Burden and Epidemiology of Surgical Smoke Evacuation

Value Analysis Brief

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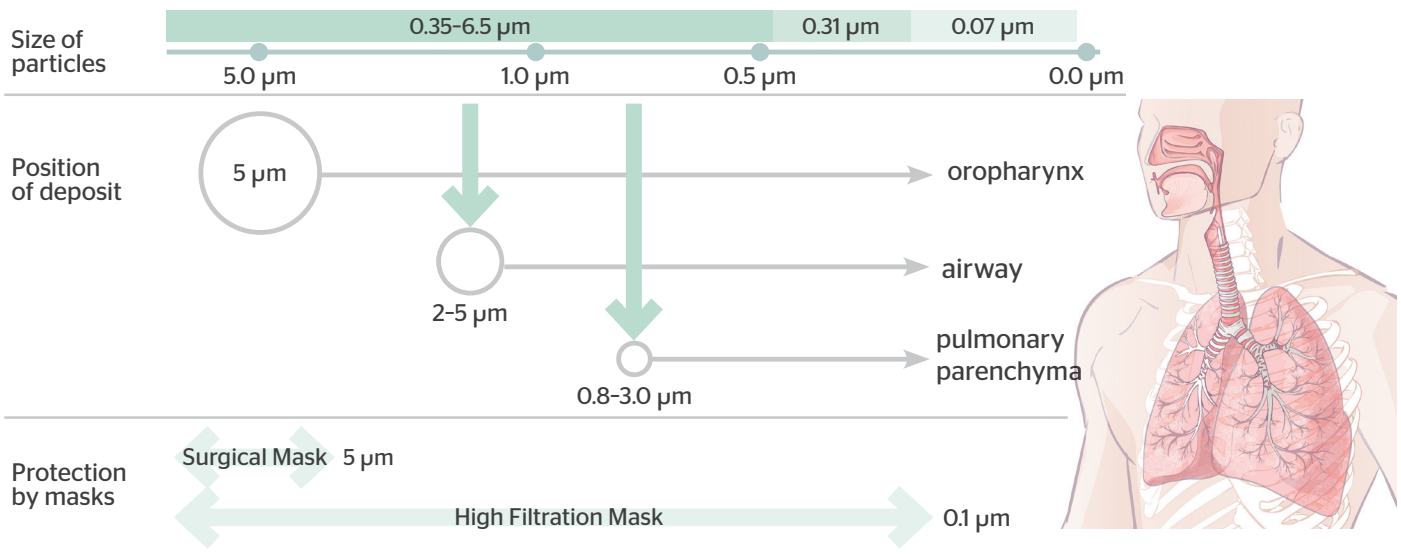
EPIDEMIOLOGY AND CHARACTERIZATION OF SURGICAL SMOKE

Surgical smoke is formed when energy-generating devices (electrosurgery units, lasers, powered instruments) raise the intracellular temperature of tissue to at least 100°C (212°F), causing tissue vaporization.[1] Electrocautery smoke may pose potential health risks for the nearly one million surgical staff around the world.[2]

- A systematic review of potential health implications of surgical smoke for operating room staff reported that the size of particles found in all types of smoke across procedures ranged from 0.05 µm to larger than 25 µm.[3] One study of laser corneal surgery noted a mean particle size of 0.22 µm (n = 98).[4]
- The size of an inhaled particle is the most important aspect in determining where it will be deposited in the respiratory tract.[4; 5]
- Particles of 5.0 µm or greater can be deposited on the walls of the nose and trachea. Smaller particles, less than 2.0 µm, may be deposited in the respiratory bronchioles and alveoli.[4; 5]

SIZE AND DEPOSITION OF SURGICAL SMOKE PARTICLES*



SURGICAL SMOKE TRAVELS FAST AND BECOMES HIGHLY CONCENTRATED IN THE OR

Particles can travel up to 18 m/s.[7†]

The concentration of the particles can rise from 60,000 particles/ cubic foot to over 1 million particles/ cubic foot within 5 minutes of electrocautery initiation.[8]

As particles get caught in air currents, they can become distributed in the OR.[8]

Note: OR = operating room

* Image adapted from Okoshi et al., 2015.[6] † Velocity for smoke particles generated by laser surgery.

BIOLOGICAL AND CHEMICAL CONSTITUENTS OF SURGICAL SMOKE

- Electrosurgery plume/smoke can contain toxic gases, dead and live cellular material – including blood fragments – and, viruses.[9-11]

MORE THAN 150 DIFFERENT CHEMICAL CONSTITUENTS WHICH MAY HAVE IMPACTS ON VARIOUS BODY SYSTEMS HAVE BEEN IDENTIFIED IN SURGICAL SMOKE.[12]

Respiratory

Acetaldehyde[5; 13; 14]
Acrolein[5]
Acetonitrile[5; 15; 16]
Cyclohexanone[17]
Decane[17; 18]
Formaldehyde[5; 16]
Furfural[13; 15; 19]
PAH[5]
Phenol[16; 20]
Pyridine[16; 20]
Styrene[5; 15; 16; 18; 21]
Toluene[5; 14-16; 18; 19; 21; 22]
Xylene[5; 16; 18]

Eyes

Acetaldehyde[5; 13; 14]
Acrolein[5]
Acrylonitrile[14-16; 23; 24]
Decane[17; 18]
Formaldehyde[5; 16]
Furfural[13; 15; 19]
Toluene[5; 14-16; 18; 19; 21; 22]

CNS (e.g. headache, nausea)

Acetylene[15; 16]
Acrylonitrile[14-16; 23; 24]
Benzene[5; 14-16; 18; 21; 23]
Carbon monoxide[16; 24; 25]
Decane[17; 18]
Furfural[13; 15; 19]
Propylene[20]
Toluene[5; 14-16; 18; 19; 21; 22]

Mutagenic

Acetaldehyde[5; 13; 14; 26; 27]
Acrolein[5; 26; 27]
Acrylonitrile[14-16; 23; 24; 26; 27]
Benzene[5; 14-16; 18; 21; 23; 26; 27]
Cyclohexanone[17; 26; 27]
Formaldehyde[5; 16; 26; 27]
Furfural[13; 15; 19; 26; 27]
PAH[5; 26; 27]
Styrene[5; 15; 16; 18; 21; 26; 27]

Chemicals are organized according to where/how they have the greatest impacts

BACTERIA AND VIRUSES PREVIOUSLY IDENTIFIED IN SURGICAL SMOKE[20; 28-30]

0.010-0.300 µm
Hepatitis B virus (HBV)

0.045 µm
Human papillomavirus (HPV)

0.180 µm
Human immunodeficiency virus (HIV)

0.500 µm
Mycobacterium tuberculosis

0.300–1.500 µm
Staphylococcus, Corynebacteriu, Neisseria

- Bacteria and viruses have been shown to survive and can be regrown from samples collected from surgical smoke.[6]
- Some viruses, such as HPV and HIV, are smaller than the mean particle size found in surgical smoke.[28; 30]
- The small size of viruses and bacteria can easily pass through the commonly used surgical masks.[31]

Note: CNS = Central Nervous System; HIV = Human immunodeficiency Virus; HPV = Human papillomavirus; PAH = Polyaromatic hydrocarbons

POTENTIAL IMPLICATIONS OF SURGICAL SMOKE

- CDC*: "Exposure to surgical smoke can cause both acute and chronic health effects ranging from eye, nose and throat irritation to emphysema, asthma or chronic bronchitis."[32]
- A 2006 study reported on potential risks to staff of surgical smoke. These risks include infection and irritation to the lungs, leading to acute and chronic inflammatory changes.[23]
- As early as 1988, scientists established a causal link between inhaling unfiltered surgical smoke and pulmonary changes, including alveolar congestion and emphysema.[33]
- Surgical smoke decreases visibility of the laparoscopic surgical field, possibly resulting in procedure delays.[34]

Physical

- Particles that range in size from 0.5 to 5.0 µm are considered to be "lung damaging dust."[15]
- Smoke plumes may cause both acute (e.g., sore eyes, dermatitis) or chronic (e.g., asthma) health effects.[5; 6; 35-41]
- Common constituents of surgical smoke can also cause neurotoxic symptoms such as drowsiness, headaches, tremor and dizziness.[5; 6; 16; 36; 40; 41]
- Smoke plumes can increase risk of pulmonary conditions. A study of surgical residents reported that several developed a lump in the throat (58%) and pharyngeal burning (22%) potentially associated with exposure to electrocautery smoke.[6; 42]
- Other studies note there is a risk of emphysema, asthma, and chronic bronchitis with exposure to surgical smoke. [6; 35]

Infection

- Blended current electrosurgery smoke can contain viable bacteria.[43]
- Viral DNA has been discovered in surgical smoke or plume[44] and may lead to disease transmission.[6]
- When asked if they were concerned about transmission of infectious disease via surgical smoke, 76% (117 out of 153) of surveyed dermatology residents responded yes.[45]

TIMELINE OF SURGICAL SMOKE RESEARCH

pre-2003

Guidelines regarding the dangers of surgical smoke emerge.[46]

N95 filters > 95% of airborne particles.[47]

Mean particle size from surgical smoke is less than that of many viruses.[4]

2003

CDC recommends mechanical LEV smoke evacuation systems, filtered central wall room suction units, and N95+ respirators.[48]

2005

Viral DNA is discovered in surgical smoke.[44]

2008

Bacterial and viral particles (0.04 to 1.3 µm) shown to readily diffuse through many surgical masks.[49]

2015

Report noting that viral DNA in laser smoke plumes may lead to disease transmission.[6]

2017

Latest AORN update recommends evacuation of all surgical smoke with stringent specifications on smoke evacuation devices (i.e., 0.1 µm filter).[50]

2018/2019

CO[51] and RI[52‡] have mandated the use of surgical smoke evacuation, and other states are examining the issue.

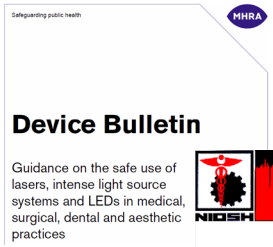
Note: AORN = Association of perioperative Registered Nurses; CDC = Centers for Disease Control and Prevention; CO = Colorado; HPV = Human papillomavirus; LEV = Local Exhaust Ventilation; RI = Rhode Island; WHO = World Health Organization

* Centers for Disease Control and Prevention ‡ Indicated by diamonds on the map below.

WIDESPREAD RECOMMENDATIONS BY GLOBAL AND LOCAL ORGANIZATIONS

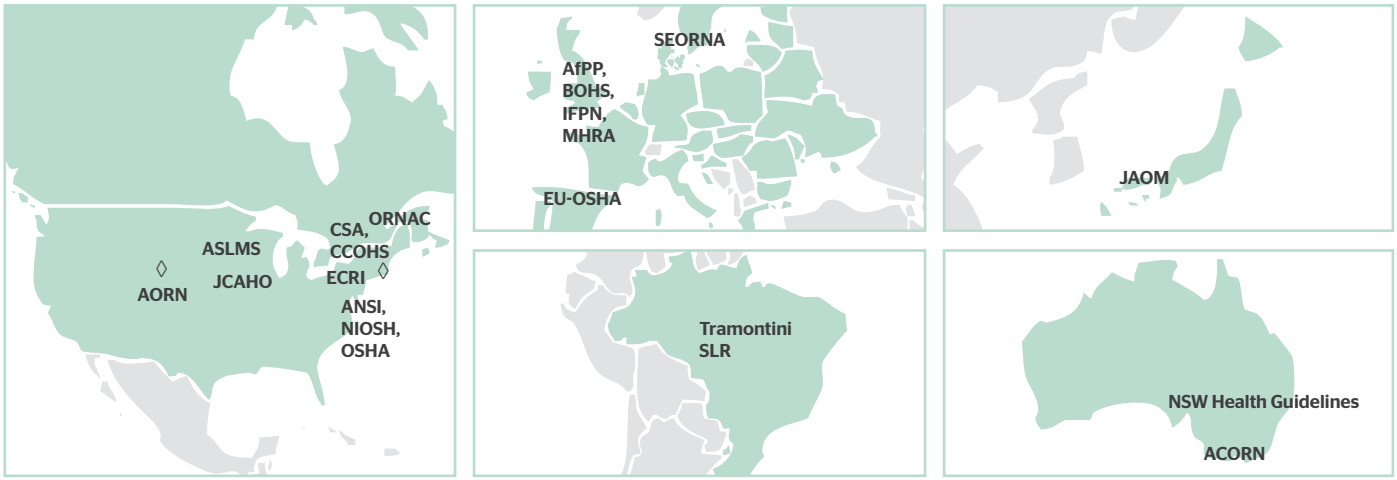
- Surgical smoke evacuation is strongly recommended by regulatory bodies and industry associations alike, such as OSHA, MHRA, NIOSH, ECRI and AORN.[5; 41; 46; 48; 50; 53; 54]

EXAMPLE RECOMMENDATIONS:



- MHRA recommended the use of robust smoke evacuation systems to reduce the risks of smoke plume generated from electrocautery and laser devices.[41]

- NIOSH recommends evacuation and filtration of smoke produced by surgical procedures and specifies that a smoke evacuator or suction must be within two inches of the surgical site.[46]



COMMON HISTORICALLY USED METHODS AND THEIR LIMITATIONS

Masks

- Standard surgical masks are ineffective at filtering many substances from surgical smoke.[5] Most are designed to filter particles > 5 µm.[31]
- Respirator masks are bulky, impede function, and cause discomfort;[55] also need to be fitted.
- Masks worn too loosely or for too long are less effective.[6]

Wall Suction

- Pulls less than 5 cubic feet per minute; only effective in procedures that produce a small amount of smoke.[5]
- Must be used with an inline filter; or else smoke can begin to occlude the smoke particles suction line.[5]
- May be ineffective at removing smoke directly where it is generated.[56]
- Noisy and disrupts communication between staff.[57]

Note: ACORN = Australian College of Operating Room Nurses; AfPP = Association of Perioperative Practice; ASLMS = American Society for Laser Medicine and Surgery; AORN = Association of perioperative Registered Nurses; ANS = American National Standards Institute; BOHS = British Occupational Hygiene Society; CCOHS = Canada's National Centre for Occupational Health and Safety information; CSA = Canadian Standards Association; ECRI = Emergency Care Research Institute; EU-OSHA = European Agency for Safety and Health at Work; IFPN = International Federation of Perioperative Nurses; JAOM = Japanese Association for Operative Medicine; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; MHRA = Medicines and Healthcare products Regulatory Agency; NSW = New South Wales; NIOSH = National Institute for Occupation Safety and Health; ORNAC = Operating Room Nurses Association of Canada; OSHA = Occupational Safety and Health Administration; SEORNA = Swedish Operating Nurse Association; Tramontini SLR = Tramontini Systematic Literature Review

HAND-HELD DEVICE FEATURES THAT DIFFER FROM HISTORICALLY USED METHODS

- Studies have shown that the further a smoke evacuation device is from the site of plume generation, the amount of smoke evacuated will decrease significantly, thus allowing residual plume to escape into the air.[58]
- Using a smoke evacuation pencil design allows plume to be evacuated at the tissue impact site through a vortex motion which promotes greater plume capture.[58]
- Given their smaller designs, hand-held smoke evacuation devices may not interfere with the operative field.[31]
- The MegaVac Plus™ smoke evacuator has a flow rate adjustable to at least 90 liters per minute (lpm) for the HIGH (OPEN) setting and a flow rate from 4 ± 1 lpm to at least 18 lpm for the LOW (LAP) setting,[59] enabling rapid smoke evacuation in procedures with different requirements.
- Can sometimes be integrated right into the surgical tool, such as an electrosurgery or electrocautery pencil.[57]
- A study demonstrated that a hand-held device was able to capture 99% of surgical smoke when placed one inch from the source.[57]

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