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INTERNATIONAL SOCIAL SECURITY ASSOCIATION

Section on *Prevention of Occupational Risks in Health Services*



Surgical smoke: Risks and preventive measures

Working document for occupational safety and health specialists



Surgical smoke: Risks and preventive measures

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Published by the

International Section of the ISSA on prevention of occupational
risks in health services
D 22089 Hamburg, Pappelallee 33/35/37
Germany

Layout

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ISSA Prevention Series
ISBN 978-92-843-1194-1
ISSN 1015-8022 No Serie 2058
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Foreword

Since 1993, one of the working groups of the International Social Security Association's (ISSA) Section on prevention of occupational risks in health services has focused on various aspects of the use of chemicals and hazardous products in this field. Working group members come from: the German Statutory Accident Insurance Fund (*Berufsgenossenschaft Gesundheitsdienst und Wohlfahrtspflege* – BGW, Dr Inga Fokuhl); the French Research and Safety Institute (INRS, Dr Michel Falcy, Martine Bloch); and, the Swiss accident insurance fund (Suva, Dr Martin Rüegger, Dr Brigitte Merz). Dr Udo Eickmann (BGW) heads this working group.

Previous publications (on safety in the use of cytostatics, disinfectants, anaesthetic gases and occupational risk prevention in aerosol therapy – pentamidine, ribavirin) were mainly aimed at OHS professionals.

This publication is mainly directed at operating theatre personnel who are exposed to surgical smoke. The aim is to establish the state of current knowledge on existing hazards, and above all to indicate the preventive measures that can be implemented to protect the health of exposed personnel.

The authors hope that this document will be of interest to those concerned and will contribute to the prevention of disorders and diseases due to smoke and gases in operating theatres.

1 Introduction

For a number of years, minimally invasive surgical techniques using heat or, more recently, ultrasound have been used to resect and cauterise tissues or to stop bleeding. They use the following equipment, in particular:

- electro-surgical instruments such as the mono- or bipolar electrocautery [which is used for tumour resection – e.g. peritonectomy (Andreasson, Anundi *et al.*, 2008), laparoscopy and other endoscopic procedures (Ball, 2004)]
- lasers such as the Excimer laser, used in ophthalmology (ASORN, 2002)
- devices used for specific interventions such as removing bone cement using ultrasound during re-interventions on endoprostheses (Aldinger *et al.*, 2004)

These techniques produce smoke, the composition of which has been the subject of numerous articles. Based on findings from *in vitro* studies and some animal tests, one has to consider that smoke might be hazardous for the health of operating theatre personnel.

This smoke consists of a mixture of chemical pollutants in the gas or vapour phase and in the form of particulate components. Its composition varies widely depending on the technique used, how it is used and the type of intervention. However, the presence or absence of evidence-based effects such as diagnosable disorders and damage to health in exposed personnel remains poorly documented. For a few years, prevention institutions such as the NIOSH in the United States have studied exposure and applicable preventive measures. In the United States alone, an estimated several hundred thousand health care workers are exposed (Ball, 2004), and figures should be at least equal in Europe where the population is greater.

The precautionary principle requires all the measures allowing the elimination, or at least reduction, of risks for health to be taken. Therefore, we will present the hazards linked to surgical smoke based on published data; we will also present the preventive measures which should be applied to ensure adequate protection of operating theatre personnel against discomfort and potential health risks linked to this smoke.

This document is aimed at both personnel directly concerned (surgeons, operating theatre assistants), safety officers in the health care sector, hospital and health service directors, as well as anyone with an interest in these questions.

2 Composition and effects of surgical smoke

According to operators, smoke generated during surgical incision or laser intervention causes an unpleasant odour, but few ask themselves if these gas, vapour or solid particle emissions represent a health risk. Exposure is both mixed and complex, combining biological, cellular, liquid or solid aerosols and gas components. It is often non-negligible: for example, during some surgical tumour reductions, resection of the tumour, parietal peritoneum, multiple organs, and electrocoagulation of tumour nodules at the surface of the visceral peritoneum can last between 2 and 12 hours. This constitutes prolonged exposure to surgical smoke (Sugarbaker, 2003). This technique, with electrocoagulation, is used in the preparatory phase before hyperthermic chemotherapy, and produces a lot of smoke.

Before analysing the potential risks linked to these methods it is appropriate to study the qualitative and, if possible, quantitative composition of surgical smoke.

2.1 Qualitative composition

We will see in the following that the quantitative composition of smoke varies considerably depending on the technique used and the tissue involved (Al Sahaf *et al.*, 2007). However, a general notion of qualitative composition can be given.

Water vapour is the main component of these emissions, estimated to represent up to 95%, although the exact proportion obviously depends on the nature of the tissues treated. This water vapour is a vehicle for the other components (Al Sahaf *et al.*, 2007).

2.1.1 Particulate composition

The size of particles formed varies between over 200 micrometres and less than 10 nanometres. The mean diameter of particles depends in particular on how intensely the energy applied acts on tissues. Alp, Bijl *et al.* (2006) indicate the following values:

- Electrocoagulation → mean diameter $d < 0.1 \mu\text{m}$
- Laser (tissue resection) → mean diameter $d, \sim 0.3 \mu\text{m}$
- Ultrasonic scalpel → mean diameter $d, \sim 0.35 - 6.5 \mu\text{m}$

This indicates that a very significant proportion of the smoke may be inhaled and deposited in the pulmonary alveoli. One of the unknown elements is the nanoparticle fraction, which has certainly not been sufficiently evaluated, and for which we currently do not know the effects. Recent articles have attempted to answer this topical question. Andréasson et al. (2008) measured particle emission during peritoneal carcinomatosis and other gastro-intestinal interventions. Respiratory tract samples revealed particles between 1 and 10 μm for classical particles and from 0.02 to 1 μm for “nanometric” particles. (NB: the limit between “classical” and nanometric particles corresponds, in the literature, to a diameter of 0.1 μm). The results indicate a higher level of pollution during high-voltage cauterisations of peritoneal carcinomatosis than during the use of classical techniques (resection of colon cancer). The cumulated levels are $9.3 \times 10^6 \text{ particles.ml}^{-1}.\text{h}^{-1}$ versus $4.8 \times 10^5 \text{ particles.ml}^{-1}.\text{h}^{-1}$ for individual samples and $2.6 \times 10^6 \text{ particles.ml}^{-1}.\text{h}^{-1}$ versus 3.9×10^4 for ambient samples. These results were confirmed by Bröske-Hohfeld et al. (2008) who assessed exposure to ultrafine particles (0.01 to 1 μm) during different surgical interventions. Argon laser electrocautery and tissue coagulation are the most polluting techniques. These authors detected average concentrations of $1,930 \text{ particles.cm}^{-3}$ with a maximum of 183,000 during removal of adhesions by electrocautery. The highest concentrations were measured during operation of a hepatic haemangioma: average 12,200 - maximum $490,000 \text{ particles.cm}^{-3}$. Ablation of retroperitoneal tumours and hernia incision are sources of significant pollution, in contrast with gall bladder ablation.

2.1.2 Organic pollutants

Numerous pyrolysed organic products have been detected in this type of smoke. A non-exhaustive list includes: aromatic hydrocarbons (benzene, toluene, ethylbenzene and xylenes), hydrogen cyanide (HCN), formaldehyde, and, of course, polycyclic aromatic hydrocarbons (see table 1). Several authors have attempted to better define the chemical components of smoke linked to surgical procedures (see Chapter 3). One of the conclusions is that smoke composition is very variable, depending on the type of intervention and the material used.

Al Sahaf *et al.* (2007) indicate, however, that hydrocarbons, nitriles, fatty acids and phenols are always present. These authors performed their analyses in various conditions and were thus able to determine quantitative differences in the composition of the smoke produced.

Table 1: Main chemical compounds found in smoke produced by laser surgery (qualitative)
(Barrett)

Acetonitrile	Ethylene
Acetylene	Formaldehyde
Acrolein	Hydrogen cyanide
Acrylonitrile	Methane
Alkyl benzene	Phenol
Benzene	Polycyclic aromatic hydrocarbons
Butadiene	Propene
Butane	Pyridine
Butene	Pyrrole
Carbon monoxide	Styrene
Cresol	Toluene
Ethane	Xylene

2.1.3 Inorganic pollutants

Like any combustion, electrosurgical interventions produce oxides of carbon (CO and CO₂), of sulphur and nitrogen, as well as ammonia. These substances are respiratory tract irritants and can cause effects related to tissue hypoxia.

2.1.4 Biological pollutants

As indicated previously, vaporisation of tissues by lasers or electro-surgery generates smoke and aerosols which may contain large quantities of particles. These could be intact cells, cellular fragments, blood cells or fragments of viral DNA.

Viable bacteria have been cultured from laser smoke, these included *Bacillus subtilis*, *Staphylococcus aureus*, and also mycobacteria, of which *Mycobacterium tuberculosis* (Walker, 1990).

As early as 1987 Byrne et al. (1987) studied the dispersion and survival of bacteria during electrocoagulation by CO₂ laser in tubes containing nutritive medium seeded with *Escherichia coli* and *Staphylococcus aureus*. The interior of the tube was submitted to electrocoagulation and the smoke produced was collected. It contained viable germs, in particular staphylococci.

Infectious viruses such as HIV (human immunodeficiency virus), HBV (hepatitis B virus), BPV (bovine papilloma virus) and HPV (human papilloma virus) have also been detected in this type of smoke. The nature of the microorganisms present depends largely on the intervention. Most studies involve HPV; the DNA of this virus is found in numerous samples of smoke produced during electrocoagulation of warts using lasers (Garden, 1988 – Sawchuk, 1989 – Kashima, 1989 – Gloster, 1995). A case of laryngeal papillomatosis was even recognised as an occupational disease in a nurse who served as an assistant during the treatment of papillomatosis (Calero, 2003) (also see chapter 2.2).

No specific test exists to evaluate the biological activity of DNA detected in smoke, making it difficult to determine. In 1988, Garden studied the presence of bovine papilloma virus (BPV) and human papilloma virus (HPV) DNA in smoke produced by CO₂ laser. To establish whether the DNA remained infectious, the study was completed by inoculating three sheep with smoke collected during the excision of bovine condyloma by CO₂ laser. Of the three animals, two presented a characteristic tumour at the point of inoculation (Garden, 1988 and 2002).

During an *in vitro* assay, Johnson et al. (1991) inoculated HIV into cell cultures. These cultures were then treated with a range of surgical power tools, all of which produce aerosols. Only instruments generating "cool" aerosols could transmit viable viruses. Smoke generated by electrocoagulation or by instruments used during resection did not contain viable viruses. However, in 1991 Baggish detected viral DNA from HIV in the smoke produced by a CO₂ laser used on an infected cell culture using PCR (polymerase chain reaction). Fletcher et al. (1999) showed the presence of viable melanoma cells in the smoke produced by electrocautery of melanoma. If the intervention was carried out at high power (30 W) the number of viable cells was lower than at 10 W.

2.2 Hazards of compounds found in smoke

Surgical smoke may be responsible for signs of acute intoxication, such as headache, asthenia, nausea, muscle weakness, and irritations to the eyes and respiratory tract; these effects are dose-dependent. Asthmatics in particular are often very sensitive to particle inhalation.

In addition, this smoke may hinder the surgeon's view of the surgical site, and be responsible for odours often described as unpleasant by personnel.

2.2.1 Particles

The effects of particles on the body depend on their size and chemical composition. Particles smaller than 3 µm are called the "alveolar fraction", while those under 10 µm are the "thoracic fraction". Elements of this size can

penetrate and be deposited in the bronchial tree where they may cause cellular damage. The effects are variable, from a simple overloading of the lungs for inert particles (titanium dioxide) to local irritation (rhinitis, bronchitis) or even cancer (paranasal sinus or broncho-pulmonary). Some may also pass into the circulatory system and result in general toxicity (metals).

The case of **nanoparticles**, whose toxicity for man is still poorly known, is of particular note. Most of the available data are from studies carried out on cells or animals.

However, it has been shown that ultra-fine particles in atmospheric pollution, produced by factories and diesel engines in particular, present toxic properties. These properties can be harmful to human health, particularly in fragile people, by provoking allergic respiratory diseases - rhinitis, asthma, bronchitis - and cardiovascular disorders. Some elements found in laser smoke are identical to those present in atmospheric pollution.

In addition, it has been clearly established that the toxicity of nanometric particles is different from that of the same components present as micro- or macroscopic particles (e.g. nanometric titanium dioxide).

2.2.2 Chemical pollutants

For more details on the toxicology of the substances cited below, see the INRS's "toxicology data sheets" or the DGUV's¹ GESTIS² database (www.inrs.fr and www.gestis.de). The effects mentioned are described as general indicators and do not refer directly, as a rule, to the concentrations measured during electro-surgery.

From the aromatic hydrocarbon family, three main chemical compounds are found.

Benzene, listed by the IARC³ as carcinogenic to humans, can provoke medullary aplasia and leukaemia. Acute exposure results in signs of depression of the central nervous system such as: asthenia, dizziness, nausea, vertigo, headache, narcosis. These signs appear at concentrations above those observed in surgical smoke.

Toluene and **Xylene** have a similar depressive effect on the central nervous system. In addition, they cause skin and mucosal irritations, both ocular and respiratory.

Aldehydes: formaldehyde, acetaldehyde and acrolein are airway irritants. They act at low concentrations and can cause serious lesions of the bronchial

¹ Deutsche Gesetzliche Unfallversicherung

² Gefahrstoffinformationssystem

³ International Agency for Research on Cancer

mucosa. In addition, formaldehyde is a skin and respiratory allergen and is a carcinogen of the paranasal sinus.

PAH (polycyclic aromatic hydrocarbons): among the effects observed, we can cite irritations of the eye, nose, throat, skin and airways, tiredness, headache, nausea, sleep disorders etc. Some reports mention non-malignant effects on the lungs such as bronchitis, emphysema and asthma.

A certain number of **polycyclic aromatic hydrocarbons** (of which benzo[a]pyrene or dibenzo[a,h]anthracene) are listed as class 2 or sometimes class 1B carcinogens by the European Union. Other aromatic compounds, among which some heterocyclic compounds (e.g. benzonaphthothiophene), or substituted PAHs can also be genotoxic.

Cresols: the three isomers of cresol can produce effects on the nervous system, digestive difficulties and dermatitis. Hepatic, renal or pulmonary lesions have also been observed to greater or lesser degrees. Cresols are absorbed through the mouth, the skin and the respiratory route. Exposure to high levels rapidly induces: eye irritation with conjunctivitis, headache, dizziness, visual and auditory disturbances as well as tachycardia and dyspnoea. Repeated exposure, on the other hand, causes: vomiting, loss of appetite, neurological disorders, headache, dizziness and dermatitis.

Phenol: is an irritant for the eyes and the ocular and respiratory mucosa. Chronic exposure leads to swallowing difficulties as well as diarrhoea, vomiting, loss of appetite, headache, dizziness, behavioural problems, haematuria, dark urine and skin rashes.

HCN: the amounts of hydrogen cyanide present in laser smoke cannot cause acute effects. Chronic intoxication, on the other hand, is not impossible for those who are frequently exposed. This is mainly revealed by headaches, asthenia, vertigo and palpitations, nausea, vomiting, stomach pains and weight-loss, conjunctivitis. Finally, thyroid problems are also a possibility.

CO: the signs of early acute intoxication are very banal: headache, vertigo, asthenia and some digestive problems. More severe forms can lead to coma and death; significant (neurological) sequelae are possible. The problem of chronic exposure is discussed; it may be linked to vascular problems with an increased risk of myocardial infarction. In addition, some neurological disorders such as Parkinson's disease could also be a consequence.

The table below summarises the general toxic effects of the main compounds usually found in laser smoke (after Frenette, 2003).

Table 2: Some chemical compounds found in surgical smoke and their effects on health.

2 -Methyl furane	Carbon monoxide	m-Cresol ^{1,11}
2-Methylpropanol	Carbon sulphide ^{1,6,7}	Methane
3-Methyl butane	Creosote ²	PAH ³
6-Methyl phenol	D-1-decene	Palmitic acid
Acetonitrile ¹	D-2,3-dihydroindene ¹	Phenol ^{1,9}
Acetylene	Ethane	Polypropylene ^{1,8}
Acroleine ¹	Ethylbenzene	Pyridine ^{1,11}
Acrylonitrile ^{1,3,5}	Ethylene	Pyrrole ^{1,11}
Alkyl benzene sulfonate	Formaldehyde ^{1,2,4,8}	Styrene ¹
Benzaldehyde ¹	Furfural ^{1,3,9}	Toluene ^{9,11}
Benzene ^{1,2,4,9,11}	Hydrogen cyanide ¹	Xylene ¹¹
Benzonitrile	Indole ¹	
Butadiene ^{1,3,4,9}	Isobutane	

1- Skin and respiratory system irritants

2- Suspected human carcinogens

3- Confirmed human carcinogens

4- Suspected human mutagens

5- Suspected animal mutagens

6- Substances liable to affect human sperm

7- Molecules which may cause both cellular asphyxia and embryo-foetotoxicity

8- Respiratory sensitisers

9- Teratogenic in animals

10- Teratogenic in humans

11- Substances which may cause central nervous system depression

The unlabelled substances are either insufficiently characterised from the toxicological point of view or cause only asphyxiation at high concentrations.

Some of the organic pollutants belong to the heterogeneous group of "Volatile Organic Compounds" (VOC), a mixture of substances from various chemical families. These can be found at varying concentrations in the atmosphere of houses.

2.2.3 Biological pollutants

Very few studies give an idea of the biological effects linked to inhaling laser smoke in operating theatres. The main ones considered, besides general effects, are mainly mutagenesis and carcinogenesis.

2.3 Effects of surgical smoke

2.3.1 General effects

The general effects/symptoms were listed by Alp (2006) based on the usual composition of laser smoke. This inventory, which includes both acute (irritation) and chronic (cancer) effects, is therefore not based on epidemiological studies. It is a list of the theoretically conceivable hazards based on the compounds usually present, covering acute (irritation) and chronic (cancer) effects.

Table 3: Conceivable risks according to Alp (2006) based on the composition of surgical smoke.

Acute or chronic inflammation of the respiratory tract (bronchitis, asthma, emphysema)	Hepatitis
Anaemia	HIV infection
Anxiety	Hypoxia, dizziness
Carcinoma	Lacrimation
Cardiovascular dysfunction	Leukaemia
Colic	Nausea, vomiting
Dermatitis	Sneezing
Eye irritation	Throat irritation
Headache	Weakness

Potential irritation of the respiratory tract was shown in two experimental studies carried out by Baggish and collaborators (1987, 1988). In one of these studies, instillation of particles produced by vaporisation of tissue by a CO₂ laser in the alveoli of rats caused congestive interstitial pneumonia, bronchiolitis and emphysema. During the other trial, smoke produced by a CO₂ laser had an irritant effect on the lung in rats. The effect is less significant when the smoke first passes through a standard smoke evacuator. No effect (clinical or histological) is noted when rats are subjected to smoke filtered by a high-performance filtration system retaining particles down to 0.1 µm. Freitag et al. (1987) also showed that smoke produced by lasers could have an irritant effect on the respiratory system. In this study, carried out in sheep, the exposure concentration was 0.92 mg particles.litre⁻¹ and the mean diameter of particles was 0.54 µm; the irritant effect was evaluated on cells collected through bronchoalveolar lavage.

2.3.2 Specific effects

So far, only genotoxicity and cytotoxicity have been assessed specifically for surgical smoke, but the number of studies remains low and does not lead to a firm conclusion.

Genotoxicity

Only mutagenicity by the Ames test (with and without metabolic activation) was assessed.

Tomita et al. (1981) evaluated the mutagenic potential of smoke produced by CO₂ laser surgery on the mucous membrane of canine tongue. Condensate was collected by aspirating the smoke through filter paper. It was then diluted in DMSO. Salmonella strains TA 98 and 100, used in the Ames test, were exposed to the mixture obtained. The result was positive on TA 98 (with and without metabolic activation) and on TA 100 (with metabolic activation by S9 mix, prepared from rat liver pre-treated with polychlorobiphenyl).

Gatti et al. (1992) carried out a similar study, but collected air samples from an operating theatre during use of an electrocautery knife for reductive mammoplasty. The condensate collected was also tested on TA 98 and 100 Salmonella strains. Mutagenic activity was found on TA 98 after metabolic activation (S9 mix from rat liver pre-treated with Aroclor 1254).

These results, although positive, are unfortunately quite restricted. They are not necessarily representative of all types of smoke produced by lasers. Results may differ depending on laser power, the tissues treated and the environment.

Cytotoxicity

The smoke produced in experimental conditions through repeatedly cutting pig liver with an electrocautery knife at high frequency was applied to mammary carcinoma cells (MCF-7) in culture. Cell viability in these cell cultures was reduced by at least 30%, demonstrating the cytotoxicity of this smoke. This test was carried out in specific conditions (under helium atmosphere) and is not necessarily representative of the smoke generated in operating theatres (Hensman, 1998).

2.4 Data in humans

In the preceding section (chapter 2) the health hazards potentially associated with smoke and particles in operating theatres were discussed. The literature contains abundant toxicological data on this theme (see chapter 8). However, these data mainly rely on *in vitro* studies and on a small number of animal studies. The conclusions drawn from these sources, with regard to risks for exposed personnel, seem plausible and have been corroborated by data from

environmental medicine. This applies both to the effects of particles (in comparison with fine dust) and their potential infectiousness, and to the toxicological properties of the various harmful substances present in operating theatre smoke.

However, there is relatively little data on the real practical impact of these hazards on the exposed personnel. Besides isolated cases of laryngeal papillomas which were probably contracted in the work environment by personnel exposed to laser smoke, there are barely any epidemiological studies which would allow us to establish on a wider scale whether the hazards identified in laboratory data are effectively measurable in the population concerned. Various authors underline the lack of information on this point:

"a specific link between exposure to surgical smoke and adverse health effects to perioperative personnel has not been made" (Ulmer, 2008)

"the long term effects of surgical smoke on surgeons and theatre personnel have not been determined" (Al Sahaf, 2007)

"further research using authentic surgical conditions rather than laboratory simulations may produce more convincing findings to assist regulatory agencies such as the OSHA" (Bigony, 2007)

"many surgeons and OR personnel argue that they have been exposed to surgical smoke for years with no ill effects" (Barrett, 2003)

Others have attempted to make up for the lack of data through risk assessment (Scott, 2004). Using theoretical toxicological information for substances combined with information on the nature and significance of exposure they quantitatively evaluated personnel health risks.

Therefore, we will now review the few studies attempting to validate theoretical risk assessments in real conditions by investigating actual incidences of personnel discomfort or diseases linked to operating theatre smoke. These are generally case studies or studies on epidemiological data.

Hallmo (1991) described the case of a surgeon with a pharyngeal papilloma. He had been regularly exposed to laser smoke for long periods through exeresis of ano-genital warts, and no other possibility of contact with the virus could be established.

Laryngeal papillomatosis was also recognised as an occupational disease in a nurse assisting surgeons during treatment of papillomatoses (Calero, 2003). Once again, no other possibility of contact with the virus could be identified.

In a questionnaire-based survey addressed to 4,200 members of the American Society for Laser Medicine and Surgery (ASLMS) and the American Society for Dermatologic Surgery (ASDS), Gloster and Roenigk (1995) noted that, compared to the population of Olmsted (Minnesota) and to patients treated for warts between 1988 and 1992 at the Mayo Clinic, the 570 doctors answering the survey did not present a significant increase of this type of cutaneous modification (5.4% versus 4.9%, $p = 0.569$). Indeed, older sources indicate that the frequency of warts in the population varies between 2.8 and 5% (Beutner, 1991), which is not significantly different from the Gloster data. However, for dermatologists performing this type of surgery, 58% of warts were located on the hands, 26% on the face and 13% in the nasopharyngeal area. This contrasts with the distribution reported for patients treated at the Mayo Clinic, for whom warts were mainly located on the soles of the feet or in the anogenital region.

Gloster's study also showed that the incidence of warts in surgeons was not affected by the application of some preventive measures, including: smoke capture and wearing gloves, masks, eye protection or special gowns. It didn't show any cumulative effect either, such as increased incidence of warts as a result of extended use of CO₂ lasers. Although Gloster's study has some weaknesses (in particular the low response rate), it leads to the conclusion that a low risk for the health of exposed medical personnel, related in particular to the inhalation of infectious particles, cannot be excluded.

A simpler and more restricted questionnaire-based survey was carried out by the NIOSH in 2001 on a 687-bed clinic in Dunedin (Florida) (King & McCullough, 2006). 48 questionnaires were returned, corresponding to an 80% response rate. 43.7% of participants reported at least one symptom that they linked to smoke exposure in operating theatres over the preceding four weeks. In decreasing order, the following symptoms were mentioned (several answers possible): headache (16.7%), burning sensations in the nose and pharynx (12.5%), rhinitis (12.5%), eye irritations (10.4%), coughing (10.4%) and other disorders mainly affecting the airways (8.4%). In total, 28 people (58.3%) indicated discomfort due to the smell of the smoke. In addition, people spending 50% or more of their time close to the operating theatre indicated more symptoms than others.

The only prospective study published to date on operating theatre smoke-related health damage is that of Gates et al. (2007). The authors studied a population of 121,700 nurses (Nurse Health Study) recruited from 1976 and having undergone periodic examinations to look for a potential link between exposure to smoke in operating theatres and the occurrence of bronchial carcinoma. The number of years of activity in operating theatres before 1984 was taken as an indicator of exposure to surgical smoke. All cases of bronchial carcinoma declared before the close of the study in 2000 were counted. Five groups were defined by taking a series of confounding factors into account (age, active or passive smoking, BMI, dietary factors, and

physical activity). The use of different epidemiological models did not show a significant relationship between the duration of exposure to smoke in operating theatres and the occurrence of bronchial carcinoma, nor a trend indicating a dose-effect relationship in the more exposed groups. On the contrary, the group with the longest exposure duration presented a significantly lower relative risk of bronchial carcinoma. The authors could not find a convincing explanation for this.

These few epidemiological data are insufficient to relieve the doubts and reserves expressed above about the clinical relevance of the, mainly experimental, data establishing the existence of health hazards linked to smoke in operating theatres. It is therefore not surprising that, although the problem is known to most of the involved parties and while various recommendations have been published, mainly by professional organisations or federations independent of state authorities, preventive measures are neither consistently applied nor imposed by regulations.

In 2007 an Internet survey was carried out on American and Canadian operating theatre personnel (almost exclusively assistants). This survey revealed that during the use of electrocautery knives, between 8 and 59% of operators used a dedicated smoke capture system, and in 17 to 67% of cases they used the operating theatre's wall-mounted system. The percentage differences are linked to differences in the use of apparatus depending on the type of intervention (most frequently condyloma exeresis, more rarely excision of malignant cutaneous lesions (electric cautery) or as part of laparoscopy (laser)). The survey also showed that during electrocautery, in 80 to 90% of cases operators wore simple noncertified surgical masks rather than particle respirators capable of blocking airborne pathogens (N95 type, certified in America). These differences in the frequency of use of safety devices reflect individual perceptions of risks and indicate, according to the authors, that most exposed personnel are insufficiently protected (Edwards, 2008).

A study by Spearman et al. (2007) based on 169 questionnaires addressed to general surgical consultants, surgical registrars and senior theatre nurses in the Wessex region (Great Britain) obtained similar data but gave a more reserved interpretation. The aim of the study was to gauge awareness of the problem of health risks linked to smoke in operating theatres on the one hand, and the preventive measures implemented on the other. Of a total of 111 responses, 97% indicated frequent or consistent use of diathermy at the operating block. Only 51% of general surgical consultants considered smoke as hazardous to health against 78% of specialist registrars and 91% of senior nurses. In these groups, 60, 58 and 64% of answers indicated that the preventive measures implemented were insufficient. 43% of general surgical consultants and 70% of specialist registrars regularly used smoke extractors, the majority of them using wall-mounted suction systems. Additional protective measures (mainly dedicated masks) were only applied by 7% of general surgical consultants and 20% of specialist registrars. The authors concluded,

in particular, that "knowledge of the dangers of surgical smoke is limited, but is a cause for concern amongst staff exposed to surgical smoke in theatres."

2.5 Evaluation of available data

The data presented in chapter 2 undoubtedly show that we have toxicological information relating to the hazards of smoke in operating theatres based on *in vitro* assays and animal studies, as well as on the toxicity of their main constituents, but that the effects on exposed personnel have not been adequately evaluated. Because of this, exposed personnel are not inclined to take the available data into account, or to implement preventive measures. This "wait and see" attitude is favoured in many cases by the absence of precise instructions given by OHS bodies. The question is to know whether steps to reduce health risks for workers should be taken only once sufficient consistent scientific data is available, in particular results of epidemiological studies, or whether a pro-active approach should be adopted in line with the precautionary principle. This type of approach represents a greater effort than a *post-hoc* approach as well as problems related to costs and alignment of measures. It is therefore viewed, as a last resort, as a risk management process which will be differentially interpreted depending on the country of application.

It is, however, certain that exposure to smoke in operating theatres may pose serious risks for health, as indicated by the toxicological data. We will see below what steps should be taken to reduce these risks. Measures can be implemented taking applicable national regulations into account.

3 Exposure during activities producing smoke and how to assess it

In the preceding chapters we saw that various medical activities result in gas phase or particulate emissions which may present health risks for operating theatre personnel.

As indicated in the introduction, in the United States alone, the health sector population concerned is evaluated at several hundred thousand (Ball, 2004). In Europe, where the population is greater, the figures must be at least equivalent.

3.1 Description of emission sources (also see Chapter 2)

The intensity of emission of substances and the composition of the gas and solid phases depend on the nature of the energy source, of the tissue treated; and on the duration and extent of the intervention.

During the use of lasers, typical values cited in the literature for particle emissions can be as high as 120 mg/min for a laser power density of 7.2 kW.cm^{-2} . The highest levels of emissions are observed for interventions on fatty tissues, followed by interventions on hepatic tissues. According to the literature, the lowest emissions are observed during interventions on skin (Wäsche, Wagner et al., 1993).

The global rate of vapour production during laser use, including the emission of gas phase components, is even higher (200 to 600 mg.m^{-1}) (Wäsche, Albrecht et al., 1995).

3.2 Description of parameters determining exposure

The health sector activities during which surgical smoke is produced may vary from one intervention to the next, even at the same work station. A series of organisational and technical parameters may increase or decrease operator exposure. It is known that atmospheric concentrations vary both in the short term, over the course of a day, and in the long term, over a month or a year, with regard to values weighted according to the duration of a work station (e.g. Rappoport, 1998).

Below we will present the determinants liable to affect personnel exposure to surgical smoke.

3.2.1 Surgical instruments

Surgical smoke is the result, as we know, of thermal energy acting on various tissue types and capable of causing tissue browning, incision and coagulation, burns and vaporisation (VDI Sonderband, 1988). Energy transfer to the tissue can be through optical waves (laser), by electrical current (electro-surgical apparatus) or by ultrasound.

a) Laser

Laser applications in medicine depend both on medical indications (in particular the energy/intensity to be used depending on the tissue type), and on technical factors such as the optical properties of the tissue to be treated, i.e. its reflective, absorptive, dispersive, transmissive etc. properties. Various types of laser are used, the following table gives an overview of the main ones (based on INRS ED 5009, 2004).

Table 4: Lasers for medical use (based on INRS ED 5009, 2004)

Active material	Wavelength (nanometres)	Operating mode: continuous or pulsed	Pulse frequency	Energy or power	Uses
Excimers	190 to 350, 248, 308	pulsed	1 to 400 Hz	a few joules	angioplasty, ophthalmology
Metal (gold) vapour, plasma	511 and 578 Gold: 628	pulsed	10 kHz	5 to 20 W	dermatology, plastic surgery, phototherapy
Helium - Neon	632	continuous		0.1 to 50 mW	acupuncture, sports and beauty medicine, rheumatology
Argon krypton (plasma)	488 - 515 - 647 – 976	continuous		0.1 to 20 W	dermatology, pump for dye laser, ophthalmology, photocoagulation, plastic surgery
Carbon monoxide (CO)	5,300	continuous		1 to 20 W	ENT, gynaecology, dermatology, odontology
Carbon dioxide (CO ₂)	10,600	pulsed - continuous	10 kHz	100 J to 100 W	cardiovascular, ENT, dermatology, gynaecology, plastic surgery, gastrology, odontology
YAG - Erbium	2,930	pulsed	a few Hz	10 J.cm ⁻²	dermatology, combined effect of CO ₂ lasers and excimers, ophthalmology
YAG frequency-doubled with Kr crystal	532	pulsed - continuous	1 to 50 Hz	1 to 120 W	dermatology
Ruby	694	pulsed	a few Hz	10 or 50 mJ	lithotripsy, dermatology, destruction of kidney stones
Laser diodes	850	pulsed - continuous		a few W	ophthalmology, angioplasty
YAG frequency-doubled with KDP, KTP crystal	1,064 532 (doubled frequency)	pulsed - continuous	1 to 50 Hz	1 to 60 W	ENT, gynaecology, urology, neurology, general surgery, odontology, ophthalmology, dermatology
Titanium sapphire	700 to 1,070 - doubled: 350 to 535	pulsed - continuous	1 to 50 kHz	a few mJ – 1 W	phototherapy
YAG - Holmium	2,100	pulsed	1 to 5 Hz	0.5 to 100 J.cm ⁻²	lithotripsy
Dyes	320 to 1,200 particularly: 504 and 630	pulsed - continuous		a few W	lithotripsy, phototherapy, dermatology, photochemotherapy, photocoagulation

How the laser acts on tissues depends on the **type** of laser (see table 4), on its **power density** (power/surface) and on its **operating mode** (pulsed or continuous). In Europe, lasers are classed depending on their harmful effects on humans, from class 1 (no hazard) to class 4 (very hazardous for the skin and hazardous for the eyes, even when diffusely reflected, in addition to the risks of fire and explosion). Most applications of medical lasers are class 4 (for a definition of laser classes see BS EN 60825-1).

b) Electro-surgical units (ESU)

Electrosurgical interventions use high frequency (>300 kHz) current units whose **power** can vary from a few watts to several hundred watts. The energy passes through **monopolar electrodes**, a large surface area neutral electrode, or grounding pad, is placed under the patient to allow current to flow off. In the case of **bipolar electrodes**, the current only passes between the two poles, which are located near each other. Thermal energy at points where the density of electrical energy is high has varying effects depending on **current intensity**, the chosen **voltage** and the **frequency** of the current as well as the **shape of the electrode** used: tissue dessication, coagulation, possible surface carbonisation due to the electrode producing sparks when placed just above the tissue, or incision achieved using small-sized electrodes allowing exeresis of the tissue and coagulation of the borders of the incision through explosive vaporisation of cellular liquids.

c) Other units (e.g. for re-intervention on endoprostheses)

Removal of synthetic bone cement (generally acrylic resin made from methyl methacrylate) from the medullary cavity of long bones, e.g. during artificial hip replacement, can be done using ultrasound devices.

3.2.2 Local exhaust ventilation (LEV)

One of the main factors influencing smoke production is the capture of emissions at source. Thanks to this, most vapour, gas or particles never reach the respiratory zone of the operator. There are different types of local exhaust ventilation:

- capture integrated into the handpiece of the laser or ESU
Laser device or ESU manufacturers offer handpieces with integrated aspiration systems. This design allows the collection orifice to remain at a constant distance from the source of smoke.
- wall-mounted capture devices, stationary
In this configuration, the gases captured are not rejected into the room but are discharged by a central aspiration system. They must first be decontaminated by filtration, this avoids contamination of the system. Their aspiration rate is, however, significantly lower than that of independent capture devices.

- separate capture devices

Most frequently, these are mobile devices whose aspiration nozzle is separate from the laser or handpiece of the ESU. In this case, the localised aspiration system must be able to follow the handpiece. The gases captured must also be sufficiently filtered within the mobile unit to allow the air to be rejected back into the room. Mobile collection devices have a much higher aspiration rate than stationary devices.

The main factors influencing gas release and, therefore, operator exposure are the following, in the case of localised aspiration modules:

- aspiration rate (litres/minute):
efficiency of capture increases with aspiration rate
- speed of air at the aspiration orifice (m/s):
capture efficiency increases with air speed. At equivalent rate however, air speed decreases as a function of the increase of the square of the diameter of the collection orifice.
- distance between the aspiration orifice and the source of emission:
air speed during capture decreases as a function of the square of this distance.
- specific filtration capacity for substances to be filtered:
the filters used must retain gas, vapour and particles, which they do only to a certain degree.
- how and at what speed air is recycled:
recycled air is not totally devoid of smoke; the recycling rate therefore influences the concentration of airborne pollutants in the workroom.

We can clearly see that the factors influencing capture efficiency (e.g. air speed, aspiration rate and diameter of the aspiration nozzle) are not independent of each other, and that they must be individually optimised to meet specific constraints in different cases. For more information on this point, see chapter 4.2.

3.2.3 *General ventilation*

Gas which is not captured at source during an intervention is dispersed in the air of the room. The room's ventilation system dilutes pollutants and removes them from the breathing zone of operators. The following parameters influence the level of personnel exposure:

- type of ventilation system (natural or mechanical) and rate of introduction of outside air into the work zone.
The efficiency of ventilation at work stations considerably influences exposure. In zones where medical interventions are carried out, natural ventilation is generally insufficient; only mechanical ventilation

allows sufficient air renewal to eliminate pollutants from the breathing zone of personnel and patients.

- type of air flow (e.g. laminar flow ceilings, exhaust openings at floor level), flow orientation (descending or ascending ventilation).
- Surgical smoke is formed during thermal processes; it is hot and therefore tends to rise. If the air flow is directed from top to bottom, as is the case for a laminar flow ceiling, the smoke will affect ventilation efficiency.
- rate of reintroduction of air into the work zone. Where air is recycled, surgical smoke which has not been eliminated from the extracted air is reintroduced into the room, increasing personnel exposure.
- nature and efficiency of air filters.
- Particles and gas/vapour contained in smoke require different filtration methods. The efficiency of the filtration elements must be adapted.
 - To filter suspended compounds/particles HEPA (High Efficiency Particulate Air) filters are generally used. These are characterised by a retention power up to 99.995%, including for particles of critical size (0.1-0.3 μm) (see BS EN 1822-1:1998).
 - Considerations relating to the effects of even finer particles (Ultra fine particles or nanoparticles) have resulted in the use of even more powerful filters, ULPA (Ultra Low Penetration Air) filters, whose retention power is 1,000 times higher than that of HEPA filters.
 - Gas/vapour contained in air can only be eliminated by activated charcoal filters capable of adsorbing gas and vapour molecules. This is the only way to eliminate strong smelling gases, in particular when extracted air is partially or totally reintroduced into the work zone.

3.2.4 Activity

The nature and extent of interventions, as well as the body parts or tissues involved, are important parameters for exposure to surgical smoke. The factors described in point 3.2.1 determine the choice of laser or electrosurgical unit that will be used. The length of the intervention has an impact on the total duration of exposure, while the duration of use of the instrument responsible for emissions determines the total quantity of smoke emitted. The operating mode of the instrument (pulsed or continuous) significantly influences the quantity of smoke produced, as does the type of intervention: endoscopic interventions do not have the same consequences in terms of exposure as

interventions on external body parts. Finally, a person standing close to the source of emission is more exposed than someone standing further away in the work zone.

3.2.5 Aspects relating to work organisation

In addition to the parameters cited above, the number of interventions per unit of time (workstation, day, etc.) must be considered when assessing exposure.

Assessment of global exposure must also integrate all the chemical factors present (because of disinfection, sterilisation or cleaning operations, use of anaesthetics etc.).

3.2.6 Individual factors

Most of the previous parameters are easy to determine and measure. This is not the case for parameters linked to individual factors which can also vary over time. For example:

- operator qualification for the intervention
- experience of the personnel as a whole in the type of intervention performed
- some exclusively individual factors such as work technique, cleanliness, potential tiredness etc.
- specific factors linked to the patient (e.g. adiposity, extent of the tumour).

3.2.7 Quality assurance measures

Finally, the influence of quality assurance measures on the material used must not be forgotten, in particular, measures ensuring periodic control and maintenance of electrosurgical devices, but also of smoke capture and ventilation devices. Changing filters, in particular, is essential to ensure constant performance levels for capture systems.

3.3 Description of exposure

Surgical smoke is a mixture of a large number of compounds which can be present as gases, vapours or particulate components (see Chapter 2). Analyses have allowed the identification of various substances, mainly hydrocarbons, nitriles, fatty acids and phenols. Among these substances, formaldehyde, acroleine, mixtures containing benzene, toluene, ethylbenzene, xylene and polycyclic aromatic hydrocarbons are the most significant (see Chapter 2). To this list must be added: cellular residues from the tissue treated and, if applicable, fragments of viral DNA (Gloster, Roenigk, 1995).

These multiple components create a mixture which is difficult to measure, composed of products present in diverse forms. It is therefore not surprising that we only have very little quantitative information on exposure to surgical smoke.

3.3.1 Metrology data from the literature

a) Lasers

The first data on exposure by inhalation during medical applications of lasers were obtained in the 1970s. In their study identifying human papilloma virus (HPV) DNA in smoke from CO₂ lasers, Kashima et al. (1991) cite the work of Mihashi et al. (1975), who were able to establish the presence of cellular fragments and combustion products in laser smoke. In the case of patients presenting "recurrent respiratory laryngeal papillomatosis (RRP)" treated by CO₂ laser, Kashima et al. showed that 17 of 22 samples of air collected in the air expired by the patients contained HPV DNA, while for control samples (patients without RRP), no HPV DNA was detected. They thus confirmed the studies of Garden et al. (1988) who had shown the presence of bovine and human PV DNA in laser smoke during treatment of warts. However, it was not possible to quantify the biological exposure or assess risks.

In other laser applications too, emission of inhalable particles of unknown biological activity is to be expected. Taravella et al. (2001) demonstrated this during the use of Excimer lasers in ophthalmology. They detected a few rare particles of mean geometric diameter 0.22 µm +/- 0.056 µm in air samples. However, they were not able to quantify or assess exposure.

Wäsche et al. (VDI-Sonderband, 1998) studied the phenomena induced and the products of pyrolysis during laser treatment of human tissues. They described the interaction between laser energy and cells precisely, and for a variety of tissues they extensively analysed the smoke and studied the products of pyrolysis by chromatography. They were thus able to identify volatile and particulate components. During the use of CO₂ lasers, they were able to show that vaporisation of hepatic, muscle and adipose tissue at power densities of approximately 0.1 to 10 kW/cm² was around 17.5 mg/min/(laser power in W). The laser power setting was 10, 20 or 40 watts. The distribution of particle diameters in smoke was also recorded. The majority of particles were shown to have a diameter of less than 1 µm and, for a non-negligible proportion, this was under 100 nm.

Binding and Wäsche (1998) conducted measurements during a simulation of the use of lasers in operating theatres. They simulated a 30-minute intervention on the liver with a CO₂ laser (power = 20 W, ray diameter 0.6-1.2 mm, laser activity time = 5 min). The results showed alveolar aerosol concentrations between 3 and 8 mg.m⁻³ in the surgeon's breathing zone.

Measurement of volatile organic compounds emitted over 5 min (laser activity time) at the surgeon's work station gave the values reported in table 5.

Note that the lowest power densities gave higher VOC concentrations, although the values remained generally low, of the order of $\mu\text{g}/\text{m}^3$ or ppb, both units being of similar order of magnitude.

Table 5: Concentrations of various VOC at the surgeon's work station (Source: Binding and Wäsche, 1998)

Name	Power density approx 4 kW/cm ² atmospheric concentration [$\mu\text{g}.\text{m}^{-3}$]	Power density approx 0.3 kW/cm ² atmospheric concentration [$\mu\text{g}.\text{m}^{-3}$]
n-Butanal	43±8	91±25
2-Butanone	12±2	14±3
3-Methylbutanal	80±16	203±19
2-Methylbutanal	69±4	138±11
Benzene	60±5	64±4
Pyrrole + Pyridine	34±4	52±7
Toluene	23±9	41±15
Ethylbenzene	7±1	5±3
Styrene	9±3	3±1

b) Electro-surgical units (ESU)

In a literature review, Barrett and Garber (2003) point out that, during laparoscopy, surgeons are exposed to significant levels of acrylonitrile (1.0 – 1.6 ppm) and hydrogen cyanide (approx 10 ppm) (Wu, Luttmann et al., 1997). They also indicate very high concentrations of benzene (up to $7.4 \text{ mg}.\text{m}^{-3}$ in the air of the operating theatre). But they do not mention whether these are for short or very short exposure periods or are time-weighted values that could be compared to the exposure limit values at the work station.

The authors also indicate exposure to particulate pollutants (0.4 to $9.4 \text{ mg}.\text{m}^{-3}$ in the air of the operating theatre) during electrocautery for breast reduction.

The NIOSH has carried out studies of exposure during electrocautery in various hospitals in the United States (King, McCullough, 2006 a,b,c). Participants' activity was documented over several days and volatile and particulate pollutants were measured. The results were similar for all institutions:

- For volatile compounds, only formaldehyde, acetaldehyde and toluene were detected at significant concentrations.
- The concentrations of these compounds were, however, always far below the American occupational exposure limit values (OELs).

The work of the NIOSH is well documented, but does not provide any information about factors determining exposure. This means that the atmospheric concentrations indicated cannot be related to the protective measures implemented, such as capture and ventilation.

Hollmann et al. (2004) used an electro-surgical unit to measure various pollutants in the immediate vicinity (at about 2 cm) of intervention points (see Table 6). The values measured correspond to maximum possible exposure concentrations. This equates to the worst case scenario because the pollutants captured at this level have not yet been diluted in the surrounding air.

Table 6: Gas components identified in electrocautery smoke, their calculated concentrations, and corresponding occupational exposure limit, as available (Source: Hollmann et al., 2004)

CAS No.	Substance	Formula	Detection limit [ppm V]	Concentration [ppm V]	OEL [ppm V] Switzerland 2001
100-80-1	1-Ethenyl-3-methyl-benzene	C ₉ H ₁₀	0.3	12	na
106-99-0	1,3-Butadiene	C ₄ H ₆	0.016	1.5	5.0
107-12-0	Propanenitrile	C ₃ H ₅ N	1.1	18	na
108-88-3	Toluene	C ₇ H ₈	0.2	17	50
556-64-9	Methyl thiocyanate	CH ₃ SCN	0.4	22	na
592-76-7	1-Heptene	C ₇ H ₁₄	0.1	8.5	na
74-85-1	Ethylene	C ₂ H ₄	0.00007	0.065	10000
7664-41-7	Ammonia	NH ₃	0.00007	0.12	20
872-05-9	1-Decene	C ₁₀ H ₂₀	0.8	190	na
98-01-1	2-Furaldehyde	C ₅ H ₄ O ₂	0.2	24	2
115-11-7	Methylpropene	C ₄ H ₈	0.02	7.2	na

na: not available

CAS = Chemical Abstracts Service registry number

Moot et al. (2007) also studied volatile organic compounds in smoke during electro-surgical interventions, and found hydrogen cyanide (3-51 ppm), acetylene (2-8 ppm) and 1,3-butadiene (0.15-0.69 ppm) directly at the point of emission.

Barrett and Garber (2003) noted that carbon monoxide was one of the main constituents of surgical smoke, reaching concentrations of up to several hundred ppm during interventions in the peritoneal cavity.

Bröske-Hohlfeld et al. (2008) found that during operations using laser or ultrasonic scalpels, nanoscaled particles and larger particles (< 1 µm) were formed as a result of the energy applied. Concentration peaks were over 100,000 particles.cm⁻³.

c) Other apparatus

Measurement of the pyrolysis products formed during the withdrawal of bone cement from the femur in experimental conditions (Aldinger, Kleine, Goebel et al., 2001) showed that the methyl methacrylate (MMA) concentration in air samples collected in the breathing zone of participants could reach up to 20 mg.m^{-3} . In the ascending smoke plume, MMA concentrations could reach up to 140 mg.m^{-3} . Gravimetric measurement of the mass of smoke particles collected on a fibreglass filter showed 76.89 mg in 7 minutes, which equates to particle emission at almost 11 mg.min^{-1} . The level of MMA emission measured can, however, be explained by the fact that the experiment was carried out on bones where the bone cement was only introduced during preparation of the test. We can assume that it contained more MMA than would cement that had been in place for a number of years.

Gas chromatography and mass spectrometry of volatile pyrolysis products showed, in this case, that only a few compounds were present: carbon dioxide, carbon monoxide, methyl acrylate, methyl methacrylate and dimethyl-p-toluidine.

3.3.2 Other information on exposure

Compared to data on the release of substances during the interventions presented, the metrology data on personnel exposure are rare and very incomplete. This leads to the application of alternative, non-metrological, methods to determine exposure. These would allow better use of the metrology data available. Modelling exposure using the available information on pollutant sources, techniques used, configuration of the room and work organisation, should allow personnel exposure to be assessed based on variations to the different parameters (BS EN 689, 1995; TRGS 400, 2008; TRGS 402, 2008; Eickmann, 2008).

Binding and Wäsche (1998) calculated that during intervention on the liver using a CO_2 laser (power: 30 W, duration of use: 5 or 30 min) in a 100 m^3 operating theatre with air renewal at 19/h, the **toluene concentration** could reach $3.5 \text{ }\mu\text{g.m}^{-3}$ (concentration peak) with 5 minutes' use. After 30 minutes' use, all other parameters remaining stable, the average toluene concentration reached $4.5 \text{ }\mu\text{g.m}^{-3}$.

If we consider that the surgeon is the most exposed due to proximity to the source of pollutants, and we therefore apply a two-zone exposure model (Nicas, 1996), the surgeon's peak exposure is $25.5 \text{ }\mu\text{g.m}^{-3}$ and the average exposure over the whole intervention is $4.4 \text{ }\mu\text{g.m}^{-3}$ with 5 minutes' laser use. For 30 minutes' laser use, the exposure peak for the surgeon is $26.4 \text{ }\mu\text{g.m}^{-3}$ and average toluene exposure during the intervention is $25.98 \text{ }\mu\text{g.m}^{-3}$. The small difference between the exposure peak ($26.4 \text{ }\mu\text{g.m}^{-3}$) and average exposure ($25.98 \text{ }\mu\text{g.m}^{-3}$) for a relatively long duration of laser use can be

explained by the fact that a high rate of air renewal in the operating theatre ensures stable exposure conditions within a few minutes, during which the peak rapidly approaches average levels. Surgeon exposure is almost 6.1 times higher than the average exposure for other personnel in the operating theatre. According to the available data on substance emission during laser surgery (Wäsche, Albrecht, 1995), personnel exposure to **particulate pollutants** in the operating room is probably much more worrying. Assuming that the thermal power of the laser or ESU is entirely used to vaporise cellular material, and that the percentage of aerosols emitted reaches 13%, as indicated by Wäsche and Albrecht, this results in an average particulate exposure for the surgeon of approximately 1.6 mg.m^{-3} over the course of the intervention (duration of laser use: 5 minutes, power: 20 W, duration of intervention: 30 minutes, operating theatre volume: 110 m^3 , ventilation: approximately $2,000 \text{ m}^3.\text{h}^{-1}$). In the same conditions, we can calculate that the short duration exposure peak would be 10.6 mg.m^{-3} . Doubling the laser usage time (to 10 minutes) increases the average airborne concentration to 3.5 mg.m^{-3} , but the concentration peak does not exceed 11 mg.m^{-3} .

The thermal power of electro-surgical units can be much higher than in the example presented. However, this power is only partially used to vaporise cellular material. A number of other effects are mainly observed, including heating, browning and coagulation of tissue, and carbonisation.

3.4 Assessing exposure

As indicated, the information on individual exposure to surgical smoke is generally incomplete. It does, however, allow some general remarks to be formulated:

- Assessing gas-phase components
Exposure to gases or vapours is relatively low during the use of laser or electrosurgical techniques in modern operating theatres. While olfactory discomfort can be encountered, exposure levels for substances such as toluene, butanone or ethylbenzene are far from the limit values (see Table 7). Smoke does, however, contain volatile substances in the CMR class (e.g. benzene). As for comparable pyrolysis products (e.g. tobacco smoke), the general rule to keep exposure at the lowest level possible must be applied.

Table 7: Limit values for the concentration of some compounds present in surgical smoke
(source: GESTIS data base. International ELV: see
www.dguv.de/ifa/en/gestis/limit_values/index.jsp, 05.07.2010)

Country	Values in [mg.m ⁻³] threshold limit value/short-term exposure limit		
	Toluene	Butanone	Ethylbenzene
France	192/384	600/900	88.4/442
Germany	190/760	600/600	440/880
USA/NIOSH	375/560	590/ 885	435/545
Switzerland	190/760	590/590	435/435

- Assessing particulate components
Personnel are mainly exposed to very fine particles (nanoparticles). For the processes described here, the atmospheric concentration is a few mg.m⁻³, which, from the quantitative point of view, is problematic for the airways of the exposed personnel. (Exposure limit value for total dust in Germany: respirable fraction = 3 mg.m⁻³, inhalable fraction = 10 mg.m⁻³; European limit value for ultrafine dust = 40 µg.m⁻³). Adequate protective measures must therefore be taken.
- Assessing Nanoparticles
It is not currently possible to assess exposure to ultrafine particles. They can penetrate through the whole body, in addition to the usual pathways for substance absorption (this is termed "translocation"). This means that even exposure to very small quantities of substances cannot currently be considered without effect.
- Assessing biological components
It seems certain that biologically active cells or cellular elements are dispersed in the air during electrosurgery or laser interventions. It is not, however, possible to quantitatively evaluate the corresponding exposure. It is therefore advisable to avoid the release of smoke.
- Assessing olfactory discomfort
The products of pyrolysis of human tissues cause very unpleasant odours, often reported as nauseating.

4 Preventive measures

To avoid exposure to surgical smoke, it is advisable to use traditional protective measures, such as those applied in industry for the prevention or reduction of exposure. A certain number of these measures have already been described in point 3.2, relating to parameters determining exposure. In the health care sector, as in the other fields, the order of priority fixed by the OSH “Framework Directive” must be respected for the choice of preventive measures:

- I. Substitution (replacing the dangerous by the non-dangerous or the less dangerous);
- II. Collective protective measures (enclosing the source of risks, localised aspiration);
- III. Organisational preventive measures (keeping a distance from the source of risk);
- IV. Use of personal protective equipment (masks etc.).

Below we will summarise the recommendations of various groups of experts in the field advising on how to reduce exposure to surgical smoke, and we will present the recommendations of the INRS, the Suva and the BGW (sources: Ball, 2005, 2001; Barrett et al., 2003; Frenette, 2003; NIOSH, 1999; TRGS 525, 1998].

4.1 Substitution

The choice of treatment method is at the discretion and under the responsibility of the practitioner, and relates to the expected benefit for the patient. It is also limited to the methods that the operator is familiar with. During the choice of method, the exposure risks for personnel must also be taken into account. It is therefore important, before initiating treatment, to define the criteria that may constitute critical factors where electro-surgery or laser is used, in particular:

- Specific biological risks (bacterial or viral)
- Underequipped premises (e.g. without ventilation).

Given the multitude of applications of the intervention techniques described, the possibilities for substitution are limited. If it is not possible to offer alternative methods presenting the same medical advantages and lower personnel exposure levels, collective, organisational and individual protective measures must be applied.

4.2 Technical preventive measures

Technically, capture of surgical smoke at its source is the most effective preventive measure. Other methods to keep operators away from the point of smoke emission (e.g. radio-guided interventions) can be imagined, but do not exist in practice.

As of today, the technical standards (e.g. [osha.gov/SLTC/laserelectrosurgeryplume/standards.html] in the USA, [IEC/TR 60825-8:2006] in Germany) only provide general prevention objectives, rather than precise requirements in terms of smoke capture. We can, however, formulate the following recommendations:

a) Systems for the capture of surgical smoke

If only a small amount of smoke is produced it is possible to use an adapted aspiration system to which a disposable filter has been fitted to eliminate smoke from the surgical site (BS EN 60602 and Ball, 2005). The filter added must be capable of protecting the capture system against contamination or corrosion of its ducts. Classical wall-mounted capture systems are generally not powerful enough to evacuate large quantities of smoke. It is therefore advisable to use mobile capture devices which can have over 20-fold higher aspiration power. While the aspiration power of surgical capture systems does not exceed $100 \text{ L}\cdot\text{min}^{-1}$, that of autonomous systems is in the region of $\text{m}^3\cdot\text{min}^{-1}$ (see Point b).

b) Mobile smoke capture devices

Individual capture devices are provided by manufacturers of laser or electrosurgical equipment. They can either be integrated into the handpiece of the unit, or be independent. They are generally composed of the following elements:

- the aspiration device itself,
- a filter system for particulate pollutants and gas/vapour,
- a hose linked to the handpiece or to a suction duct,
- a handpiece or suction pipe.

The capture device must offer sufficient aspiration when in use. A speed of 0.5 to $0.75 \text{ m}\cdot\text{s}^{-1}$ (or 100 to $150 \text{ feet}\cdot\text{min}^{-1}$) at the opening is considered sufficient (NIOSH, 1998). For a 20 mm diameter opening this corresponds to

an air flow rate of 0.6 to 0.9 m³.h⁻¹, for a suction duct approximately 100 mm in diameter this equates to 15 to 20 m³.h⁻¹. Like for domestic vacuum cleaners, the suction power is generated by a rotating turbine, and depends on the air flow resistance of both the suction duct and of the filter system. If the duct is blocked, suction power can be greatly reduced. When choosing a device, it is advisable to take the noise level of the unit into account, this can be linked to the motor, but also to the suction process.

In traditional capture systems with air recycling, the **filtration system** must induce lower concentration of particles, as well as gas and vapour. While the literature recommends devices equipped with active charcoal filters and ULPA (Ultra Low Penetration Air) filters (Ball, 2005), these recommendations are not yet set down in the standards. The NIOSH publication from 1998 recommends HEPA (High Efficiency Particulate Air) filters, but does not impose an active charcoal filter. The IEC/TR 60825-8 standard recommends ULPA filters, which offer a retention coefficient of at least 99.999% for particles of at least 0.1 µm. This requirement corresponds to the exposure assessed in point 3.4, according to which the risk is particularly linked to particulate pollutants. However, the NIOSH recommendations (1998) did not take exposure to ultrafine (nanoscale) particles into account. A definitive assessment of the risks linked to exposure to this type of particles is impossible today because of the lack of sufficient toxicological data in this field.

However, if surgical smoke is frequently produced in areas equipped with only natural ventilation, such as medical practices or outpatient rooms, given the olfactory discomfort and the release of pyrolysis products in the form of gas and vapour, the use of active charcoal filters as part of the aspiration system is recommended. Removable filters must be regularly examined and replaced according to the manufacturers' recommendations. Because particle filters can be loaded with biologically active cells or cellular fragments, basic rules of hygiene should be applied when changing filters (Ball, 2004). At the very least, these should include the use of disposable examination gloves. Used filters should be stored in plastic bags prior to their disposal as waste. As part of the waste management process, it is necessary to decide, by assessing the operations carried out, whether filters should be treated as non-specific waste or as hazardous, potentially infectious waste. In Germany, for example, the AS 15 02 02 waste category includes aspiration and filtration devices (including oil filters), wipes and protective clothing soiled with hazardous substances.

The **hose and aspiration nozzle**, as well as the handpiece, increase resistance and reduce suction power. Their length and shape should therefore be adapted to the use intended. The capture efficiency of the smoke aspiration device is greater when the nozzle is close to (less than 5 cm from) the point of smoke production. Thus a handpiece with an integrated capture system is recommended, in line with the recommendations for laser use.

However, this can result in reduced manoeuvrability of the handpiece and, hence, reduced acceptance of the capture device by the surgeon.

c) Mechanical ventilation systems

Medical treatment rooms are generally equipped with mechanical ventilation in compliance with national regulations and applicable hygiene requirements for this type of premises (e.g. in Germany, DIN 1946-4). In the operating theatre, for example, the ventilation system must reduce the number of airborne germs and particles, while also evacuating heat generated and any hazardous substances emitted. This can be achieved by various ventilation and air extraction systems, for example by bringing in new air from above and extracting from below, or by the use of a laminar flow ceiling placed above the surgical site and guaranteeing air flow from top to bottom without turbulence. This type of system requires large air volumes, in the range of 1,000 to 2,000 m³.h⁻¹ fresh air, which corresponds to 10 to 20 air changes per hour.

Air flow at this rate rapidly eliminates small quantities of smoke from the premises, and there is no significant accumulation of smoke in the work zones.

The situation is different during interventions inducing electrocoagulation of important quantities of tissues. The performance of ventilation systems used in operating theatres are 20 to 40-fold higher than mobile capture devices, given the volumes of fresh air mentioned above. Mobile devices cannot therefore significantly affect the general ventilation system of the premises. However extracted air is generally recycled and recirculated to adjacent corridors and premises (induction room and preparation room). As a consequence, gases can be spread to these areas. This is one of the main reasons why olfactory discomfort due to surgical smoke is reported throughout the operating theatre.

d) Smoke capture during endoscopic interventions

The capture of smoke from body cavities during endoscopic interventions, for example, presents technical difficulties. This smoke is not an occupational medicine issue for the person carrying out the intervention, but it can cause visibility problems for the surgeon. This point will not be treated further here.

4.3 Organisational aspects

Improving work organisation, e.g. through the use of optimised schedules, can reduce unnecessary personnel exposure to surgical smoke. Operating theatre personnel are more likely to protect themselves from surgical smoke if they are aware of how smoke forms, the hazards it presents and the preventive measures that can be applied. **Preventive training sessions** should be provided regularly on these topics. The incidence of factors influencing exposure should be detailed. Some manufacturers of smoke capture devices supply training supports which can be used to this end.

Preventive training must be provided before the person occupies his or her post, when there are significant changes to operating procedures, and at regular intervals (e.g. once a year). This training should, of course, respect national regulations, which may, for example, require all training sessions to be documented.

4.4 Individual protective measures

a) during surgical interventions

When smoke capture and ventilation of the premises are adequate, it is not necessary to use specific personal protective equipment. The general requirements for hygiene during surgical interventions determine the requirements for personal protective measures.

Surgical masks used for hygiene do not supply adequate protection against gases or vapours. Nor do they retain biological agents (viruses, cellular fragments) or the finer particles which may be formed during pyrolysis.

In Europe, personal protective measures against chemical and/or biological agents must satisfy the PPE (personal protective equipment) directive and its requirements, including those relating to proof of conformity with the technical standards [PPE directive 89/686/EEC]

Appropriate protection against the particulate components of surgical smoke is provided by face masks of class FFP2 or higher. However, they do not protect against the nanometric fraction of these particulate components. Gas and vapours can only be retained by appropriate active charcoal filters.

b) during maintenance

Particle filters in capture devices may be charged with biologically active cells and cellular fragments, or bacteria and viruses. Therefore, when changing filters general rules of hygiene should be borne in mind, in particular, operators should wear disposable gloves.

4.5 Preventive medical surveillance

Occupational medicine does not currently have many criteria applicable for prevention as part of medical surveillance for the activities presented here. As we have seen, there is very little data on diseases linked to smoke in operating theatres, and this situation is unlikely to change. Thus, it is not conceivable to implement preventive medical surveillance to detect illnesses linked to operating theatre smoke.

No specific prevention programme for personnel exposed to surgical smoke is routinely applied to our knowledge.

However, periodic occupational medicine examinations are carried out in many countries, and it seems appropriate to take advantage of these to ensure surveillance of personnel exposed to smoke, allowing any problems to be detected and acted upon appropriately. It also seems relevant to identify personnel with individual risk factors (e.g. suppressed immune system or history of respiratory illness) and to avoid their exposure to smoke in operating theatres. This preventive medical examination could be limited to anamnesis, clinical evaluation, and perhaps, biochemical analyses and spirometry testing. Data gathered on exposure must be conserved in the medical records.

It is likely that exposure to operating theatre smoke will be evoked during medical visits at recruitment and annual check-ups which are carried out in most institutions in the health care sector. In any case, this is the approach we would advise given the current state of knowledge.

5 Information and training

The surgical techniques described above are only used by specialists who are fully informed of the therapeutic and technical advantages and disadvantages of these methods. It is therefore up to these specialists, given their expert knowledge, to inform the other personnel present of any risks they may be exposed to during interventions. This will ensure that all personnel involved implement the required safety measures. However, surgical smoke is only one risk among many, linked in particular to infectious agents, to electrical material, to sharp objects, or to chemical agents (disinfectants, drugs, anaesthetics etc.).

According to the framework directive 89/391/EEC, all workers must be provided with appropriate health and safety training when taking up a post, when changing post, when work equipment is modified or new technologies are introduced. This training must provide the worker with information and instructions appropriate for his or her work station and role.

The practicalities of these training sessions, periodic updating and documentation of training sessions must be in line with national provisions for medical devices or chemical agents.

Training sessions for prevention cannot be dissociated, in practise, from the normal dialogue within the surgical team. Indeed, in the case of laser and electrosurgical techniques, preventive measures are generally included in the procedures. The following aspects, for example, can be part of a training session for protection against surgical smoke:

- Dangerous properties of the pyrolysis products formed.
- Other hazards linked to the techniques used.

- Details of the procedures used.
- Parameters influencing exposure to surgical smoke (exposure determinants).
- Preventive measures applicable both locally (in particular extraction systems) and at the level of the whole site (general ventilation system).
- Cleaning and maintenance/repair of the devices used.
- Risk assessment: under what conditions are the measures taken considered to be sufficient for operator protection?

Various sources – among the publications cited in chapter 8, in particular – can be consulted to create structured training sessions. For example the following documents:

- Information from manufacturers of medical devices.
- Risk assessment and description of the preventive measures applicable, published by the NIOSH, ASORN etc.
- Data sheets on lasers (e.g. AUVA document on lasers: Merkblatt M140).

6 Checking the efficacy of preventive measures

Regular control of the preventive measures taken contributes to improved prevention. The efficacy of measures taken must be checked at regular intervals (capture devices, ventilation system), as should staff behaviour.

- All equipment should be in a good state of repair. Maintenance operations carried out on equipment which, as a medical device, often has to meet specific safety and performance requirements, should comply with the manufacturer's indications and with national regulations.
- Mechanical ventilation must comply with national regulations. In Germany, for example, DIN 1946-4 and VDI 2167-1 are applicable in hospitals and in the health care sector (maintained capture system efficiency, requirements for filter changes, hygiene requirements etc.).
- Maintenance of Local Exhaust Ventilation (LEV) must comply with the manufacturer's instructions and with national regulations. This is also the case for maintaining aspiration efficiency, filter changes and necessary measures to comply with general hygiene requirements.

- Personal protective equipment (PPE) must be maintained in a good state of repair, in particular protective masks used to reduce exposure to the products of pyrolysis. In Europe, PPE must comply with directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment and to directive 89/656/EEC on the minimum health and safety requirements for the use of personal protective equipment by workers in the workplace. Protective masks must be changed after every use (for disposable masks) or at regular intervals depending on the manufacturer's instructions.
- Operators (doctors, assistants, nursing staff, technicians) must be regularly trained in accordance with chapter 5. The aim is to maintain the quality of the organisational steps taken to reduce exposure to pyrolysis products.
- Conducting individual measurements in the respiratory zone of workers (e.g. in industry) usually provides the necessary elements to assess the efficacy of the preventive measures implemented at different work stations. With regards to the pyrolysis products formed during surgical acts, however, this type of measurement would not be appropriate as there is no reference value based on medical or technical data against which to evaluate the mixtures formed. As of today, it has not been possible to define a single component which could act as an indicator of exposure. The same problem is encountered for biological monitoring data.

It is also appropriate to regularly check whether risk assessment, which helps to determine which measures must be taken, is still valid and corresponds in effect to the actual conditions at the work station.

7 Summary

Since the introduction of medical applications of laser and electrosurgical techniques, exposure to pyrolysis products formed during interventions (surgical smoke) is a source of worry and study. Surgical smoke is a mixture of extremely diverse substances, present as gases, vapours and solid or liquid aerosols, and which can present (almost) all the possible effects of hazardous products, local or systemic, reversible or irreversible. Thermal decomposition of tissues mainly produces a strong smell leading to operator discomfort, or even disgust. Finally, it has been established that surgical smoke can contain biologically active elements (cells, cellular fragments, viruses etc.).

The composition and intensity of emissions depend on the treatment technique used and on the tissues treated, and can vary considerably depending on various factors influencing smoke release.

The main factors affecting exposure are the electrical parameters (power, current intensity, frequency), the characteristics of the procedure (type and shape of electrode, laser type), device operation mode (continuous, pulsed) and the tissue treated (fatty tissue, muscle, organ etc.) as well as the characteristics of the premises (dimensions, ventilation mode, ventilation intensity).

In zones where surgical interventions are carried out, if we consider each of the substances present, operator exposure is much lower than the exposure limit values. However, as we are dealing with a mixture of pyrolysis products it is essential to reduce exposure as much as possible, because many compounds found in smoke have carcinogenic, mutagenic or teratogenic properties.

Based on this observation, the main applicable preventive measures can be summarised as follows:

- Lasers, electrosurgical units and other medical devices involving intense smoke production should only be used in work areas equipped with a ventilation system (e.g. operating theatres), in particular when fragments of infectious tissues or tumour cells may be produced.
- To protect operators, smoke emitted should, as far as possible, be captured at source.
- If the air extracted by localised aspiration is to be rejected after filtration back into the work area (provided this area is correctly ventilated), filtration must at least be through a HEPA filter.
- The hazards of ultrafine particles (nanoparticles) emitted during pyrolysis raise the question of whether it would not be preferable to use ULPA filters in smoke capture systems. The absence of medical and toxicological data on the effects of nanoparticles does not, however, allow the use of ULPA filters to be recommended in all cases.
- The use of active charcoal filters in correctly ventilated zones within operating theatres does not appear justified. However, if surgical smoke is produced in poorly ventilated areas (e.g. consultation rooms only equipped with natural ventilation, or outpatient consultation rooms) it may be necessary in certain cases to use mobile capture devices equipped with active charcoal filters. This would at least help reduce unpleasant smells.
- It does not appear necessary, given current knowledge, to implement specific preventive medical surveillance for personnel exposed to

surgical smoke. The medical records should include elements allowing exposure to be traced.

- It is obvious that all workers should be informed of the hazards of surgical smoke and of the preventive measures applicable in areas where interventions producing it are carried out.

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