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To: Grace V. Delizo 9 January 2019
Senior Safety Engineer
Cal/OSHA Research and Standards Health Unit

From: Leonard Schultz, M.D.
Chief Manager
Nascent Surgical, LLC

Re: Comments to the Final Rules Committee of Cal/OSHA Standards Board

Dear Ms. Delizo,

This is the third in a series of comments that I have asked Cal/OSHA to consider on the topic of Occupational Exposure to Surgical Plume.

I believe that the deliberations currently being pursued by the members of the Cal/OSHA Rules Committee regarding capture and removal of surgical plume from the operating room will have significant, continuing impact on the short and long-term health of the State of California's operating room workers and likely, others within the United States. The recognition of surgical plume as a potentially toxic environmental contaminant has taken over fifty (50) years to accept. This realization was hastened because of the efforts of the International Standards Board (ISO 16571:2014), the Joint Commission on the Accreditation of Hospitals (TJC) and the Rhode Island state legislature (Law # H 5324). Despite these advances, progress in protecting the health of the perioperative employee will not occur until an effective minimum standard for smoke evacuation is established by this Rules Committee.

In an effort to affect the discussion that will establish such a Standard, I offer the following statements of fact followed by a preliminary, some might call naïve, cost vs. benefit analysis.

A. Statement of Facts.

1. Surgical smoke or "plume" consists of 80% nanoparticles as well as viruses, bacteria, cellular debris, trace gases with mutagenic and carcinogenic potential and vapor and associated particulates.
2. Such smoke components are capable of contributing to the development of various worker illnesses which include:

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a. Infectious diseases such as tuberculosis and human papilloma viral lesions.
b. Various respiratory illnesses at a rate twice that found in the general United States population resulting in increased absenteeism.
c. Cancers such as breast, pancreatic and prostate.
d. Coronary artery disease and cardiac arrthymias.
e. Collagen diseases such as lupus erythematosus and arthritis.
f. Neurodegenerative diseases such as Parkinsonism and Alzheimer's disease.

Workers who develop these illnesses through chronic inhalation of smoke, reflect individual variances of genetic, pre-existing illnesses and dose/duration of exposure. As I have argued in previous correspondence, we cannot forecast any one worker's sensitivity to exposure to smoke, thus the need for the universal capture and removal of plume from the working environment.

3. Face masks that are currently in use, do not protect the worker from chronically inhaling harmful nanoparticles ("ultrafine particles") present in the plume.
4. Operating room filtration systems do not adequately remove harmful smoke particulates during surgery because the procedure itself replenishes the particulates faster than they can be cleared by the in-place filters. This has led to the need for local exhaust ventilation (LEV) in the form of point-of-care smoke capture devices to supplement current ventilation systems.
5. Modern day smoke evacuation "system" machines are turbines that can, with a point of contact disposable smoke capture device and connected to a 7/8" I.D. tubing, generate the 25-35 cubic feet/minute (CFM) of air flow needed to capture smoke at the minimum requirement of 90% "smoke capture efficiency" as recommended by ISO 16571 published in 2014.
6. Current smoke capture technology is available that achieves superb protection of personnel while protecting their employers from the potential financial liability of future workman compensation claims. Such technology is also in the process of showing that it can reduce the rate of post-operative wound infections through capture of ambient bioaerosols that contaminate the surgical wound. Such

reductions in infection rates hold the promise of reducing the cost to hospitals treating such infections by millions of dollars on a yearly basis.

7. Use of smoke evacuation systems in the United States is currently about 15% vs. Canada where it is used in 80% of surgical cases. The difference lies in the lack of education of American surgeons about the dangers of chronic smoke inhalation as reflected by the absence of articles on the topic in our surgical journals. This is not true of United States nursing journals (AORN) that have educated their readership about smoke issues resulting in that group (eg. California Nurses Association) being the strongest advocates for smoke removal from our operating rooms.
8. Lack of education of physicians about the dangers of smoke has led to a significant problem regarding their compliance with the requirements of TJC to adhere to smoke evacuation policies in our hospitals. Current technology is often rejected by surgeons citing interference with their vision and hand fatigue although a newer cell foam based non-handheld capture device is available as an alternative which can overcome their objections for use.

Now is the time to establish a minimum Standard for smoke capture in California's operating rooms , primarily because of currently available technology that can allow a 90% "smoke capture efficiency" as recommended by the ISO 16571:2014 publication. Such a Standard should provide the protection for the perioperative worker from the short and long-term effects of chronic inhalation of nanoparticles within the surgical plume.

The question now is, "What is the economic argument for use of such technology in the State of California hospitals?"

B. Cost of Smoke Evacuation Technology.

Smoke evacuation "systems" consist of:

1. Disposable smoke capture device.
   a. Electrosurgical monopolar unit "pencil" or "pen."
   b. Cell foam based plenum or pad.

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2. Tubing.
   a. "Wand" or 7/8" I.D. tubing.
   b. 3/8" I.D. corrugated flexible tubing embedded or attached to the electrosurgical electrode; collectively called the "ESU pencil."
   c. 1 ¼" I.D. corrugated, flexible tubing attached to the cell foam based plenum called the "miniSquair."
3. The Filter.
   a. ULPA filter. Most commonly used for smoke filtration in evacuator systems. Specified to be able to contain particulates down to 0.1 um (100 nanometers) in size at 99.9999% efficiency.
   b. HEPA filter. Used to capture particulates down to 0.3 um (300 nanometers) usually in a closed system where the filtered air is removed from and not replaced back into the operating room ambient air. Most commonly part of a canister fluid removal system.
4. The LEV (local exhaust ventilator) or "smoke evacuator" which most commonly is a stand-alone device but more recently, made part of a fluid management system (eg. Stryker Neptune). The air flow rate or suction generated, ranges from 22-25 cfm to 45 cfm and their noise levels range from 45 db to over 55db with continued exposure to 60 db or greater, being capable of impairing human hearing.

C. The Average Cost/Use of These Components (end piece, and tubing considered as a single unit):

1. End piece (smoke capture device and attached tubing)
   Average cost/use: $20
2. ULPA filter
   Average cost/use: $17.50
3. Smoke evacuator
   Average cost/use: $1.20

Total Cost/use (Case) $38.70

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Above based on an average cost/ULPA filter of $350/U. with an average use of 20 hours and an average cost of a smoke evacuator is $3,000/U. with a 5 year life or $600/year used in approximately 500 cases/year.

D. Assumptions:

1. California has approximately 1/10th the U.S. population. Assume they do 1/10th the surgical cases /year in the U.S. (20,000,000) or 2 million invasive, therapeutic cases/year.
2. 40% of the cases are "open" and 60% are laparoscopic or minimally invasive not requiring open smoke capture systems. This results in about 800,000-1 million cases/year.
3. The total potential cost to California/year for mandated smoke evacuation in all open surgical procedures ; $39,710,000.
4. There are 500,000 perioperative employees in the United States; assume 1/10th as many in California or 50,000 operating room workers.
5. Assume 5% of those workers will file workman compensation claims/year or 2,500 claims made /year. For comparison, there were 81,842 "open" worker compensation cases in 2017 at a min/max payment of $15,884/$47,652 or an average of $31,768/case. This required $1.3B. in medical and indemnity payments with $4.5 B. in estimated claim reserves.
6. The potential workman/disability compensation costs/year in the State of California:

   $79,420,000.

   To this number, add the cost of perioperative worker absenteeism with overtime payments to compensate for the absence rate and then subtract the savings to the health systems by reducing the millions + cost of caring for those with post-operative infections readmitted to the hospitals for care.

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Conclusion:

Data suggests that it would more than pay to do the right thing and mandate smoke capture for open surgeries done in California's operating rooms so long as a high minimum Standard for "smoke capture efficiency" is issued as the Final Rule, perhaps modeled after the ISO 16571:2014 guidelines.

Respectfully submitted,
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