Declining reimbursement has become a way of life for America's hospitals. Recently, in a renewed effort to balance the federal budget, a compromise was worked out by the House and Senate of the United States Congress that would slash Medicare spending by $270 billion over the next seven years. In addition, federal contributions for state Medicaid programs would be reduced by $180 billion under the same budget proposal. The likelihood of these cuts becoming a reality is bolstered by a recent Medicare trustee report that forecast the bankruptcy of Medicare Part A by 2002. While the magnitude and mechanics of these budget cuts have yet to be finalized, it is clear that a substantial decline in both federal and state healthcare reimbursement will occur, with hospitals expected to directly absorb the majority of the proposed reductions.

With the seemingly unending negative financial news, hospitals are increasingly required to evaluate every aspect of their operations to remain solvent, while still maintaining the highest possible quality of care for each patient. According to Wendy Kuran, Vice President, Strategic Planning and Marketing at St. Mary Medical Center in Long Beach, California, "Many believe that technology is, at least in part, responsible for the problems we face today. Now, technology must be used in a way that can help hospitals..."

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Sterilization Cycle Times

Sterilization cycle times can be defined as the length of time from the loading of instruments into the sterilizer until they are again safe to use with patients. Traditional sterilization technologies tend to have fairly long cycle times—ethylene oxide (EtO), for example, routinely removes instruments from use for as long as 24 hours.

Since almost all heat- and moisture-sensitive medical devices and surgical instruments are sterilized with EtO, the effect of prolonged cycle times is significant. Instruments to replace those in sterilization, including equipment such as expensive microsurgical devices, must be on-hand for additional surgeries and procedures throughout the day. As a result of the long sterilization
cycle time with EtO, large, duplicative inventories must be maintained in order to provide adequate coverage. Excess inventories can be particularly expensive to maintain in today’s healthcare environment due to the high cost of many of the emerging microsurgical instruments and devices.

In order to address the problems of cycle times, there has been an increasing interest in minimum-inventory sterile processing. Investing in technologies that permit rapid cycle times can provide the institution with an increased level of flexibility in the use of its expensive surgical instruments. Combining rapid cycle times with the ability to store sterile instruments can further expand flexibility by allowing immediate access to sterile items several times each day.

According to Natalie Lind, C.C.S.M.C., Director of the Central Service Material Management Program at Northwest Technical College in East Grand Forks, Minnesota, there are a number of changing demands being placed on central supply because of faster surgical and diagnostic procedures and an increased number of outpatient procedures. “Hospitals don’t have the luxury of keeping patients on site for long-term care—they need to get them out as quickly as possible. Because of this, there will be an ever-increasing reliance on minimally invasive surgical procedures. The instruments used in these surgeries do not fit with the principles we were taught about sterilization—they are far too complex to be adequately sterilized with traditional technologies,” said Lind. Importantly, she notes, EtO is not the answer because of its very long cycle times. “With an increasing number of minimally invasive surgical procedures, administrators will have to accept that the cost of the technology is more than simply the purchase of the instruments. New cleaning and sterilization technologies must be considered hand in hand with the acquisition of expensive new surgical instruments,” she added.

Compliance with State and Federal Regulations

The two most commonly used sterilization technologies in hospitals today—steam and EtO—are subject to extensive local, state, and federal regulations. While the operation of steam generally falls under state and federal Occupational Safety and Health Administration (OSHA) rules, EtO systems incur a host of additional regulatory mandates.

With the scheduled phase-out of chlorofluorocarbons (CFCs)—used as a carrier gas for EtO to reduce flammability and explosiveness—to occur by the end of 1995, the harmful environmental effects of CFCs will no longer be an issue. Institutions are scrambling, however, to replace CFCs. One method of addressing this is to retrofit existing EtO systems to operate on hydrochlorofluorocarbons (HCFCs). While retrofitting CFC-based systems has provided some hospitals with a short-term solution (HCFCs are scheduled to undergo a similar production phase-out early in the next century), technical issues and increased use of EtO in retrofitted systems has unexpectedly increased operating costs for many users.

Even when an institution retrofits to replace CFCs as the carrier gas, EtO, an extremely toxic chemical, remains the sterilant gas. Because of its toxicity, a number of states—California, Michigan, New York, Texas, and Wisconsin, for example—essentially prohibit the release of EtO into the environment. Regulations such as these require the purchase of expensive EtO abatement equipment, adding to the overall operating costs of the system.

On-Site Placement and Renovation

Traditional sterilization technologies often have expensive physical plant requirements. Steam sterilization requires specialized plumbing and filtered air connections, often necessitating expensive renovations when either upgrading or replacing outdated equipment.

Literature Update: New Publication Highlights Sterilization Technology

A recent issue of Surgical Services Management (Vol. 1, No. 2), a new magazine published by the Association of Operating Room Nurses (AORN), focuses entirely on sterilization technologies. Article topics include worker safety issues, guidelines for cost analysis of sterilization systems, sterilization regulations, a user’s perspective on low-temperature gas plasma sterilization, as well as technology overviews of several systems.

Editor Suzanne Ward, R.N., M.N., M.A., C.N.O.R., noted that sterilization issues were a high priority for the editorial staff, who chose to devote the entire second issue to the topic. “The introduction of new plasma sterilization technologies and federal regulation on chlorofluorocarbons has changed everything,” said Ward, a former operating room director. “The decision to purchase new sterilization technology is very different from what it was a few years ago. We wanted to provide a resource with current information to help our colleagues become more aware of their options.”

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Ethylene oxide sterilization systems must meet complex regulatory requirements to ensure a safe working environment. Aeration (removing the toxic gas from items that were sterilized) can often be problematic, as these systems are commonly found in the lower floors of the hospital. These regulations often add substantially to the capital costs of installation and to operating costs in the form of increased maintenance.

Educational Programs and Medical Monitoring Costs

Due to the substantial toxicity of EtO, formal employee training and medical monitoring programs are mandated. These programs are neither inexpensive, nor voluntary, and often add considerably to the operating costs of an EtO sterilization system. According to Nancy G. Chobin, R.N., Director of Medical Center Education Services at St. Barnabas Medical Center in Livingston, New Jersey, “In addition to the OSHA-mandated yearly in-service training for EtO sterilization systems, the costs of training new employees, regardless of their experience, can run $2,000 or more per person.” Chobin noted that training included not only the operation of existing EtO systems but also the EtO spill plan, aeration contingencies, and other EtO-specific issues.

Emerging Technologies for Cost-Effective Sterilization

In the last several years, a number of novel sterilization technologies have undergone unprecedented testing in order to receive approval from the United States Food and Drug Administration (FDA). Included in these technologies is low-temperature hydrogen peroxide gas plasma, which has been sold in the United States since 1993.

In a recent cost analysis by Chobin in the Journal of Healthcare Material Management (Volume 12, 1994), the operating costs of three low-temperature sterilization systems were compared. In addition to general operating costs, such expenses as EtO and CFC recovery costs, carrying costs of excess inventory due to excessive cycle times and additional risk management costs were evaluated. Chobin studied two different EtO systems and one low-temperature hydrogen peroxide gas plasma system. According to her study, the low-temperature hydrogen peroxide gas plasma system was significantly less expensive to operate than either EtO system. Chobin’s study showed that the low-temperature hydrogen peroxide gas plasma system “…proved to be less expensive overall than either EtO system due to quicker total cycle times, lower utility use, and virtually no regulatory compliance issues.” While her hospital is not yet entirely EtO-free, that goal has been set for early 1996. “Our low-temperature hydrogen peroxide gas plasma system runs around-the-clock—we just need another unit to have the capacity to eliminate EtO completely,” said Chobin.

Conclusion

Unprecedented reductions in federal reimbursement to hospitals, coupled with the increasing role of tightly managed capitated programs, have left hospitals with little alternative to further reducing operating costs. Emerging sterilization technology can make a critical contribution to reduced operating costs while maintaining quality patient care. “Hospital administrators must decide to support technology as a whole. Minimally invasive surgery can offer enormous potential cost savings. Technology to clean and sterilize these new devices must also be available to the central supply staff—using 40-year-old technology (EtO) on instruments of the 21st century will not solve the problems of today,” noted Lind. “The hospital of the future must compete at all levels, including behind-the-scene technology, in order to offer the consumer the highest possible value for their healthcare dollar,” said Kuran.

Preparing for a Sterilization Emergency: New Technologies Reduce Risks for Patients and Employees

Hospital workers are exposed to numerous occupational health risks, including physical, infectious, and chemical hazards as part of their daily professional routine. Since the 1950s, central supply departments have used ethylene oxide (EtO), a colorless, odorless gas, for sterilization of heat- and moisture-sensitive surgical instruments. Though there is little question that EtO is an effective sterilant, it has also been recognized as a significant occupational hazard that requires hospitals to take special precautions in order to reduce the possibility of exposure for both workers and patients.

Ethylene oxide can cause a range of health problems, depending on the level of exposure. Symptoms such as eye, skin, and respiratory irritation, nausea, vomiting, and diarrhea have been reported from acute exposures, often at very low levels of EtO. Long-term EtO exposure may lead to cancer, neurological disease, or reproductive abnormalities, including genetic damage and spontaneous abortion.

In 1984, after several studies were published that identified these risks, the federal Occupational Safety and Health Administration (OSHA) issued a new standard that set the permissible exposure limit for EtO on a time-weighted average at one part-per-million (ppm) for an eight-hour shift. Later, OSHA established a short-term exposure...
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limit of five ppm over a 15-minute period. Along with these daily exposure limits, OSHA required employers to implement extensive exposure monitoring techniques as well as employee EtO emergency training programs to prepare workers in the event of an EtO spill or leak.

According to George Notarianni, President of Logan Associates, an occupational safety and health consulting firm in Novi, Michigan, “There have been dramatic improvements since OSHA introduced the EtO standard in 1984, but the OSHA rule doesn’t negate EtO’s problems. There is always a chance for human error or equipment malfunction.” Shanna Halpern, Executive Director of the Emergency Care Research Institute (ECRI) Center for Healthcare Environmental Management (CHEM), agrees, “As long as hospitals are using EtO, there is an exposure concern.”

In the August 1993 issue of Healthcare Hazardous Materials Management, ECRI Laboratories reported on surveys of central supply departments which showed that “emergency preparedness is rarely what it should be and rarely in compliance with the emergency requirements of the OSHA EtO standard.” Notarianni said that emergency preparedness varies dramatically from one hospital to another. Some hospitals have installed state-of-the-art alarm systems and have practiced emergency evacuation procedures, while others have yet to implement some of even the most basic protections. “Many hospitals have a l’aissez faire attitude about OSHA compliance. They say, ‘it can’t happen to me’,” he added.

In a 1992 paper in the American Journal of Industrial Medicine, LeMongagne and colleagues described a similar disparity among hospitals in the implementation of EtO training programs, noting “previous EtO training programs in some workplaces to be frequent, conscientious and well-received by workers. The norm, however, is that training is ineffective. It is typically brief and infrequent (on the order of an hour or so per year), instructor-centered and therefore passive, insensitive to the perspectives of the trainees, and disinclined to addressing organizational barriers to improvement of the workplace.”

While hospitals undoubtedly want to protect the safety of their employees, EtO emergency preparedness may assume a lower priority because of increasing time and cost constraints. (See previous article in this issue.) Recently, new sterilization technologies have become available that simplify training and reduce risks by eliminating the use of toxic sterilizing agents.

According to Halpern, many CHEM members, who include hospital safety officers, risk managers, and infection control supervisors, are exploring these new options when evaluating worker safety and compliance issues associated with EtO sterilization. “Our members are increasingly looking at alternatives to traditional EtO technologies in order to ensure compliance with regulatory mandates and reduce the risks of EtO exposure,” Halpern said.