming a low-temperature plasma requires a closed chamber, a deep vacuum, a chemical precursor from which to derive the plasma, and a source of electromagnetic energy, such as radio frequency (RF) energy, to create an electromagnetic field to generate the plasma. The electromagnetic field interacts with the chemical—hydrogen peroxide, for example—and creates a number of highly reactive species. Hydrogen peroxide and the highly reactive agents are capable of quickly destroying the difficult-to-kill bacterial spores with no toxic residues.

**Mixed Chemical Plasma**

A mixed chemical plasma (MCP) device became available in January 1995. The MCP system uses a two-phase process that is repeated for a total of six times during the 4-hour sterilization cycle to achieve full sterilization.\textsuperscript{79} In the first phase, a 5% liquid peracetic acid is infused into the sterilization chamber and vaporized. This vapor then diffuses throughout the sterilization chamber for a period of time.\textsuperscript{68} It is during this phase that the majority of vegetative bacteria is destroyed. The remaining vapor is vented directly into the atmosphere.

In the second phase, a plasma is formed in a separate reaction chamber when vaporized hydrogen, oxygen, and argon are exposed to an electromagnetic field. The products of this reaction then flow into the sterilization chamber to complete the sterilization cycle.

Currently, the MCP method has been cleared by the FDA to sterilize stainless steel surgical instruments. One advantage of this system is that it can be used with Tyvek\textsuperscript{®} and Tyvek/Mylar packaging.

While considerably faster than EtO, the MCP system still has a relatively slow sterilization time—over four hours.\textsuperscript{79} In addition, the system must be permanently placed with a vent to the exterior of the building to allow the removal of the vaporized peracetic acid directly into the atmosphere. Finally, the MCP system requires the storage of large, high-pressure gas cylinders and smaller
Advantages of the low-temperature hydrogen peroxide gas plasma system include an excellent safety profile for employees. Unlike EtO, liquid chemical sterilants, and other alternative sterilization technologies, the low-temperature hydrogen peroxide gas plasma sterilizer poses little risk to operators and the environment. Exposure to hydrogen peroxide has been limited to 1 ppm over eight hours by OSHA. Monitoring by OSHA of the external environment of the sterilizer during operation demonstrated that the average concentration of hydrogen peroxide in the atmosphere over eight hours was 0.018 ppm while the personal sample exposure was determined to be 0.013 ppm.\textsuperscript{82}

Safety for patients has been established through laboratory tests of the low-temperature hydrogen peroxide gas plasma technology prior to marketing clearance in 1993. These tests demonstrated that this technology destroys a broad spectrum of microorganisms, including Gram-negative and Gram-positive vegetative bacteria, mycobacteria, yeasts, fungi, and viruses, as well as highly resistant aerobic and anaerobic bacterial spores.\textsuperscript{81,83} In addition, as the hydrogen peroxide breaks down into water and oxygen, there are no concerns about toxic residues following the completion of a sterilization cycle. Studies have demonstrated that items processed by this technology are nonirritating and nontoxic to cells and tissues.\textsuperscript{81,84}

Significant economic advantages have been associated with low-temperature gas plasma sterilization as well. For example, because of its extremely rapid cycle time (about one hour), inventory of expensive surgical instruments such as rigid endoscopes can be reduced while still ensuring that every patient receives a
sterilized—not just disinfected—device at any given time of the day. In addition, for a wide range of medical and surgical instruments processed by low-temperature hydrogen peroxide gas plasma sterilization, significantly less deleterious effects on metal items have been observed compared with steam sterilization, reducing replacement costs of expensive surgical instruments.\textsuperscript{81,84} Since there are no installation requirements except a modified 208-volt electrical outlet, the system can be placed almost anywhere—including the surgical suite—to facilitate the distribution of sterile instruments.\textsuperscript{85} Finally, since preparation of items for sterilization is similar to EtO processing, consisting of instrument cleaning, reassembly, and packaging in commercially available, nonwoven polypropylene wraps, employee training costs can be kept to a minimum.

Environmental concerns are addressed in the fundamental manner in which the technology operates: self-contained ampoules of hydrogen peroxide are used that virtually eliminate concerns about exposure to the chemical. In addition, following the completion of the sterilization cycle, the hydrogen peroxide degrades primarily into vaporized water and oxygen, free of toxic materials associated with other low-temperature technologies.

Disadvantages of this technology include the inability to sterilize linens and other cellulose-containing materials, as the hydrogen peroxide reacts with the organic material found in these items.\textsuperscript{86} In addition, because the technology relies upon diffusion, materials such as powders and liquids cannot be sterilized. The technology currently has restricted applications for narrow-lumen devices in the United States.

As the shift occurs away from traditional low-temperature sterilization technologies such as EtO and liquid chemical germicides to the newer methods, the full spectrum of medical sterilization technology comes into focus. While no single technology can hope to fulfill all the sterilization needs of a hospital, a range of safe, economical choices is imperative. Dry heat and steam will probably always have an appropriate place in the provision of this service. Low-temperature systems that are potentially dangerous and costly will not.
Sterilization is a fundamental link in the prevention, and thus control, of hospital-acquired infections. Modern sterilization technology provides the margin of safety necessary to allow physicians and other healthcare professionals to diagnose and treat the wide range of diseases and injuries that can affect us all.

In the 1990s, those who are involved with decisions that affect the way in which sterilization is performed in the healthcare institution must evaluate three main issues: safety, economics, and the environment. These issues are neither simple nor are they fully addressed by traditional sterilization technologies.

Safety of the sterilization equipment and processes for employees and patients cannot be underestimated. Employees should not be placed at risk from dangerous gases, chemicals, or the hazard of potential explosions during their work day. Patients need to be assured that the instruments and devices used on them for diagnostic and therapeutic procedures are not potential sources of harm, and that, in particular, they do not become victims of lowered safety margins in institutions struggling with economic problems. As has been demonstrated, the cost to an institution to address these risk management issues can be substantial with traditional low-temperature technology.

In an era of increasingly lowered revenue expectations for healthcare institutions, the economics of sterilization are very important.

All sterilization technologies have hidden costs—training, facilities management, storage, and monitoring, for example—that must be considered and compared. Environmental regulations add significant burdens to the operating costs of ethylene oxide sterilization equipment. Abatement, personnel monitoring, taxes, and even fines affect the economics of both the department responsible for sterilization and the institution itself. All major forecasts of the future of surgery suggest that minimally invasive procedures will grow in number. Instruments designed for these procedures are delicate and often expensive. New sterilization technologies should be able to effectively and rapidly sterilize these instruments without damage.

Finally, environmental concerns are increasing at every level in this country, and safety for the community becomes an important consideration when evaluating new sterilization technologies. The release of overtly toxic gas or other by-products of sterilization into the environment has become increasingly difficult to justify. Choices in low-temperature sterilization technology must be made with a complete understanding of these problems at the local, state, and federal levels.
The complexities of modern medical technology preclude a single form of sterilization; therefore, dry heat, steam, and low-temperature technologies will continue to coexist in the hospital to ensure that patient care is not compromised.

Ethylene oxide, for many years the mainstay of low-temperature medical sterilization, has a number of significant liabilities that hospitals cannot easily ignore. Fortunately, the synergism between low-temperature sterilization and the provision of safe medical and surgical care does not need to suffer. Newly available technologies, relying on novel engineering concepts, have been shown to be capable of meeting most, if not all, requirements identified by hospitals for low-temperature sterilization of their medical devices and surgical instruments.

Ethylene oxide sterilization has contributed greatly to advancements in medical care over the last 40 years. The liabilities directly associated with EtO sterilization, however, call into question its continued use as a medical sterilant. Low-temperature sterilization is not unsafe or expensive, however, when alternative technologies are utilized. As healthcare institutions rapidly move away from the dangers of EtO, the problems with burdensome environmental regulations, and the protracted cycle times associated with its use, hospitals are increasingly relying on safe, economical alternatives to ethylene oxide sterilization.
References


82. Anderson GJ. Written communication, May 23, 1995. U.S. Department of Labor, Occupational Safety and Health Administration, Calumet City, Ill.


