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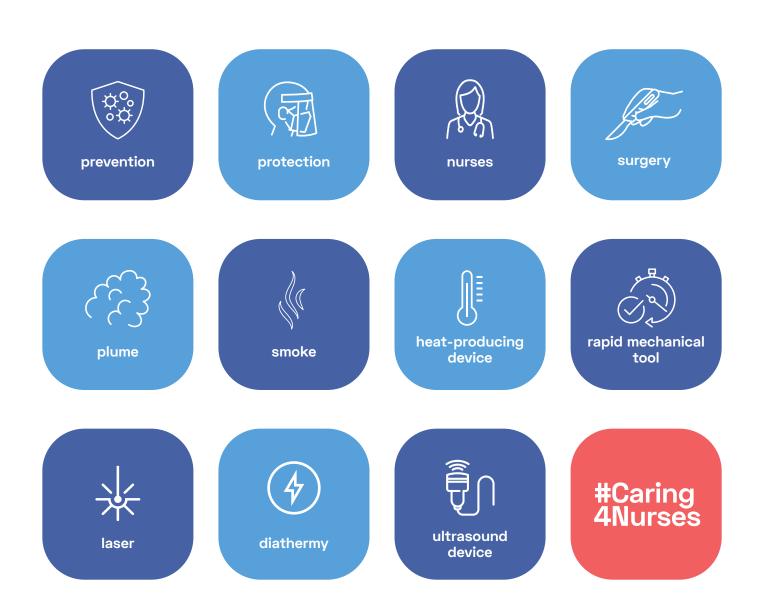


Reading guidance

Our aim is to create an accessible information, education and communication guide, created by nurses for nurses working in areas where surgery creates surgical smoke. The guide is also aimed at student doctors and all professionals working in this area, as well as regulators and people responsible for policy-making. The guide is based on the position statement of the European Operating Room Nurses Association (EORNA) and on publications on this topic.

Because the guide has been created in the midst of the COVID-19 pandemic, it will include data and information up-to-date at time of publication. Research is ongoing on the impact of surgical smoke in COVID-19.

Key words



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Foreword

Health institutions must contribute to a safe working environment.

Over the years, people working in hospitals have faced many occupational risks. While a lot of these risks have been resolved, the impact of hazardous surgical smoke still seems to be under the radar.

Surgical smoke has been linked to a range of serious health problems. Because nurses make up the largest group that works in operating rooms, and spend the longest time there, they are the most vulnerable. Health institutions, supervisors and policymakers not only have a legal duty to protect personnel against health risks, but they also have a moral and ethical duty. After all, we cannot focus on saving patients' lives if we are then going to overlook the people who make this possible.

Policymakers and regulators play an important role in this protection. In addition, employers have a responsibility to protect everyone against harm based on EU legislation in relation to health and safety at work. Institutions in turn should regularly assess risks and take precautions when risks are identified. Policy makers and institutions must work together closely to help ensure the health and safety of medical personnel.

It is important that there is a broader awareness of this problem, and healthcare professionals, including nurses, need to take the lead in promoting policy changes and initiatives. Promoting protection against hazardous surgical smoke also fits into the program of Europe's Beating Cancer Plan and the Roadmap on Carcinogens initiative.

I want to congratulate the EORNA and the ESNO team for its work.

Adriano Friganovic.
President Specialist Nurses organisation (ESNO)



Introduction

The health and safety of nurses and other health professionals is supported and protected at work by employers, institutions and European legislation and regulations. Health and safety protection covers a range of areas, such as violence, mental health, sharps, chemicals, toxic medications such as cancer drugs, and surgical smoke. 'Hazardous surgical smoke: Nurses' Information, Education and Communication Guide' is the first of a <u>series of eight guides</u> to 'Safety at work'. This guide provides information for nurses on the full impact of surgical smoke, with a particular focus on nurses and other healthcare professionals working in the operating room.

Whether seen or unseen, smoke in operating theatres is often taken for granted, despite the fact that we know much more about the environmental, social and personal impact of air pollution. It is a topic that needs to be taken far more seriously, because surgical smoke can damage health, sometimes irreversibly.

In one study examining surgical smoke generated during plastic surgery procedures, it was found that the smoke produced in one day was equivalent to 27 to 30 cigarettes.¹

Managing surgical smoke requires awareness, knowledge, competence, and skills, as well as regulation at the local and national level. Surgical smoke needs to be placed in context to ensure that, through prevention, and good management and leadership, nurses and other healthcare professionals can be protected.

Without context there is no sustainable awareness, attitude, management, leadership and policy.

The purpose of this guide is to provide a knowledge base for operating room nurses and healthcare personnel working in the perioperative environment, ensuring that they are aware of the risks of surgical smoke/plume of gaseous by-products used during surgical interventions, and understand about prevention and protection from hazardous ultrafine particles.

¹ https://pubmed.ncbi.nlm.nih.gov/22445358/

According to the Position Statement² of the European Operating Room Nurses Association:

- Perioperative nurses report twice as many respiratory issues compared with the general population,
 based on disproportionally higher health risk at work
- Protecting your team and patients from the hazards of surgical smoke indicates an attitude based on mutual respect and transparency
- Attracting and retaining the best clinicians and healthcare professionals through a healthier, smokefree environment requires action
- Providing education on the risks of surgical smoke and methods for smoke evacuation needs ongoing communication to prevent any avoidable harm
- Increasing smoke evacuation compliance on all surgical smoke generating procedures requires all possible available measures.

Surgical smoke in a nutshell

Surgical smoke, generated when heat-producing electrosurgical devices and powered surgical instruments are used during surgery to cut or vaporise tissue or to coagulate blood vessels, is a risk to both surgical staff and patients. The smoke irritates the eyes, nose, throat and lungs, is linked with dizziness, headaches and light-headedness, and can cause long term problems including lung conditions, anaemia, cancer and cardiovascular disease. It can also lead to pregnancy complications and infertility.

The impact of smoke can be reduced by use of appropriate PPE, and by installing mobile or central evacuation systems. These precautions are particularly important when working with patients with suspected or proven COVID-19.

Nurses play a vital role in reducing and preventing the impact of surgical smoke, by being aware of the issues, taking ownership in the policies and decision-making processes, and providing role models to the rest of the team by protecting themselves, their patients and their colleagues.

Europe has employment/worker safety legislation in place to protect all sectors, including nurses and other surgical staff. The legislation provides the minimum requirement for levels of protection, and must be transposed into national laws by member states. The legislation is continually monitored and updated, with an update to the Carcinogens and Mutagens Directive expected in 2023. Policymakers need to ensure that workers are protected from the impact of smoke to a level that equals, or preferably exceeds, the minimum requirements laid out by Europe. While the legislation in place provides a basis for addressing the risk, the general awareness of the hazards of surgical smoke is still limited and initiatives like this guidance are important to help protect health of staff and patients in operating room.

² https://eorna.eu/wp-content/uploads/2019/09/Prevention-and-Protection-of-Surgical-Plume-PNC-EORNA.pdf



Introduction to surgical smoke



An introduction to surgical smoke

- Surgical smoke is generated when heat-producing electrosurgical devices and powered surgical instruments are used during surgery to cut or vaporise tissue or to coagulate blood vessels
- Surgical smoke is a risk to both staff and patients
- Smoke particles can physically affect the lungs, eyes, nose and throat, causing both short-term and long-term irritation and inflammation
- Smoke particles can also cause problems because they are toxic, mutagenic, carcinogenic or infectious

According to Merriam-Webster³, smoke is the gaseous products of burning materials especially of organic origin made visible by the presence of small particles of carbon. Aerosols of fine particles, including smoke, can remain suspended and be carried through the air, both inside and out.

Focusing on surgical smoke

Plumes of surgical smoke are generated when heat-producing electrosurgical devices and powered surgical instruments are used during surgery to cut or vaporise tissue or to coagulate blood vessels to prevent or stop bleeding (haemostasis). Examples of smoke-generating devices include monopolar and bipolar diathermy, laser surgery, dissection with argon gas, ultrasound, high speed burrs, saws, drills, cutters and mechanical morcellators.⁴

The smoke generated by these devices spreads differently and contains different materials. For example, the plume from a carbon dioxide laser spreads more explosively and travels further away from the surgical field compared with the plume from electrosurgical devices.⁵ Diathermy or laser surgery techniques generate high concentrations of ultra-fine particles (UFPs) in the first few seconds. The spread of the plume changes with the use of curved or straight blades, and with the materials used in the blade.⁶

Surgical smoke names and synonyms

Cautery smoke

Aerosols

Diathermy plume

Bioaerosols

Plume

Vapour

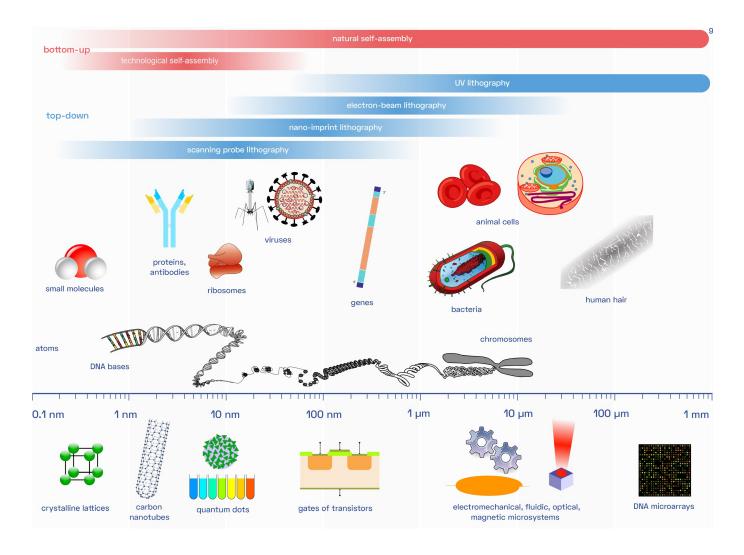
Smoke plume

Air contaminants

³ https://www.merriam-webster.com/dictionary/smoke ⁴ https://www.sciencedirect.com/science/article/pii/S0195670105000770 ⁵ https://www.conmed.com/-/media/conmed/documents/bf-articles/the_visualisation_of_surgical_smoke_produced_by_energy_delivery.ashx ⁶ https://occup-med.biomedcentral.com/articles/10.1186/1745-6673-3-31

Surgical smoke is 95% water or steam. The remaining 5% includes UFPs, gases, dead and living cell materials, and other particles. The particles in surgical smoke come in a range of sizes: 7.8

Viruses:	0.01-0.1 μm
Electrocautery/electrosurgery particles:	0.07 μm
Laser tissue ablation particles:	0.31 μm
Ultrasonic dissection particles:	0.35-6.5 μm
Bacteria:	1–10 µm
Human cells:	5–150 μm



⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6584931 ⁸ https://eorna.eu/wp-content/uploads/2019/09/Prevention-and-Protection-of-Surgical-Plume-PNC-EORNA.pdf ⁹ https://commons.wikimedia.org/wiki/File:Biological_and_technological_scales_compared-en.svg

Smoke particles can physically affect the lungs, eyes, nose and throat, causing both short-term and long-term irritation and inflammation. Particles that are 5 μ m or smaller in size, which includes surgical smoke particles, bacteria, viruses and the smallest of human cells, can be deposited in the bronchioles and alveoli. They can irritate the lungs, and have been linked with lung disease, including occupational asthma and chronic pulmonary conditions. Particles between 6 and 12 μ m can be deposited in the upper airways. ^{10,11,12}



Smoke particles can also cause problems because they are toxic, mutagenic, carcinogenic or infectious:

Toxic:

Material that can cause serious illness or death.

Mutagenic:

• Something that can change genetic material, and increase the chance of mutations and DNA damage. Mutations are often, though not always, carcinogenic.

Carcinogenic:

 Promoting the formation of cancer, for example by damaging the DNA or affecting the cell's metabolism. The effect of carcinogens may not be seen for many years.

Infectious:

· Infection-causing particles such as bacteria, viruses and fungi.

Smoke particles can cause:14,15,16

Acute and chronic inflammatory changes in respiratory tract (emphysema, asthma, chronic bronchitis), Allergies, Anaemia, Anxiety, Cancer, Cardiovascular dysfunction, Colic, Dermatitis, Hypoxia, dizziness, headaches and light-headedness · Infections (viral and bacterial), including HPV o Potential risk of infection from HIV and HBV, Irritation in the eye, nose and throat, including eye watering, sneezing, sinus problems and nasopharyngeal, lesions, Leukaemia, Nausea and vomiting, Pregnancy complications and infertility, Weakness

The different types of surgical smoke can have different effects.

¹⁰ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6584931 ¹¹ https://link.springer.com/article/10.1007/s00595-014-1085-z ¹² https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30323-4/fulltext ¹³ https://www.medscape.com/viewarticle/741245_3 ¹⁴ https://www.sciencedirect.com/science/article/pii/S0195670105000770 ¹⁵ https://pubmed.ncbi.nlm.nih.gov/24499532/ ¹⁶ http://prevencion.umh.es/files/2012/04/2-surgical_smoke.pdf

Risks with different types of surgical smoke

Surgery type	Highest concern components Acrylonitrile – eye and skin irritation, nausea, vomiting, headache, sneezing, weakness, light-headedness, increased cancer risk Viruses – HPV (potentially HIV)			
Electrosurgery				
	Benzene – irritation in eyes, nose and respiratory tract, headache, dizziness, nausea, increased risk of blood disorders			
Laser	Carbon monoxide – reduces the oxygen-carrying capacity of the blood · Hydrogen cyanide – headache, weakness, eye and throat irritation, vomiting, problems breathing, colic			
	Formaldehyde – eye, nose and throat irritation, asthma, increased cancer risk			
	Acrolein – eye, nose and throat irritation, increased cancer risk			
	Viruses – HPV (potentially HIV and other viruses)			
Ultrasonic scalpel	Cellular debris – risks not yet clear			

Each year, around a million healthcare professionals worldwide, including surgeons, nurses, anaesthesiologists and surgical technologists, are exposed to smoke from lasers, and from ultrasonic electrosurgical devices. ¹⁷

- In a survey of female surgeons in the US, there were higher rates of pregnancy complications and infertility compared with the general population. 18
- A survey of over 750 perioperative nurses in the US showed an increased rate of allergies, sinus problems, asthma and bronchitis. These rates can be as much as over twice the rate in the rest of the population.¹⁹

Surgical smoke is also a potential risk for patients. In patients who have laparoscopic cholecystectomy (keyhole gall bladder removal), chemicals found in surgical smoke have been seen in their urine.²⁰ Because of the risk to patients and healthcare professionals alike, preventing the effects of smoke is vital.

¹⁷ https://pubmed.ncbi.nlm.nih.gov/24499532/ ¹⁸ https://jamanetwork.com/journals/jamasurgery/article-abstract/2757728 ¹⁹ https://kebomed.co.uk/files/9/making_things_clear_uk.pdf ²⁰ http://ijomeh.eu/Chemical-composition-of-surgical-smoke-formed-in-the-abdominal-cavity-during-laparoscopic-cholecystectomy-assessment-of-the-risk-to-the-patient,2054,0,2.html



Reducing the effect of smoke



Reducing the effects of smoke

- Plume/smoke evacuation devices should always be used during procedures using heat-producing instruments or devices
- Smoke should be removed from the air using mobile or central evacuation systems
- · Personal protective equipment (PPE) can help to protect healthcare staff from the effects of smoke

Personal protective equipment (PPE) protects healthcare workers from the smoke. Smoke evacuation devices and filters remove the smoke from the air, and measures to reduce pneumoperitoneum leaks during laparoscopy and thoracoscopy prevent smoke escaping; these measures protect both healthcare workers and patients.

The STOP principle lists the measures to prevent or reduce exposure to dangerous substances, such as surgical smoke, in order of priority. Eliminating smoke by removing it from the air using smoke evacuation devices and filters, and reducing pneumoperitoneum leaks during laparoscopy and thoracoscopy prevent smoke escaping, is the first priority. PPE remains very important, and ensures optimum levels of protection once the other steps are put in place.²¹

S = Substitution or elimination

= Technological measures

= Organisational measures

P = Personal protective measures

Smoke extraction

Particles that are 5 µm or smaller (which includes the range of smoke particles, and the smallest of human cells) can remain airborne indefinitely, unless they are removed.²² Because of the airborne potential of smoke particles, plume/smoke evacuation systems should always be used during procedures using heat-producing instruments or devices. Smoke extraction systems close to the surgical site, for example filters built into trocars in laparoscopic surgery or hand-held devices such as smoke evacuation pencils keep the area clear of smoke, reducing people's exposure to the particles and harmful chemicals, improving visibility and reducing smells.

²¹ https://osha.europa.eu/en/publications/info-sheet-legislative-framework-dangerous-substances-workplaces/view, ²² https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30323-4/fulltext

Some smoke-producing surgical instruments such as bipolar diathermy or ultrasonic dissection devices and electrosurgical unit pencils have built-in smoke evacuation systems, including ULPA (ultra-low particulate air) or HEPA (high efficiency particulate air) filters. Hand-held smoke extraction systems need to be close (within 2 cm) to the source of smoke, and should have a grid over the end to prevent sponges or tissue being pulled in. Cell foam smoke capture devices are flat and have an open foam core sandwiched between two layers of plastic. The open edge pulls in the smoke, where it is captured by the foam. The benefit of the flat design is that it does not obstruct the field of view. The effectiveness of smoke extraction devices depends on the flow of the suction, the distance between the suction and the source of smoke production, the size of the suction hose and the amount of plume produced during the operation. 23,24,25,26

The most effective way to remove smoke from the air is using a stand-alone evacuation system that includes a high-efficiency filter. The most effective mobile evacuation systems include a prefilter that removes the largest particles, an ULPA or HEPA filter that captures particles 0.1 microns and larger, and an activated charcoal filter that absorbs gas and vapour, removes toxic chemicals, and reduces smells. Mobile evacuation systems can be noisy and bulky.^{27,28,29,30}

Non-filtration smoke extraction systems use electrostatic precipitators (ESPs) to remove the particles of surgical smoke as they are created. The charged particles either attach to wires and are then cleaned off, or are attracted to the patient's inner abdominal wall and are eliminated by processes in the body. 31,32

Personal protective equipment

Personal protective equipment (PPE) can help to protect healthcare staff from the effects of smoke.^{33,34,35,36,37} PPE includes glasses to cover the eyes, and fit-tested high-quality filter masks, such as N95 respirator masks to reduce inhalation of smoke particles, as well as standard operating room PPE. Masks with activated carbon fibre filters reduce levels of inhaled carcinogens. Masks with face seal technology offer greater protection than standard facepiece filtering respirators.³⁸

Personal protective equipment (PPE)







The challenge of respirators, particularly those with higher filtration levels, is that they can interfere with breathing, vision and communication, and the people wearing them can get overheated. Masks may not be effective at removing smaller particles.^{39,40}

ESNO has produced guides on Microbial Issues that include more information on the correct use of PPE.⁴¹

²³ https://pubmed.ncbi.nlm.nih.gov/28902038/ ²⁴ https://pubmed.ncbi.nlm.nih.gov/9134439/ ²⁵ https://pubmed.ncbi.nlm.nih.gov/25421864/ ²⁶ https://pubmed.ncbi.nlm.nih.gov/25421864/ ²⁶ https://pubmed.ncbi.nlm.nih.gov/25421864/ ²⁶ https://pubmed.ncbi.nlm.nih.gov/25421864/ ²⁶ https://www.journal.acorn.org.au/cgi/viewcontent.cgi?article=1019&context=jpn ²⁶ https://susl.co.uk/wp-content/uploads/2017/10/MHRA-Smoke-Plume-Poster.pdf ³⁰ https://www.hse.gov.uk/research/rrpdf/rr922.pdf ³¹ https://bjssjournals.onlinelibrary.wiley.com/doi/10.1002/bjs.11679 ³² https://pubmed.ncbi.nlm.nih.gov/31433468/ ³³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6584931 ³⁴ https://www.sciencedirect.com/science/article/pii/S0195670105000770 ³⁵ https://www.jcancer.org/v10p2788.htm ³⁶ https://pubmed.ncbi.nlm.nih.gov/29953600/ ³⁷ https://pubmed.ncbi.nlm.nih.gov/31057262/ ³⁸ https://www.tandfonline.com/doi/full/10.1080/02786826.2017 .1373180 ³⁶ https://pubmed.ncbi.nlm.nih.gov/26865858/ ⁴⁰ https://pubmed.ncbi.nlm.nih.gov/25421864/ ⁴¹ https://www.esno.org/microbialissues.html



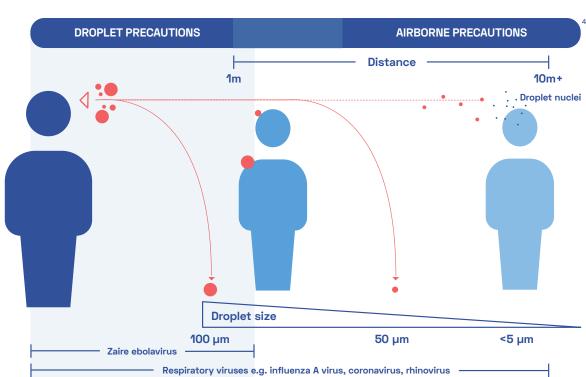
Surgical smoke and COVID-19



Surgical smoke and COVID-19

- The main route for transmission of SARS-CoV-2, the virus that causes COVID-19, is through droplets and aerosols
- Precautions should be taken when operating on patients who are or who are suspected to be COVID-19-positive, such as wearing appropriate PPE and setting up zones in the operating area
- Surgical procedures in patients who are COVID-19-positive need to limit the risk of the spread of the virus

The main route for transmission of SARS-CoV-2, the virus that causes COVID-19, is through droplets and aerosols.



Simple sketch of droplet & airborne virus and bacterial transmission

The virus has been detected in the oropharynx, nasopharynx, respiratory epithelium, gastrointestinal epithelium and placenta. It is also found in a range of body fluids:⁴³









⁴² https://i0.wp.com/virologydownunder.com/wp-content/uploads/2020/02/Particles-v6.png ⁴³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7518359/

Did you know? If someone with COVID-19 or any other infectious disease is smoking a cigarette in the street, the smoke can carry the virus at least 9 metres?⁴⁴

There is no evidence so far that SARS-CoV-2 can be transmitted through surgical smoke. However, precautions should be taken when operating on patients who are or who are suspected to be COVID-19-positive. These precautions include: 45,46,47



- · Nasopharyngeal swab for each patient
- · In laparoscopic procedures, a double swab with interval of one week
- Balance the risks and benefits of surgery, and postpone elective surgery if possible
- Minimise face-to-face meetings where possible
- Wear appropriate PPE
- Use a designated operating theatre
 - Use negative pressure ventilation if available; switch off positive pressure ventilation
- Work with the minimum number of staff and the minimum amount of equipment
- Ensure all equipment is in place at the beginning of surgery, to limit the movement of equipment between rooms
- Evacuate surgical smoke
- Create zones in the operating theatre
- Deep clean the operating theatre at the end of the day

⁴⁴ https://pubmed.ncbi.nlm.nih.gov/24218368/ ⁴⁵ https://bjssjournals.onlinelibrary.wiley.com/doi/10.1002/bjs.11679 ⁴⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7370871/ ⁴⁷ https://link.springer.com/article/10.1007/s00464-020-07565-w

Operating theatre zones

Zone 1:	Entry dressing room, where the basic PPE is donned
Zone 2:	Anteroom, where the disinfection and surgical dressing take place
Zone 3:	Operating theatre (COVID-19 room)
Zone 4:	Exit room, where the PPE is removed
Zone 5:	Exit dressing room, where the staff shower

Suggested PPE:

FFP2/N95 mask

FFP3/N99 facial mask (if high risk of generating aerosolized particles)

Disposable long sleeve waterproof coats, gowns, or Tyvek suits

Disposable double pair of nitrile gloves

Protective goggles or visors

Disposable head caps

Disposable long shoe covers

Surgical procedures in patients who are COVID-19-positive need to limit the risk of the spread of the virus, for example in laparoscopic surgery (minimally-invasive surgery; MIS), the patient's abdomen is inflated with carbon dioxide. Pressurized carbon dioxide can escape during surgery, potentially leading to an aerosol of virus. This can be limited by the use of lower pneumoperitoneum pressures, as well as the use of systems that include ULPA filters. At the end of the surgery, decompressing the abdomen using a suction device will also reduce risk. Even though MIS procedures are associated with the risk of carbon dioxide leaks, it is important to remember that the procedures include significant measures to reduce this risk. In contrast, open surgery exposes the OR personnel to direct contact with uncontrolled surgical smoke.^{48,49,50}

⁴⁹ https://bjssjournals.onlinelibrary.wiley.com/doi/10.1002/bjs.11679 ⁴⁹ https://www.contemporaryobgyn.net/view/smoke-evacuation-in-the-age-of-covid-19 ⁵⁰ https://link.springer.com/article/10.1007/s00464-020-07565-w



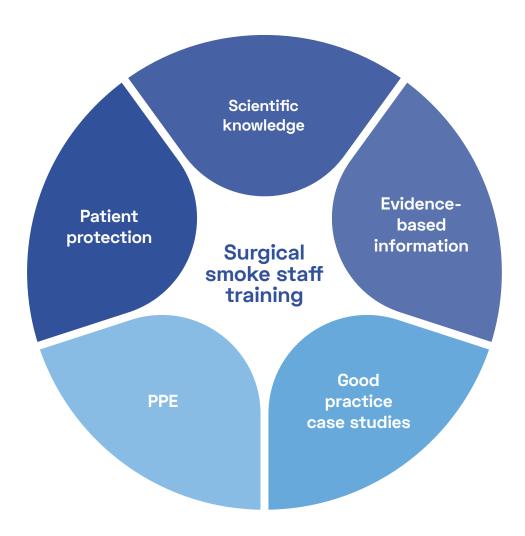
Education, awareness & leadership



Education, awareness and leadership

- Training helps nurses and other operating room staff to be more aware of potential hazards and to understand how to protect themselves and people around them
- Nurses play a vital role in evaluating and choosing the equipment used for smoke evacuation
- Nurses must be involved in the multidisciplinary teams that put smoke evacuation policies in place and ensure that they are adhered to every time
- Training needs to make sure that nurses are confident enough to speak out

Training helps nurses and other operating room staff to be more aware of potential hazards and how to protect themselves and people around them, such as wearing the right PPE, ensuring that smoke extractors are used, understanding cleaning and maintenance of smoke extractors, and complying with policies and procedures. The manufacturers of the surgical devices and the extractors may be a source of training materials. 51,52,53



⁵¹ https://www.jcancer.org/v10p2788.htm ⁵² https://pubmed.ncbi.nlm.nih.gov/29953600/ ⁵³ http://prevencion.umh.es/files/2012/04/2-surgical_smoke.pdf

As part of a team including surgeons and scrub personnel, nurses play a vital role in evaluating and choosing the equipment used for smoke evacuation. This includes looking at:⁵⁴

- Whether the equipment has a variable flow rate to accommodate different smoke levels?
- What are the noise levels, automation, types of filter and types of filter monitoring systems?
- Is the system compatible with other systems?
- Is the system efficient and effective?
- Can the system be used for open and MIS procedures, and with all types of energy devices?

<u>Nurses also should be involved in the multidisciplinary teams</u> that put smoke evacuation policies in place and ensure that they are adhered to every time. This team should include a programme coordinator, interdisciplinary champions from surgical specialties, anaesthesia and other departments such as obstetrics, radiology and dermatology, representatives from infection prevention, materials management, risk management, patient safety and employee health. Nurses can also act as role models.^{55,56}

<u>Training is an important part of implementation</u>, and needs to include the hazards of surgical smoke, the evacuation methods, and the need for compliance. Nurses play an important role in developing and delivering the training.^{57,58}

Training also needs to <u>make sure that nurses are confident enough to speak out</u>, and provide them with the skills and tools in order to make them:

- Sure that they know the correct procedures in dealing with surgical smoke
- Able to speak to colleagues, including senior colleagues and physicians, about correct practices
- Secure that speaking out will not affect their role

Training is important as it will improve the protection of both the patient and the healthcare team from the harmful effects of smoke.

⁵⁴ https://pubmed.ncbi.nlm.nih.gov/29953600/ ⁵⁵ https://pubmed.ncbi.nlm.nih.gov/29953600/ ⁵⁶ https://www.journal.acorn.org.au/cgi/viewcontent.cgi?article=1019&context=jpn ⁵⁷ https://pubmed.ncbi.nlm.nih.gov/29953600/ ⁵⁶ https://pubmed.ncbi.nlm.nih.gov/29953600/



Surgical smoke footprint in European policy



Towards a surgical smoke-free footprint in European policy

Specialist and operating room nurses are protected from exposure to surgical smoke by EU legislation – the Biological Agents Directive and the Carcinogens and Mutagens Directive

Because of the EU Treaty, the EU has significantly more power in employment/worker safety legislation than it does in public health. Specialist and operating room nurses are protected from exposure to surgical smoke by two key pieces of EU legislation – the Biological Agents Directive and the Carcinogens and Mutagens Directive – which provide the minimum requirement for levels of protection, and must be transposed into national laws by member states.⁵⁹

Some countries in Europe have stricter guidelines than others to protect the health of employees, for example Denmark has a requirement to install extraction systems that remove smoke and other harmful substances as close to the source as possible, which reduces exposure to the damaging effects of surgical smoke. However, such regulations are not in force in other EU countries.

Policymakers, at an institutional, local, and national level need to ensure that workers are protected from the impact of smoke to a level that equals, or preferably exceeds, the minimum requirements laid out by Europe. Surgical smoke needs to be on the agenda for inclusion in Occupational Safety and Health Administration (OSHA). The European policymakers need to listen to nurses to ensure that they have the protection that they need, by ensuring that surgical smoke is incorporated into European directives.

Other countries are taking a lead on surgical smoke. New legislation has been signed into law in Kentucky, USA⁶⁰ that will require licensed hospitals and ambulatory surgery centres to adopt and implement policies to prevent human exposure to surgical smoke. The passing on the law was driven by the Association of periOperative Registered Nurses (AORN) and the Kentucky Nurses Association. Colorado and Rhode Island have also put legislation in place.

Carcinogens and Mutagens Directive

Workers in the EU are protected from cancer-causing agents (carcinogens) in the workplace under a network of 24 EU occupational safety and health directives. These include the Directive 89/391/EEC (the Framework Directive), the Chemical Agents Directive 98/24/EC, and the Carcinogens and Mutagens Directive 2004/37/EC2. The Carcinogens and Mutagens Directive focuses on chemical risks through inhalation or skin exposure, so is key for surgical smoke. There were three amendments adopted in 2017 and 2019, with an aim to improve protection and limit exposure, increasing the number of carcinogens listed to 29, and updating the occupational exposure levels (OELs). E2

⁵⁹ https://eorna.eu/wp-content/uploads/2019/09/Prevention-and-Protection-of-Surgical-Plume-PNC-EORNA.pdf ⁶⁰ https://ortoday.com/kentucky-governor-signs-surgical-smoke-bill/ ⁶¹ https://www.bc-legal.co.uk/bcdn/232-198-carcinogens-and-mutagens-directive-amended.html ⁶² https://www.concawe.eu/wp-content/uploads/QA-ON-DIRECTIVE-2004-37-EC.pdf

In March 2021, the European Parliament's Employment Committee approved a fourth amendment for the Carcinogens and Mutagens Directive, 63 including increasing its coverage to include substances that affect fertility and pregnancy, and adding extra OELs for carcinogens. Negotiations are ongoing, with changes expected to come into force in all member states in 2023.

The Carcinogens and Mutagens Directive includes formaldehyde and benzene, both of which are in surgical smoke.

Biological Agents Directive

The Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work (Biological Agents Directive) divides biological agents into four risk groups depending on whether they can cause disease, and how the diseases can be treated or prevented.⁶⁴

The Biological Agents Directive includes SARS-CoV-2, which may be aerosolised in surgical smoke.

What the directives cover

Based on the EU horizontal framework for occupational health & safety, your employer's responsibility includes:

- Undertake regular risk assessments in the OR to identify any exposure to substances of concern
- · Put in place measures to mitigate the risk using the risk assessment
- Invest in process change and use of technology to mitigate the risks
- Train and instruct the nurses about the risks and mitigation measures
- Monitor the nurses' health over time if they have been exposed to a substance of concern

Nurses are entitled to these protections by EU law.

⁶³ https://www.etuc.org/en/pressrelease/important-step-fight-cut-work-related-cancer-deaths 64 https://eorna.eu/wp-content/uploads/2019/09/ Prevention-and-Protection-of-Surgical-Plume-PNC-EORNA.pdf



Guidelines & appendix

Guidelines, recommendations and position paper

Guidelines and recommendations

Australian College of Perioperative Nurses (ACORN) - Australia

ACORN new standard: Prevention and management of surgical plume (www.acorn.org.au/client_images/2207849.pdf)

Association of periOperative Registered Nurses (AORN) - US/International

• Guideline for surgical smoke safety (aornjournal.onlinelibrary.wiley.com/doi/abs/10.1016/j. aorn.2017.03.006)

Association for Perioperative Practice (AfPP) - UK

Standards and recommendations for safe perioperative practice (www.afpp.org.uk/books-journals/afpppublications/Standards-Recommendations-for-Safe-Perioperative-Practice-2016)

International Federation of Perioperative Nurses (IFPN) - International

IFPN guideline for smoke plume (www.ifpn.world/download_file/77/220)

Operating Room Nurses Association of Canada (ORNAC) - Canada

ORNAC standards (www.ornac.ca/en/standards)

European Operating Room Nurses Association (EORNA) - Europe

EORNA recommendation on prevention and protection of surgical plume 2018 (eorna.eu/wp-content/uploads/2019/09/Prevention-and-Protection-of-Surgical-Plume-PNC-EORNA.pdf)

International Social Security Association (ISSA) - International

 Surgical smoke: Risks and preventive measures (prevencion.umh.es/files/2012/04/2-surgical_smoke. pdf)

Health and Safety Executive - MHRA DB2008(03) - UK

Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental
and aesthetic practices (dentallawandethics.co.uk/wp-content/uploads/2016/03/MHRA-Guidanceon-the-safe-use-of-lasers-intense-light-source-systems-and-LEDs-2008.pdf)

Position papers

European Union

- Directive 89/392/ECC General workplace safety (osha.europa.eu/en/legislation/directives/the-osh-framework-directive/1)
- EU-OSHA 2017 exposure to biological agents and related health problems for healthcare workers (osha.europa.eu/en/publications/exposure-biological-agents-and-related-health-problems-healthcare-workers/view)

Canada - Canadian Centre for Occupational Health and Safety

Laser plumes (www.ccohs.ca/oshanswers/phys_agents/laser_plume.html)

Appendix

Regulation in Europe: Chemicals

DIRECTIVE 2004/37/EC⁶⁵ OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

This Directive covers the protection of workers from health and safety risks from exposure to carcinogens or mutagens at work. It is updated regularly to add new substances and additional protection measures. Key concerns on Carcinogen and Mutagen and in key guiding principles:

- The employer shall assess and manage the risk of exposure to carcinogens or mutagens. This process shall be renewed regularly, and data shall be supplied to the authorities upon request. Special attention should be paid to investigate and take account of all possible ways of exposure (including all skin-related possibilities), and to persons at particular risk.
- Workers' exposure must be prevented. If replacement is not possible, the employer shall use a closed technological system. The employer shall reduce the use of carcinogens or mutagens by replacing them with a substance that is not dangerous or less dangerous.
- Where a closed system is not technically possible, the employer shall reduce exposure to the minimum.
- Exposure shall not exceed the limit value set in the legislation.
- Monitoring of health of exposed persons.

Regulation in Europe: Biological agents

Directive 2000/54/EC - biological agents at work⁶⁶

European Parliament and of the Council of 18 September 2000. On the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). On the COVID10 crises the European commission revised the directive and included the SARS-CoV-2

COMMISSION DIRECTIVE (EU) 2020/739 of 3 June 2020 – Amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833

⁶⁵ https://osha.europa.eu/en/legislation/directive-200437ec-carcinogens-or-mutagens-work 66 https://osha.europa.eu/en/legislation/directives/exposure-to-biological-agents/77

Abbreviations

ACORN	Australian College of Perioperative Nurses		
AfPP	Association for Perioperative Practice		
AORN	Association of periOperative Registered Nurses		
BPV	Bovine papillomavirus		
CIN	Cervical intraepithelial neoplasia		
EORNA	European Operating Room Nurses Association		
ESNO	European Specialist Nurses Organisation		
ESP	Electrostatic smoke precipitator		
HEGA	High efficiency gas absorption		
HEPA	High efficiency particulate air		
HBV	Hepatitis B virus		
HIV	Human immunodeficiency virus		
HPV	Human papillomavirus		
IARC	International Agency for Research on Cancer		
IFPN	International Federation of Perioperative Nurses		
LEEP	Loop electrosurgical excisional procedure		
MIS	Minimally invasive surgery		
NIOSH	National Institute of Occupational Safety and Health		
OEL	Occupational exposure level		
ORNAC	Operating Room Nurses Association of Canada		
OSHA	Occupational and Safety Health Administration		
PPE	Personal protective equipment		
ppm	Parts per million		
UFPs	Ultrafine particles		
ULPA	ultra-low particulate air		

Organisations



Individuals undergoing invasive surgical and/or anaesthetic procedures have the right to be cared for by appropriately qualified staff in a safe supportive environment.

European Operating Room Nurses Association, EORNA, was founded in 1980 by a group of innovative European nurses with the aim of enhancing and developing perioperative patient care across Europe. With its 23 Member Associations coming from 22 Countries, EORNA is the only recognised and leading professional organisation in the field of perioperative nursing bringing together representatives from all quarters of Europe.

Our vision is to enhance and develop better perioperative patient care across Europe. While being the influential voice of perioperative nurses in Europe we link and collaborate with relevant European and international organisations.

www.eorna.eu



The European Specialist Nurses Organisation (ESNO) is a non-profit organisation with the goal to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisations and its constituent members. ESNO represents the mutual interests and benefits of these organisations to the wider European community in the interest of the public health. Members of ESNO consist of individual European specialist nurses' member organizations and associates, both institutional and individual.

The organisation focuses on enhancing the capacity and capability of specialist nurses to deliver high quality healthcare by raising and harmonize specialist nursing education standards and actively contribute to health themes and threats, providing the best possible expertise, both national and in European cross border context.

www.esno.org

Notes

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