NIOSH Investigations of Surgical Plume and Smoke Hazards

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Cal/OSHA Advisory Meeting for Protection of Employees from Surgical Plume and Smoke

Oakland, CA
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Background

- **Surgical plume: focus of attention as a potential occupational hazard to operating room (OR) personnel**
  - surgical plume particles
  - chemical by-products produced
  - possible infectious agents aerosolized
  - widespread use of surgical plume-producing equipment
  - large number of OR personnel exposed to plume
  - concern for acute and chronic health impacts

Disclaimer

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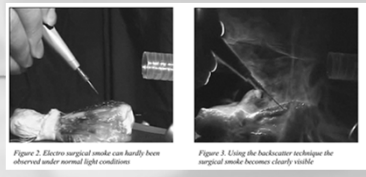


Figure 2. Electro surgical smoke can hardly been observed under normal light conditions

Figure 3. Using the backscatter technique the surgical smoke becomes clearly visible

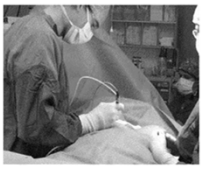


Figure 10. In the OR during a mamma reduction procedure using electrosurgery the smoke is hardly visible during normal light conditions. However, the OR personnel can smell it.

Figure 11. Using the special backlight illumination technique, the surgical smoke becomse visible and it shows to move along the face of the surgeon when no evacuation is used .

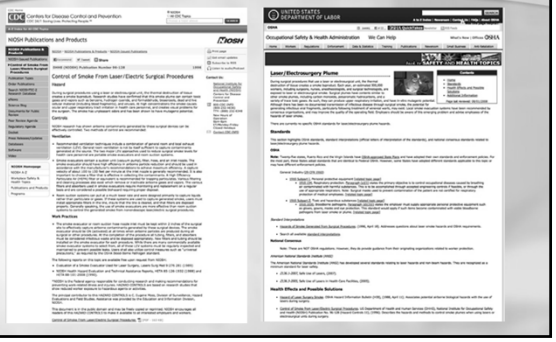
DeBoorder T, et al [2007]. The Visualization of Surgical Smoke Produced by Energy Delivery Devices: Significance and Effectiveness of Evacuation Systems. Thermal Treatment of Tissue: Energy Delivery and Assessment IV. Ed: Thomas P. Ryan. Proc. Of SPIE, Vol. 6440, 64400R.

Background

- Several energy-based instruments, including:
  - Electrosurgical unit (ESU)
  - Harmonic scalpel
  - Carbon dioxide (CO_2) and other lasers
  - Neutral plasma coagulator
- Commonality: destruction of tissue through energy applied to it and resultant production of considerable quantities of plume

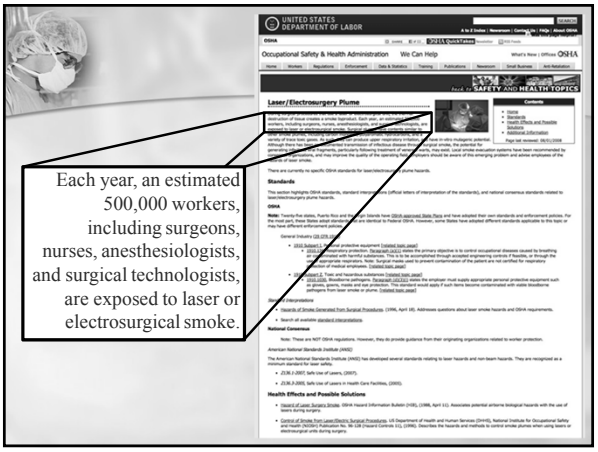
Background

Background

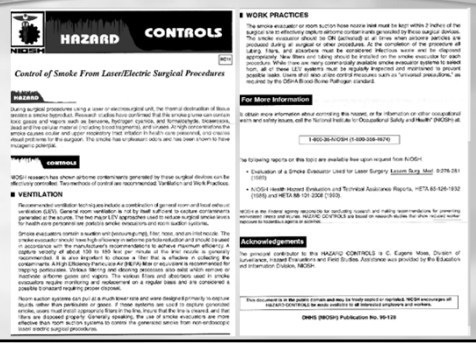


NIOSH HHEs (1985–1990)

- University of Utah, UT (1990)
  - Laser surgical procedures:
    - humans in OR or clinic
    - mice tumors in animal laser laboratory
  - Chemical compounds detected:
    - ethanol and isopropanol detected below occupational exposure limits (OELs)
    - formaldehyde detected in all but one sample
      - two short-term samples (0.21–0.44 ppm) sufficient to cause irritation in some sensitive individuals
    - cyanide detected below OEL
      - direct reading tube at laser irradiation site: 100 ppm for hydrogen cyanide
  - Solvent extracts of airborne particles found to be mutagenic
  - **Conclusion**: potential hazard from exposure to the constituents of the smoke, stressing the importance of using smoke evacuators



NIOSH Hazard Control (1996)



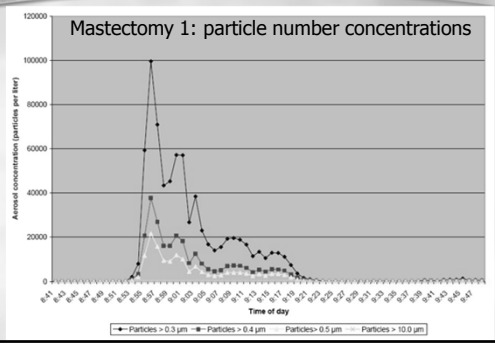
NIOSH HHEs (1985–1990)

- Bryn Mawr Hospital, PA (1988)
  - Electrocautery knife use during reduction mammoplasty surgeries
  - Health effects reported:
    - headache, nausea, upper respiratory and eye irritation
  - Particle mass concentrations:
    - range: 0.4–9.4 milligrams per cubic meter of air (mg/m^3)
    - mean: 2.75 mg/m^3
  - No specific organic vapors, other than isopropanol, detected
  - No polynuclear aromatic compounds (PNAs) or nitrosamines detected
  - Solvent extracts of airborne particles were mutagenic to the *Salmonella typhimurium* TA 98 strain
  - **Conclusion**: potential hazard from exposures on basis of mutagenicity and acute health effects reported

NIOSH HHEs (2001–2006)

- Falls Church, VA; Charlotte, NC; and Dunedin, FL hospitals:
  - symptom questionnaire (66–92% response rate)
    - surgical nurses, anesthetists, and surgical technicians
  - at least 1 symptom associated with plume exposure: 36–52%
    - eye irritation: 10–24%
    - burning of nose or throat: 13–18%
    - headache: 16–21%
    - coughing: 10–24%
    - nasal symptoms 3–16%
    - asthma or asthma-like symptoms after beginning work in OR: 2–24%
  - personal breathing zone (PBZ) and area air samples collected:
    - 15 procedures over 3 days at each hospital
    - sampled for: volatile organic compounds (VOCs), acrolein, phenol, cresols, hydrogen cyanide, formaldehyde, acetaldehyde, polycyclic aromatic compounds, carbon monoxide, direct-reading particle monitoring
    - results: quantified formaldehyde, acetaldehyde, toluene, but well below applicable OELs

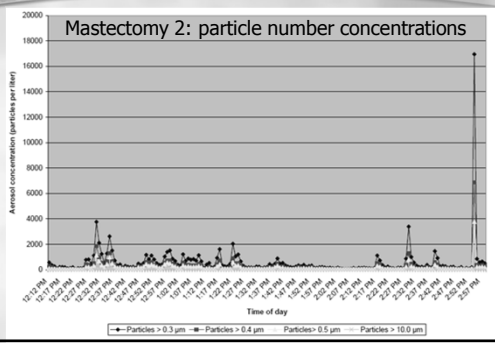
NIOSH HHEs (2001–2006)



"There have been too few studies, each accounting for different tissue types, laser devices, and operational parameters to draw any definitive conclusions with respect to the true range of particulate matter diameter. Furthermore, several of these studies sampled at locations that were within centimeters of the operative site; thus, it is not clear how the size distributions measured correspond to those experienced in the breathing zone of laser operators. The generation of a more comprehensive data set that is representative of the various possible exposure scenarios is imperative for designing adequate control strategies."

- Pierce JS, Lacey SE, Lippert JF, Lopez R, Franke JE [2011]. Laser-generated air contaminants from medical laser applications: a state-of-the-science review of exposure characterization, health effects, and control. Journal of Occupational and Environmental Hygiene. 8(7):447–466.

NIOSH HHEs (2001–2006)



Surgical Plume Particle Characterization Study

- **Aim 1:**
  - Characterize surgical plume particles at the point of generation during experimental trials of plume generation
- **Aim 2:**
  - Characterize surgical plume particle at personal breathing zone (PBZ) level at the surgical table during experimental trials of plume generation
- **Aim 3:**
  - Measure surgical plume particle concentrations at locations reflective for exposures of operating room personnel during actual surgical procedures

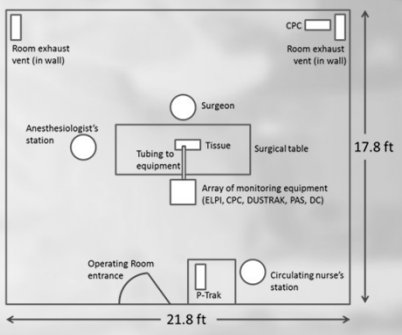
NIOSH HHEs (2001–2006)

- Falls Church, VA; Charlotte, NC; and Dunedin, FL hospitals:
  - Recommendations:
    - implement engineering controls during procedures where surgical smoke is produced
      - combination of general room ventilation and LEV positioned as close as possible to the point of smoke production
    - report instances of health symptoms thought to be associated with exposure to surgical smoke to the hospital's occupational health staff

Aim 1: Point of Generation

- Surgical instruments used for plume generation:
  - electrosurgical unit (ESU)
  - harmonic scalpel
  - carbon dioxide (CO_2) lase
  - neutral plasma coagulator
- Skin tissue
- Measurements at point of generation:
  - particle size distribution
  - particle number concentration
  - respirable mass concentration estimates
  - particle-adsorbed polycyclic aromatic hydrocarbons (pPAHs)
  - active surface area measurements
- Measurements at two locations in OR periphery:
  - particle number concentrations

Aim 1: Point of Generation

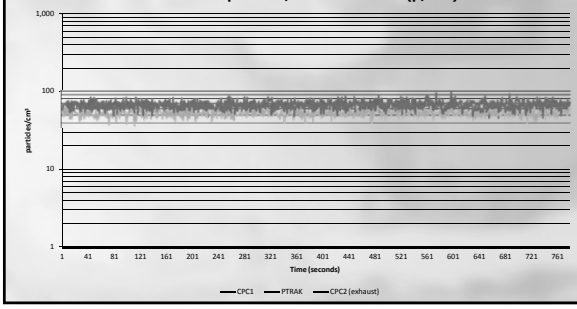


Aim 1: Point of Generation

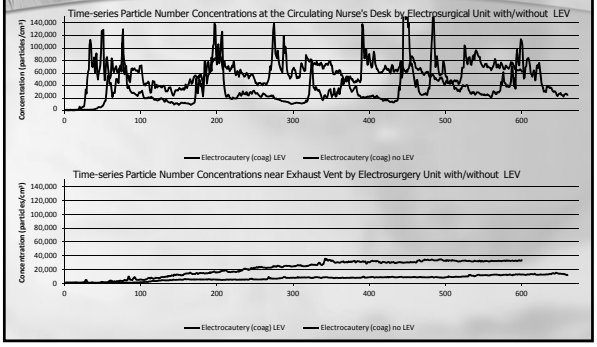
- Count median diameter:
  - smallest: 0.034 (harmonic scalpel) and 0.041 µm (neutral plasma coagulator)
  - largest: 0.095 µm (ESU)
- GM particle number concentrations:
  - lowest: 711,000 p/cm^3 (harmonic scalpel)
  - highest: 15,200,000 (neutral plasma coagulator) and 76,900,000 p/cm^3 (CO_2 laser)
  - reductions in concentrations when built-in LEV used for ESU:
    - Point of generation: 76–87%
    - Circulating nurses desk: 37–65%
    - Near exhaust vent: 60–69%
- GM respirable mass concentrations:
  - lowest: 0.0629 mg/m^3 (neutral plasma coagulator)
  - highest: 158 mg/m^3 (CO_2 laser)
- Ratio of GM pPAH/GM active surface area
  - Lowest: 0.05 (neutral plasma coagulator) and 0.09 (harmonic scalpel)
  - Highest: 0.32–0.93 (ESU)

Aim 1: Point of Generation

Background geometric mean (GM) particle number concentrations: 53–67 particles/cubic centimeter (p/cm³)

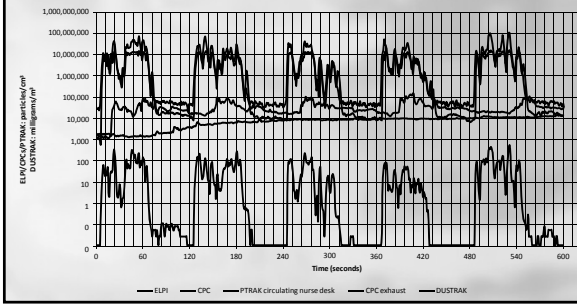


Aim 1: Point of Generation



Aim 1: Point of Generation

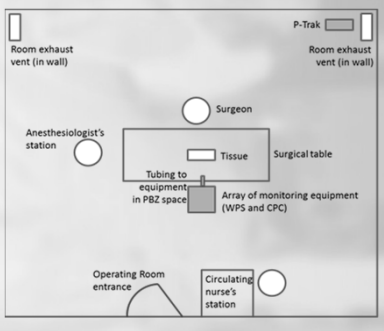
Electrocautery knife (cut), without LEV: Particle Number and Respirable Mass Concentrations



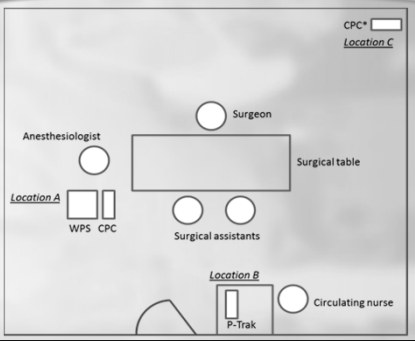
Aim 2: PBZ

- Surgical instruments used for plume generation:
  - electrosurgical unit (ESU)
  - harmonic scalpel
  - carbon dioxide (CO_2) lase
  - neutral plasma coagulator
- Skin and fat tissue
- Measurements at PBZ of surgeon:
  - particle size distribution
  - particle number concentration
- Measurements in OR periphery:
  - particle number concentrations

Aim 2: PBZ



Aim 3: Surgeries



Aim 2: PBZ

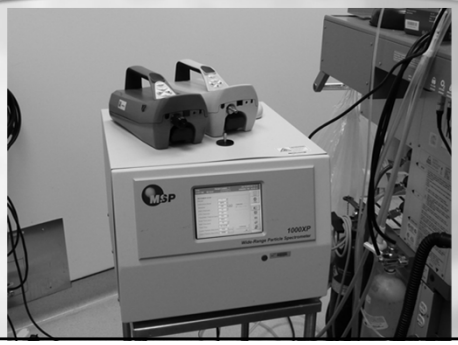
- Count median diameter:
  - smallest: 0.028–0.038 µm (harmonic scalpel) *[vs. 0.034 µm]**
  - largest: 0.088–0.190 µm (ESU) *[vs. 0.095 µm]*
- GM particle number concentrations:

  Surgeon:
  - lowest: 200–500 p/cm^3 (harmonic scalpel) *[vs. 711,000 p/cm^3]*
  - highest: 68,000–109,000 p/cm^3 (neutral plasma coagulator) *[vs. 15,200,000 p/cm^3]*

  Periphery of room:
  - lowest: 50–500 p/cm^3 (harmonic scalpel)
  - highest: 37,000–67,000 p/cm^3 (neutral plasma coagulator)

*italicized data indicate results from point of generation measurements for comparison

Aim 3: Surgeries



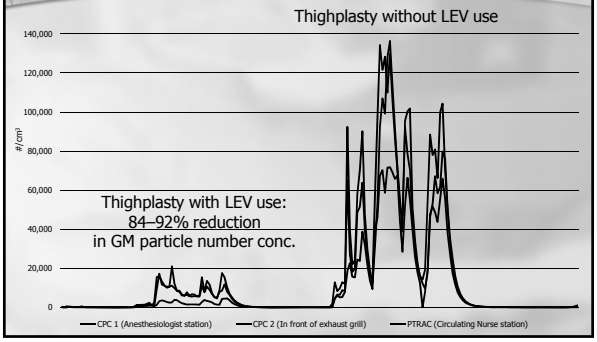
Aim 3: Surgeries

- surgical suite field studies:
  - hospital operating room in NY State
    - HEPA filtered air
    - ~22-25 air changes per hour (ACH)
- worker focus:
  - primary: near the surgical table
    - particle size distribution
    - particle number concentration
  - secondary: at the periphery of the room
    - particle number concentrations
- selected procedures:
  - two plume-producing instruments (electrosurgical unit and neutral plasma coagulator) and multiple tissue cuts
- direct-reading monitoring:
  - before and throughout the course of the procedure

Aim 3: Surgeries

- Thighplasty and brachioplasty (ESU and neutral plasma coagulator)
  - CMD: 0.091–0.105 µm
  - GM particle number concentration: 8,500–24,000 p/cm^3
  - Max particle number concentration: 136,000 p/cm^3
  - With LEV, CMD : 0.035–0.042 µm
  - 84–92% reduction in GM particle number concentrations
- Breast augmentation (ESU and neutral plasma coagulator)
  - CMD: 0.098–0.099 µm after ESU or neutral plasma coagulator use
  - CMD: 0.035 µm after neutral plasma coagulator for antibacterial use
  - GM particle number concentration: 230–250 p/cm^3
  - Max particle number concentration: 6,800 p/cm^3
- Necrotic tissue removal (ESU)
  - CMD: 0.092 µm after ESU use
  - GM particle number concentration: 890–1,900 p/cm^3
  - Max particle number concentration: 11,000 p/cm^3

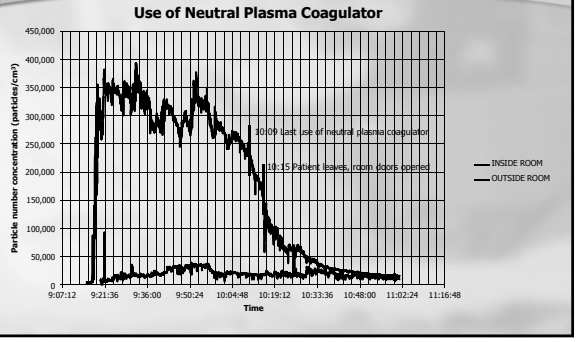
Specific Aim 3: Surgeries



Recent Research Articles

- Sisler JD, Shaffer J, Soo JC, Lebouf R, Harper M, Qian Y, Lee T [2018]. In vitro toxicological evaluation of surgical smoke from human tissue. J Occup Med Toxicol. 13. 12. DOI: 10.1186/s12995-018-0193-x.
  - surgical smoke collected in real time in cell culture media by using an electrocautery device to cut and coagulate human breast tissues, followed by exposure to human small airway epithelial cells (SAEC) and mouse macrophages (RAW)
  - airborne particle number concentration and particle distribution
  - airborne concentration of selected volatile organic compounds (VOCs)
  - chemical properties and in vitro cellular toxicity were analyzed

Sampling in Medical Office Environment



Recent Research Articles

- Sisler JD, Shaffer J, Soo JC, Lebouf R, Harper M, Qian Y, Lee T [2018]. In vitro toxicological evaluation of surgical smoke from human tissue. J Occup Med Toxicol. 13. 12. DOI: 10.1186/s12995-018-0193-x.
  - average count median diameters: 0.092 µm
  - average particle number concentrations: 900–54,000 p/cm^3
  - acetaldehyde, ethanol and isopropyl alcohol detected in every sample with higher concentrations compared to other VOCs
  - surgical smoke caused approximately 25% cell death in the SAEC and 40% in the RAW cells compared to background and field blank
    - toxic in both the SAEC and RAW although to varying degrees

Surgical Plume Particle Characterization Study

- Recommendations:
  - develop employer policies for utilizing local exhaust ventilation controls when using equipment that produces surgical plume
  - train hospital and medical office staff on the potential hazards of surgical plume and control methods that can be used to minimize exposures
  - ensure operating rooms achieve recommended minimum total and outdoor air changes per hour and are maintained under positive pressure relative to adjacent corridors

Recent Research Articles

- Lee T, Soo JC, LeBouf RF, Burns D, Schwegler-Berry D, Kashon M, Bowers J, Harper M [2018]. Surgical smoke control with local exhaust ventilation: Experimental study. J Occup Environ Hyg. 15(4):341–50. DOI: 10.1080/15459624.2017.1422082
  - surgical smoke generated from human tissue in an unoccupied operating room using an electrocautery device for 15 min
    - (1) without LEV control
    - (2) control with a wall irrigation suction unit with an in-line ultra-low penetration air filter
    - (3) control with a smoke evacuation system
  - particle number and mass concentrations were measured
  - selected VOCs were collected

Recent Research Articles

- Lee T, Soo JC, LeBouf RF, Burns D, Schwegler-Berry D, Kashon M, Bowers J, Harper M [2018]. Surgical smoke control with local exhaust ventilation: Experimental study. J Occup Environ Hyg. 15(4):341–50. DOI: 10.1080/15459624.2017.1422082
  - ethanol and isopropyl alcohol were predominantly detected in every sample with relatively high concentrations compared to other VOCs
  - average ratios of LEV controls to without LEV control ranged 0.24–0.33 (particle number concentration) and 0.14–0.31 (particle mass concentration)

NIOSH HCW Survey: Surgical Smoke

- Surgical smoke questions:
  - control practices for those who work within 5 feet of a source
  - years exposed
  - hazard training
  - workplace procedures and guidelines that address surgical smoke from laser surgery and/or electrosurgery

NIOSH HCW Survey

- Health and Safety Practices Survey of Healthcare Workers (HCW)* (Jan–Mar, 2011)
  - anonymous, web-based
  - multi-module:
    - aerosolized medications
    - anesthetic gases
    - antineoplastic drugs
    - chemical sterilants
    - high level disinfectants
    - surgical smoke

*Steege AL, Boiano JM, and Sweeney MH [2016]. Secondhand Smoke in the Operating Room? Precautionary Practices Lacking for Surgical Smoke. Am J Ind Med 59(11):1020–1031.

NIOSH HCW Survey: Surgical Smoke

Results: Local Exhaust Ventilation (LEV)

- always used: 47%^{L}, 14%^{E}
- never used: 31%^{L}, 59%^{E}
- recommendation:
  - have employees use LEV for all procedures where surgical smoke is generated

^{L}=laser surgery, ^{E}=electrosurgery

NIOSH HCW Survey: Surgical Smoke

- Study population (n=4,533 respondents):
  - members of professional practice organizations representing healthcare occupations which routinely come in contact with surgical smoke, including:
    - nurse anesthetists
    - anesthesiologists
    - surgical technologists and assistants
    - perioperative nurses

NIOSH HCW Survey: Surgical Smoke

Results: Hazard training

- never received: 49%^{L}, 44%^{E}
- received >12 months ago: 29%^{L}, 32%^{E}
- recommendation:
  - train employees on hazards and methods to minimize exposure prior to working in areas where surgical smoke is generated

NIOSH HCW Survey: Surgical Smoke

Results: Employer procedures

- no employer standard procedures addressing surgical smoke hazards: 31%[L], 29%[E]
- unknown if employer had standard procedures: 39%[L], 40%[E]
- recommendation:
  - ensure procedures that address the hazards of surgical smoke are available

Health Effects Research

- Few well-designed, large scale epidemiological studies of HCW populations investigating extent of health effects from plume exposure
  - animal model studies of effects in the literature
  - smaller comparative studies and questionnaires shown that exposure associated with acute eye and respiratory irritation, at minimum
  - handful of case reports of laryngeal papillomas
- Vital to continue to investigate the risk of health effects that health care workers are under

NIOSH HCW Survey: Surgical Smoke

Results: Personal protective equipment

- N95 always used: 6%[L], 1%[E]
- N95 never used: 90%[L], 98%[E]
- laser & surgical masks used: 90%[L], 98%[E]
- recommendation:
  - use a properly fitted, filtering facepiece respirator (e.g., N95) rather than a surgical or laser mask, especially in situations where LEV is lacking

Acknowledgements

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- Dr. Jennifer Sisler et al., Dr. Taekhee Lee et al., NIOSH/HELD
- Dr. Peter Lees, Johns Hopkins Bloomberg School of Public Health
- Dr. Denis Branson, Fayetteville, New York

NIOSH HCW Survey: Surgical Smoke

https://www.cdc.gov/niosh/topics/healthcarehsps/smoke.html

What we found	What employers/employees should do
Only half (47%) of respondents reported that LEV was always used during laser surgery and even fewer (14%) reported that LEV was always used during electrosurgery. One of every three respondents said that LEV use was not part of their employer's protocol.	Have employees use LEV for all procedures where surgical smoke is generated. Smoke evacuators should be used in situations where considerable plume is generated and room wall suction systems should be used for controlling small amounts of smoke when there is adequate room air ventilation.[3,5,6]
49% of laser surgery respondents and 44% of electrosurgery respondents said that they never had training that addressed the hazards of surgical smoke.	Train employees on the hazards of surgical smoke and methods to minimize exposure prior to working in areas where surgical smoke is generated.[4]
Approximately 30% of both laser surgery and electrosurgery respondents said that their employer did not have standard procedures addressing surgical smoke hazards and about 40% did not know if they did or not.	Ensure that procedures that address the hazards of surgical smoke are available.[3]
90% of laser respondents and 98% of electrosurgery respondents used laser masks or surgical masks which do not provide respiratory protection.	Use a properly fitted, filtering facepiece respirator (e.g., N95) rather than a surgical or laser mask, especially in situations where LEV is lacking or not functioning properly. Respiratory protection should be at least as protective as a fit-tested N95 filtering facepiece respirator when working with known disease transmissible cases (e.g., HPV) and/or during aerosol-generating procedures or with aerosol transmissible diseases (e.g., TB).[4]

Thank You

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