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Emerging Issues for Professional Practice in Healthcare

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Abstract

The health and safety professional working in health care today faces many challenges in not only meeting accreditation and regulatory requirements, but also in providing a safe environment for staff and physicians so that they can provide a healing environment for their patients. We present here just a few of those challenges that are of most concern to health and safety professionals today: maintaining a safe care and work environment, shipping materials appropriately, sustaining process improvements, providing environments that support effective infection control and prevention and that reduce exposure to toxins. Our main focus will be on maintaining continuous readiness in environment of care for Joint Commission accreditation, sustaining EH&S and clinical process improvements, shipping clinical specimens and infectious substances, emerging issues in disinfection and sterilization technology, and control of hazardous drugs in the pharmacy and chemicals in the pathology laboratory. Resource tools will be provided to attendees of this session of the 2007 PDC.

Disinfection and Sterilization

Due to changes in the design of delicate medical devices over the last 15 years, the health and safety professional has needed to work closely with their infection control, sterile processing and biomedical engineering colleagues to devise strategies that ensure medical devices are appropriately cleaned and disinfected or sterilized for reuse. At Kaiser Permanente we have developed policies for consolidation of these functions wherever practical, to take advantage of economies of scale in staffing these areas with dedicated, competent individuals. This has the added advantage of freeing up clinical staff to provide direct patient care and reduces the interoperator variability of having multiple people perform the cleaning and disinfection or sterilization tasks. Also, building spaces that adequately control hazardous chemical vapors from reprocessing technologies is expensive, so reducing the number of them throughout the medical facility makes good business sense.

Determining which disinfectant or sterilization process to use can be confusing, since substances that are good at killing bacteria, viruses and spores are also harmful to other complex living systems like humans. It is impossible to make an effective sterilant that is also not harmful to humans unless the design of the process reduces or eliminates contact. Each technology has its advantages and disadvantages. We will look first at the different low temperature sterilization technologies and then survey cold liquid sterilants that are available in the market today to

reprocess semi-critical and critical medical devices that cannot be sterilized with high temperature steam.

Medical devices are categorized via the Spaulding scheme according to which kind of tissue they come in contact with. Devices that penetrate the skin and enter the sterile cavities of the body are considered critical medical devices and must be sterilized before reuse; devices that contact intact mucous membranes are considered semi-critical and must at least be high level disinfected; devices that touch only intact skin are consider non-critical and must be intermediate or low level disinfected.

Surgical hand tools and instruments such as scalpels, retractors, electrocautery wands, arthroscopes and the like must be sterilized. Instruments that are constructed of complex materials, such as viton rubber, may be deformed or lose structural integrity when exposed to high temperature steam and must be sterilized by low temperature means. The gold standard for low temperature sterilization is ethylene oxide (EtO), a reproductive toxin and suspected human carcinogen. Other technologies, such as hydrogen peroxide plasma gas and ozone have been developed in the last few years, but are limited by materials compatibility with some metals and plastics and in the length and diameter of the lumen that they can effectively reach. The advantages of these technologies are that the sterilant is completely contained within the sterilizer and is used up in the process, leaving only non-toxic waste products (water vapor) at the end of the cycle. No special ventilation controls and exhaust gas scrubbers are necessary to ensure staff safety or to prevent neighboring communities from exposure.

Flexible endoscopes, ultrasound transducers, and transesophageal echocardiogram probes are examples of semi-critical medical devices that may be high level disinfected if low temperature sterilization is not feasible. These instruments are typically constructed of materials that cannot be steam sterilized and some, like gastrointestinal endoscopes are too long, have too many channels or their channels are too small for the ethylene oxide sterilization alternatives. These instruments could be sterilized in EtO, but with a turnaround time of about 17 hours per cycle, this is not practical for most instruments used in the clinic setting, where for example an active GI clinic may conduct dozens of procedures per day.

This leaves high level disinfection with a liquid chemical sterilant the practical choice for many clinics. Glutaraldehyde has been in use for over 40 years and was developed as an alternative to formaldehyde, which is a carcinogen. While not a carcinogen, glutaraldehyde is a potent respiratory system irritant and may cause occupational asthma as well as contact dermatitis. *Ortho*-phthalaldehyde (OPA) has been in use for a little over five years and while it does not appear to be as strong a respiratory system irritant it is a potent skin sensitizer. It is not as soluble in water as glutaraldehyde and therefore care must be taken to ensure that instruments are thoroughly rinsed after disinfection to prevent patients who may undergo repeat procedures from developing an allergic sensitivity. This is why OPA is no longer allowed to be used to reprocess urological scopes, since bladder cancer patients may undergo several cystoscopies in the course of their treatment and several patients experienced anaphyllatic shock due to OPA sensitivity. In addition, untreated OPA is highly toxic to aquatic life and in some jurisdictions may not be allowed down the drain unless it is neutralized first. Liquid sterilants made from hydrogen peroxide or peracetic acid have some materials incompatibilities that may shorten the useful life of instruments. Both hydrogen peroxide and peracetic acid in the liquid form are toxic materials and their vapors are irritating to the respiratory tract and skin. All of these sterilants

should be controlled with local exhaust ventilation at the source of vapor generation, either by using slot exhaust, movable snorkel exhaust or filtering fume hoods.

Hazardous Drugs

A lot of interest and concern has been shown recently in nanotechnology, and health care health and safety professionals may encounter nanomaterials in new medicines that will be compounded in the pharmacy. While little is known about the chronic and acute health effects of exposure to nanomaterials, it seems likely that NIOSH will consider all nanomedicines as hazardous drugs and subject to the same precautions as outlined in their 2004 Alert. We don't yet know whether Class II Type B2 biological safety cabinets will be adequate protection for pharmacy technicians handling nanomedicines. The use of fully contained barrier isolators, or glove boxes, may supplant biological safety cabinets for sterile compounding of hazardous drugs in the future.

One therapy that may have been overlooked by health and safety professionals in the NIOSH Alert is BCG, a live virus that is injected into urology patients to treat bladder cancer. According to NIOSH, all hazardous drugs should be drawn up in a Class II Type B2 biological safety cabinet or negative pressure barrier isolator. Since these cabinets are rarely found outside of chemo pharmacies there is a risk of cross-contamination and therefore a concern with drawing up a live virus in a hood that is used to compound medications for severely immuno-compromised patients.

Since early 2005 facilities have been struggling over how to meet the new USP<797> regulations governing aseptic compounding of drugs. Health and safety professionals have gotten involved mainly over the matter of environmental air and surface sampling, intended to provide some level of assurance that staff are practicing good aseptic technique, that the facility is providing air of the cleanest quality and that housekeeping is eliminating sources of biological contamination. All high risk compounding must take place in an ISO Class V environment, which must be tested with particle counters periodically. Wipe samples of the insides of BSCs and other environmental surfaces show whether drug contamination is happing inside the cabinet and whether biological growth is curtailed outside of it.

Pathology Laboratories

While not a new issue, adequate control of hazardous chemicals in the pathology and histology laboratories can be difficult to achieve. Because pathologists prefer to work on open cutting boards with formaldehyde soaked tissue, designing and installing effective ventilation controls is key to controlling exposure during grossing anatomic specimens. In addition, the process of turning that piece of tissue into a glass slide for microscopic examination also involves various dyes and solvents such as xylenes, alcohols, picric acid and toluene. Each stage of the histology process, from embedding the tissue in paraffin, to slicing wafer-thin ribbons for placement on slides, to staining and coverslipping the slides, offers the opportunity for exposure. The biggest challenge is for the health and safety professional to adequately address the needs of the pathologist to have an open work space within the limits of physics to provide adequate ventilation capture over that open surface. This can be achieved by having the pathologist work inside a fume hood equipped with a sink, work at a commercially available pre-fabricated grossing station or work on an open bench top with local exhaust ventilation, in order of

decreasing effectiveness. Slide staining and coverslipping should also be preferentially performed in a ventilated enclosure or fume hood, as should manually staining and covering slipping.

Other hazards to be considered are potential sharps injuries from scalpels and knives and ergonomic injuries from standing at fixed work heights for extended periods of time. An innovative technology for dispensing and disposing of scalpel blades allows for hands' free manipulation of the blade into and out of the holder. Use of a Head and Neck Surgeon's stool with adjustable and swing-away arms, in conjunction with a powered adjustable height grossing station allows for seated or standing grossing.

Managing the Environment of Care

The Joint Commission specifies accreditation standards for participating healthcare institutions. One area of focus is the environment of care. In years past, the Joint Commission limited surveys to periodic and, rarely, for-cause audits of an accredited survey. Surveys were predictable and survey preparation was observed as a phenomenon associated with the Joint Commission visits. The Joint Commission has recently started a process of unannounced surveys with intent of the facility achieving continuous readiness. Often EH&S professionals are challenged with ensuring compliance with the environment of care standards. The top Joint Commission survey findings for the current review cycle of which two are related to environment of care include:

- Goal 2 (59%) Improve the effectiveness of communication among caregivers.
- MM.2.20 (40%) Medications are properly and safely stored.
- Goal 8 (38%) Accurately and completely reconcile medications across the continuum of care.
- EC.5.20 (28%) Newly constructed and existing environments of care are designed and maintained to comply with the Life Safety Code ®.
- UP 1 (28%) The organization fulfills the expectations set forth in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ and associated implementation guidelines.
- MM.3.20 (26%) Medication orders are written clearly and transcribed accurately.
- PC.8.10 (19%) Pain is assessed in all patients.
- EC.1.10 (18%) The hospital manages safety risks.
- Goal 3 (18%) Improve the safety of using medications.
- IM.6.10 (17%) The hospital has a complete and accurate medical record for every patient assessed, cared for, treated, or served.
- PC.13.20 (15%) Operative or other procedures and/or the administration of moderate or deep sedation or anesthesia are planned.

Use of an environment of care checklist may help in maintaining continuous readiness and is useful in tracking actionable items to resolve issues identified in audits. PDC conference attendees will be provided with a comprehensive Environment of Care checklist in Microsoft Excel format.

Shipping Biological Specimens

The U.S. Department of Transportation (DOT) regulates the transportation of dangerous goods within the United States. Historically, the DOT offered relief from some international shipping

requirements in order to facilitate commerce with minimum burden to shippers. Since September 11, 2001; the regulatory landscape has changed. Regulations for shippers have been going through a process of harmonization with United Nations (UN) prescribed practices. The UN, through a World Health Organization workgroup, promulgates consensus standards for international shipping and shipping by air. A few organizations publish the UN shipper requirements including IATA, a commercial air carrier professional association. As a result of the harmonization process, DOT regulations are becoming more aligned with the UN requirements including those which address shipping of infectious substances, clinical specimens and biological substances. As recently as January of 2007, changes have been in effect which change the packaging, labeling and shipping documentation associated with these substances. Included in the changes are new proper shipping names and classification of biological substances into two categories for purposes of shipping. Noted are increased enforcement by the Federal Aviation Agency, DOT and CLIA (a lab certifying body). The WHO guidelines and IATA shipping guides for biological substances are provided for PPDC session attendees. More information on shipping biological substances is available from a number of vendors and the IATA and DOT websites.

Sustaining Process Improvements

EH&S professionals are often included in various process improvement initiatives and help create solutions to operational problems in delivering healthcare. The authors find it is often the case that solutions and improvements do not sustain in the long term. Perhaps we are better at problem-solving than improvement-sustaining. This topic is being included as a PDC proceedings topic in order to offer participants a newly published guide from the National Health Service Institute in the United Kingdom. PDC session attendees will receive a copy of the NHS Institute Sustainability tool. The tool is an assessment of process, staff and organizational factors leading to sustained improvement. Each assessment probe is scored with appropriate weighting and aggregate scores have shown to be reliable predictors of sustainability. Regardless of the process improvement, this tool can help the EH&S professional predict where more work needs to be done to prepare an organization for sustained improvement. The tool can be used to retroactively assess why a process may have failed. Of great benefit are our pull guides to help address issues identified in each of the areas of weakness. Have a score over 55? The process is likely to sustain itself in the work environment.

Summary

EH&S professionals in healthcare practice face a number of challenges. Hospitals have safety and environmental challenges and elements associated with the hospitality, construction, manufacturing, laboratory, security and transportation industries in addition to hazards unique to the care environment. A panel discussion with appropriate tools at a professional development conference can help EH&S professionals in healthcare address many emerging issues impacting healthcare operations.

We have provided information and tools to help maintain continuous readiness in environment of care for Joint Commission accreditation, sustain EH&S and clinical process improvements, ship clinical specimens and infectious substances and covered emerging issues in disinfection and sterilization technology, and control of hazardous drugs in the pharmacy and chemicals in the pathology laboratory.

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