### Fundación **Tecnología y Salud**



### WEBINAR SUMMARY

### **SURGICAL SMOKE: A REAL RISK**

"The healthcare technology sector is a dynamic, innovative sector whose goal is to find solutions to unresolved clinical problems, and to improve patient health and quality of life. At Fenin and the Health and Technology Foundation we are committed to promoting safety".

**Pablo Crespo** General secretary of Fenin and Secretary of the Board of Trustees of the Health and Technology Foundation

**Objective:** to understand the relationship between exposure to surgical smoke and the health effects for professionals and patients, and to establish protocols and measures aiming to minimise this risk.

### **1. COMPOSITION, RISKS AND EVIDENCE**

### Gonzalo Garrigós Ortega. Surgeon and gastroenterologist.

- The use of electrosurgical instruments in operations generates a mixture of gases, vapours and aerosols that are known as surgical smoke (SS).
- The composition of the smoke they produce differs according to which instrument is used. The most common devices are electric scalpels, lasers, ultrasonic scalpels and high-speed devices (drills, saws, burrs, etc.).
- The composition and concentration of particles is highly variable in the smoke generated, which contains chemical substances and biological agents.
- ► The toxic particles, carcinogens, tumour cells, and viable viruses and bacteria present in surgical smoke pose a potential risk to patients and healthcare staff.
- ► There is little data available on diseases related to surgical smoke.
- Awareness of the problem was addressed by a study (Murcia) using 91 questionnaires: Half of the staff considered SS to pose an occupational risk, but only 27% of operating theatre staff were aware of the toxic and carcinogenic components or the risk of disease. In conclusion, there is a significant lack of knowledge.



- ► The study entitled 'Association of Occupational Exposure to Inhaled Agents in Operating Rooms With Incidence of Chronic Obstructive Pulmonary Disease Among US Female Nurses' concluded that a professional working in an operating theatre for over 15 years is 70% more likely to develop chronic obstructive pulmonary disease (COPD). If researchers study the incidence of other diseases, we are likely to get some surprising results.
- Main preventive measures:

General ventilation systems, smoke evacuation systems with extraction equipped with the appropriate filters (HEPA, ULPA), located as close as possible to the emission source, as well as the use of gowns, gloves, eye protection and masks (minimum FFP2).

- Incorporate the topic into health and safety planning: train and inform workers, assess the measures implemented, and perform appropriate health monitoring.
- ► The relevant authorities need to be involved to develop legislation and establish obligatory measures.
- ► More studies are needed, particularly long-term research, establishing a relationship between the appearance of disorders in operating theatre staff and surgical smoke.

### 2. LEGAL FRAMEWORK

#### Pablo Crespo de la Cruz. General Secretary of Fenin.

- While protocols and recommendations exist, there is currently no specific legislation in Spain. SS is a risk that requires the development of a legal framework to protect patients and operating theatre staff.
- There is a general regulatory framework that provides partial legal coverage (occupational risk prevention, the financial liability of governmental agencies, the Civil Code, the Criminal Code), with the health and safety (H+S) protocols that hospitals and health services have in place being particularly important.
- Legislation should protect health and safety at work through: risk analyses, adopting risk prevention measures, training professionals, routine safety measures to eliminate or minimise potential harm, and supervision by public bodies.
- It would be advantageous to establish a regulatory framework that ensures safety and equity, offering the same guarantees to all healthcare professionals.



### 3. RECOMMENDATIONS OF SCIENTIFIC SOCIETIES AND HEALTHCARE PROFESSIONAL ASSOCIATIONS

#### Presenter:

#### Francisco de Águeda Pardo, representative of the surgical smoke working group.

*Lucía Fernández Yagüe.* Unit Head for the Surgical and Sterilisation Wing at Hospital del Mar, Barcelona. Similar Societies Member at the Spanish Association of Surgical Nursing (AEEQ). Spanish representative of AEEQ in the pan-European Surgical Smoke Coalition.

- ▶ Electrosurgical devices are used in 85% of surgical procedures for tissue dissection or haemostasis.
- Approximately one million health professionals across the globe are exposed to the effects of surgical smoke each day, not only through breathing it in, but by coming into contact with it via their skin or eyes.
- It is important to remember that patients are also exposed. For example, during laparoscopic surgery, the smoke is concentrated in the abdomen with no way out and can enter into the bloodstream or spread by passing through the peritoneum.
- Managing SS requires knowledge, awareness, competence and skills. This is the context in which the Surgical Smoke Coalition was formed. This is a pan-European coalition that brings together various associations and interested parties, all of which are concerned with the topic in hand.
- The coalition's primary mission is to minimise the risk of harm resulting from exposure to SS particularly for professionals working in operating theatres by helping to implement specific policies and legislation at a national and European level. The objectives are to ensure that all parties are informed about the issue, and to raise awareness about the methods available to tackle it.
- The European Operating Room Nurses Association (EORNA) produced a series of recommendations before the pandemic, such as: the use of laminar air flow; performing between 15 and 20 air changes per hour; having effective evacuation systems in place; the use of personal protective equipment (PPE) and ensuring education, risk prevention and protection, which should be the responsibility of the company and must be obligatory for healthcare staff. During the pandemic, EORNA also produced an information, education and communications guideline on SS for nurses and other health professionals.
- ► The objective set by the associations is focused on helping teams establish a safe environment with regards to SS exposure. To achieve this, organisations should promote smoke-free environments.
- Surgical teams should evacuate the smoke as close as possible to the source where it is generated; team members should receive training; and policies and procedures should be developed that are periodically reviewed. Additionally, all professionals should be allowed to participate in the improvement of these activities and in evacuation compliance.
- ▶ We mustn't forget that nurses, as part of the surgical team, play a vital role in the assessment and selection of the team that will perform smoke evacuation. They should therefore participate in the multidisciplinary teams that implement these smoke evacuation policies.

- One of the Surgical Smoke Coalition's first initiatives was to demonstrate that, despite the known health risks of SS exposure, awareness remains very low throughout the EU. This document, published in June 2022 and already translated into five languages, contains the latest scientific evidence on SS and describes the situation in various countries in an attempt to identify common strategies and/or alliances. Denmark is currently the only EU country with specific legislation.
- In the first half of 2023, the process of transferring the Technical Secretary of the Surgical Smoke Coalition to Health First Europe (HFE) was initiated, to create an alliance between the two bodies.
- ► HFE is a non-profit, non-commercial coalition of patients, workers, health professionals, academics and experts in health and medical technology industries whose objective is to guarantee equitable access to modern, innovative and reliable medical technology for all European citizens.
- One of the first actions they are taking is the launch of a survey (which will be available shortly) to raise awareness and secure commitment regarding the impacts of SS in hospital environments. The objective for 2023 is to enlarge the coalition, focusing on all the areas involved in a surgical procedure, as well as the distinct specialities, so as to expand its reach at a European level.

### **Dr Victoriano Soria Aledo.** Head of the General Surgery and Gastroenterology Department at Morales Meseguer de Murcia Hospital. 1<sup>st</sup> Vice-chair of the Spanish Association of Surgeons.

- In 1926, the National Institute for Occupational Safety and Health (NIOSH) published a report about the 'Potential Risks of Exposure to Surgical Smoke'; since then, the amount of information on the topic has been increasing.
- Despite this, there is little concern among operating theatre staff about the repercussions of long-term exposure to surgical smoke. It is therefore essential to promote a culture of safety at work.
- Solid evidence on the risks is needed, and further research in this area is necessary to help build awareness among professionals through forums such as this one.
- National and international guidelines and recommendations exist to minimise the risk of exposure to surgical smoke: these measures include the use of PPE, adequate ventilation and, above all, the use of smoke evacuators.
- Smoke evacuation systems efficiently capture almost 100% of the airborne particles at the emission source, are silent and easy to control.



#### Dr Francisco Leyva Rodríguez. Head of the Plastic Surgery Department at La Paz University Hospital.

- Hospital smoke extractors are relatively inefficient and the industry needs to improve the technology of these systems, which lose efficiency at 2 cm, operating at 50%. Further, the fact that they are outdated means that they are not used.
- ► There is uncertainty about the damaging effects of long-term exposure to surgical smoke (benzene).
- The problem lies in the fact that surgical procedures produce smoke that may result in chemical or biological harm, but little clinical proof exists since any problems that arise are long term, which makes the issue difficult to study. Evidence level 4.
- It is necessary to conduct studies on exposure and, above all, to assess cost-effectiveness, as well as improving equipment.
- Regulations are in place on environmental air quality in hospitals, but there is no consensus regarding the international regulations. Working groups do exist: AORN, OSHA, NIOSH, ANSI, CDC, The Joint Commission, Surgical Smoke.
- There is a duty to be cautious and put preventive measures in place (personal protective equipment, surgical smoke extractors and filtration systems).

### 4. THE PERSPECTIVE OF THE PUBLIC AUTHORITIES

#### Presenter:

#### Mr Ivan Schinder, representative of the working group on surgical smoke.

### *Ms Eva Moreno Campoy.* Director of the Patient Safety Strategy. Regional Department of Health and Consumption, Autonomous Government of Andalusia.

- Patient safety means minimising the risk of unnecessary harm, and it must be a priority for all health systems. We need to be aware of the high level of complexity that exists, which comes with numerous risks for patients.
- To put all the safety measures into practice, we need to understand the real situation in the setting we work in (the increasing volume of care work, use of increasingly sophisticated techniques and materials, large number of human interactions, etc.), but we also need to put the culture of blame behind us.
- We should put safety barriers into place that prevent harm from reaching patients or professionals. To achieve this, we need to pay attention to working conditions, instead of handing out blame, and focus our efforts on minimising errors through leadership, commitment and the involvement of all professionals, including leadership teams.
- In Andalusia, the patient safety strategy was updated in 2019, and its objectives were divided into 6 key areas: Organisation / Management and learning / Safe comprehensive care / Safety and health information technology (HIT) / Patients and the wider public / Knowledge and innovation.

- When it comes to surgical smoke, if we ask who is at risk in the operating theatre, the answer is everyone present, including patients. But when considering patient safety, we should be clear that the patient's risk from exposure to SS is minimal in comparison to the exposure of the professionals.
- In Andalusia, the current regulations are observed, and compliance is monitored by the Prevention Units, which assess occupational risks.
- Safety should be a genuine, ongoing, top-priority commitment for all parties, in all settings and at all levels of management (macro, meso, micro).



# **Mr Alberto Pardo Hernández.** Deputy General Director of Care Quality and Patient Safety. General Directorate of Patient Humanisation, Safety and Care. Regional Department of Health. Community of Madrid.

- We do not have many articles providing scientific evidence on the problems related to surgical smoke and this makes the issue difficult to tackle. That is why the recommendations of scientific societies about stopping unnecessary or low value practices are so important.
- The patient safety perspective is important, bearing in mind that, according to the WHO, one million patients die from surgical complications each year.
- Patient safety is a problem that affects all professionals, and it needs to be tackled from a cultural perspective, with infrastructure in place for its operational implementation (managers and commissions).
- Additionally, in order to work in a systematic manner, specific strategies need to be developed and prevention measures must be followed, using regulations to improve patient safety (for example, Decree 4/2021, Community of Madrid), and taking a suitable approach.
- There are two approaches to improving safety: Safety 1 identifying causal chains of events that lead to harm and setting out clear interventions to prevent it; and Safety 2 in addition to having a limited set of protocols in place, safety organisations should equip workers with the skills to identify risks to patient safety and adapt their working environments to optimise safety.
- We should bear in mind that the digital and technological transformation will help us improve safety and SS. For example, if we use surgical robots without the surgeon's physical presence, we will reduce the risk related to surgical smoke.
- ► Finally, it is important to remember that no single measure exists that can be considered a panacea; we need to be determined, develop interventions, and keep in mind that improvement can take time.

**Ms Anna Oliete Canela.** Technical Manager of Health and Safety in Barcelona. Catalan Institute of Occupational Health and Safety. General Directorate of Labour Relations, Self-employment, Occupational Health and Safety.

- It is necessary to identify and assess the risks, and apply the current Health and Safety at Work (H+S) regulations, paying particular attention to carcinogenic, mutagenic and reprotoxic substances (CMRs), as well as to nanoparticles and ultrafine particles.
- A holistic approach should be taken to preventive measures but, to guarantee their success, a consensus needs to be reached among the parties involved.
- It is very important to enhance the training, knowledge and awareness of health professionals through seminars, conferences, specific courses, guidelines, etc. and not to forget professionals such as veterinarians, risk-prevention specialists, workers and worker representatives, risk-prevention officers and risk-prevention services.
- We all need to play our part organisations, public authorities, scientific associations and societies, etc.
  looking at the issue through a risk-prevention lens, in order to minimise this risk in operating theatres and ensure they are as safe as possible for patients and the people who work there.

## *Mr Dennis RADTKE. Member, Group of the European People's Party (Christian Democrats). European Parliament.*

- Across Europe, healthcare workers are calling for an improvement in their working conditions to guarantee the safety of patients and professionals. These inadequate working conditions are undermining the quality of healthcare and putting professional teams at risk. While some solutions are complex, others are already available but are not being applied in Europe, such as the campaign against surgical smoke.
- Surgical smoke is released during surgery and is thought to be underestimated, posing a significant risk to healthcare workers. Exposure to surgical smoke for one day in the operating theatre is comparable to exposure to 27 cigarettes. Prolonged exposure to surgical smoke is associated with serious illnesses such as asthma and a high risk of developing cancer.
- Smoke evacuation is one of the best solutions to provide nurses, surgeons and the other professionals who work in operating theatres with that protection and, out of respect for those who work tirelessly to care for us and look after our health, we should guarantee the highest levels of protection.



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### WEBINAR CONCLUSIONS

### SURGICAL SMOKE: A REAL RISK



### SURGICAL SMOKE

The use of electrosurgical instruments in operations generates a mixture of gases, vapours and aerosols – known as **surgical smoke**– containing toxic particles, carcinogens, tumour cells, viruses and bacteria that pose a potential risk to patients and healthcare staff.

### **GENERATE MORE SCIENTIFIC EVIDENCE**

There are few **articles providing scientific evidence** on this topic and, therefore, little awareness of the problem. Only 27% of operating theatre staff are aware of toxic or potentially harmful components of surgical smoke, while around one million health professionals across the globe are exposed to its effects each day. In fact, exposure to surgical smoke for one day in an operating theatre is comparable to exposure to 27 cigarettes, and staff who have been working in an operating theatre for over 15 years are 70% more likely to develop chronic obstructive pulmonary disease (COPD).

### WORKING TOWARDS SPECIFIC LEGISLATION

No **specific legislation** on surgical smoke currently exists in Spain, despite it being a risk. A legal framework that protects patients and operating theatre staff is needed. The general regulatory framework provides partial legal coverage. The H+S protocols that hospitals and health services have in place are very important.

### THE SAFETY OF HEALTH PROFESSIONALS AND PATIENTS

The commitment to ensuring the **health and safety of professionals and patients** should be genuine, ongoing and a top priority for all parties, in all settings and at all levels of management. However, to achieve this, more studies on exposure are needed – particularly long-term research – that establish a relationship between the appearance of disorders in operating theatre staff and exposure to surgical smoke and, of course, the relevant authorities need to be involved to develop legislation and establish obligatory measures.



### **PREVENTIVE MEASURES**

The **preventive measures** include general ventilation systems, smoke evacuation systems with extraction located as close as possible to the emission source – equipped with the appropriate filters, such as HEPA and ULPA filters – and the use of gowns, gloves, eye protection and masks (minimum FFP2). Additionally, a holistic approach should be taken to these measures, about which consensus should be reached by all the parties involved.



#### **TRAINING, KNOWLEDGE AND AWARENESS**

To guarantee compliance with these and other preventive measures, the **training**, **knowledge** and awareness of health professionals – including veterinarians, health and safety specialists, representatives and officials, for example – need to be enhanced through seminars, conferences and forums, such as this one. Education is the catalyst for action.