

# The case for compulsory surgical smoke evacuation systems in the operating theatre

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## Abstract

Perioperative staff are frequently exposed to surgical smoke or plume created by using heat-generating devices like diathermy and lasers. This is a concern due to mounting evidence that this exposure can be harmful with no safe level of exposure yet identified. First, I briefly summarise the problem posed by surgical smoke exposure and highlight that many healthcare organisations are not sufficiently satisfying their legal and ethical responsibilities to protect their staff from potential harm. Second, I explore the ethical case for compulsory smoke evacuation systems using the principlist framework and its four ethical principles – autonomy, beneficence, nonmaleficence, and justice. I then consider some objections and argue that surgical smoke evacuation systems – when indicated – should be made compulsory.

## Keywords

Surgical smoke, autonomy, nonmaleficence, justice, harm, surgical plume

Perioperative staff are routinely exposed to surgical smoke or plume created by using heat-generating devices such as diathermy and lasers to cut, cauterise and dissect tissues during surgery. Surgical smoke describes the visible gaseous by-product from these devices and is primarily constituted of 95% water vapour. The remainder is particulate matter that can contain blood fragments, bacteria, viruses, viable cancer cells, and gases that are known carcinogens, teratogens, and mutagens such as benzene, toluene, acetylene, xylene, and hydrogen cyanide.<sup>1,3</sup> Experimental evidence has also shown that surgical smoke can carry human coronavirus RNA, suggesting a possibility that SARS-CoV-2 (COVID-19) could also be present;<sup>4</sup> however, at the time of writing there is no evidence of transmission.

Research into the potential for harm associated with surgical smoke exposure has led to Denmark, and several American states – Colorado, Connecticut, Georgia, Oregon, Kentucky, *et al.* – to mandate the use of surgical smoke evacuation systems for any surgical procedure that is likely to generate surgical smoke. Despite guidance from the Health and Safety Executive, the Medicines and Healthcare products Regulatory Agency, the British Occupational Hygiene Society, and The Joint Commission recommending its use – this has largely been ignored or rarely employed in practice in the UK.<sup>5,8</sup> This implies that healthcare organisations should be legally required to protect their staff from surgical smoke exposure by removing it at the point of surgery, rather than merely being recommended.

This paper will first summarise the problem that exposure to surgical smoke presents and then go on to make the case for compulsory smoke evacuation using the principlist framework and its four ethical principles – respect for

autonomy, beneficence, nonmaleficence, and justice. I conclude by responding to common objections against the use of surgical smoke evacuation use and argue that it should be made compulsory where the generation of surgical smoke is unavoidable.

## The problem of surgical smoke

There is a growing body of evidence that indicates that exposure to surgical smoke can result in adverse health effects in staff and patients. This potential for harm has been the motivation for legislation that has made surgical smoke evacuation compulsory in Denmark and several US states. Harm commonly associated with surgical smoke exposure includes acute headaches; asthma; dermatitis; eye, nose and throat irritation; drowsiness; dizziness; and nausea and in some cases leading to sickness absence.<sup>9,13</sup> Surgical smoke produces nanoparticles that are less than 100 nanometers in size (i.e. 0.1 micron) which is small enough to be deposited in the blood and lymphatic circulation and may result in adverse respiratory and cardiovascular effects.<sup>14</sup> There is also evidence from studying gynaecology surgeons showing that exposure to surgical smoke is associated with a significant increase of acquiring HPV.<sup>15</sup> Furthermore, there is evidence to

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support an association between HPV transmitted through surgical smoke and subsequent squamous cell carcinoma.<sup>16</sup> Research on in vitro human and non-human animal cells has shown that exposure to surgical smoke is cytotoxic and lends further support for the potential of long-term health risks.<sup>17,18</sup>

Concerns have also been raised about the effects of surgical smoke exposure to patients during laparoscopic procedures. There is evidence that patients can absorb known carcinogens and some of the toxic chemical by-products of surgical smoke,<sup>1</sup> however, the long-term effects remain uncertain. The levels of known carcinogens have been shown to be unacceptably high following 30 min of laparoscopic surgery.<sup>19</sup> Achieving pneumoperitoneum entails that the by-products of surgical smoke are collected in high concentrations within the patient's abdomen, which can then be absorbed and later excreted by patients.<sup>1</sup> Laparoscopic surgery may therefore pose unique long-term health risks for patients.

It has become increasingly common to read about or hear perioperative staff with concerns about surgical smoke make comparisons between surgical smoke and cigarette smoke. This is based on the findings of Hill *et al.*<sup>20</sup> who found that the average surgical smoke produced per day during plastic surgery was equivalent to the mutagenic effects of smoking 27–30 cigarettes. However, cigarette smoke is inhaled directly whilst surgical smoke is usually inhaled following dilution in a well-ventilated operating theatre.<sup>21</sup> In the UK this will be approximately 25 air changes per hour and substantially more when laminar flow ventilation is used. Surgical smoke exposure is therefore analogous to second-hand or passive smoke exposure – which has numerous well-documented health risks<sup>22</sup> – because most of the smoke generated will not be directly inhaled at the source. However, the methodological and epistemological limitations of the available evidence mean that it is difficult to draw any causal conclusions from the presence of known mutagens and carcinogens in surgical smoke.

Despite the mounting evidence there remains no definitive international requirement to limit exposure to surgical smoke. Nevertheless, surgical smoke can be harmful even if the exact nature of this harm remains undetermined – what we do know is that no safe level of exposure has been established.<sup>23</sup> Fortunately, there does exist an effective means of reducing staff exposure to surgical smoke. Smoke evacuation systems can significantly reduce exposure levels and under optimal conditions reduce surgical smoke by 99%.<sup>24,25</sup>

## Healthcare organisation and government responsibility

Despite surgical smoke evacuation not currently being compulsory in the UK, healthcare organisations are expected to

conduct a risk assessment and comply with The Control of Substances Hazardous to Health Regulations 2002 (COSHH). This is the position of the Health and Safety Executive<sup>5</sup> who are responsible for the regulation and enforcement of workplace health and safety in the UK. They make it clear that when creation of surgical smoke cannot be prevented it should be adequately controlled through use of a surgical smoke evacuation system.

To get a snapshot of the implementation of the Health and Safety Executive guidance on surgical smoke, 10 large NHS Trusts in England were contacted on 28/09/21 by freedom of information request by email or online form. As of 2013 there were 3025 operating theatres at NHS Trusts in England<sup>26</sup> and the six NHS Trusts who responded represented approximately 7% (216) of the total number of operating theatres in England.

The NHS Trusts were asked two questions:

1. Has a risk-assessment of surgical smoke exposure been conducted in the last 10-years?
2. If a risk-assessment was conducted in the last 10-years what were the recommendations?

None of the six NHS Trusts had conducted a risk-assessment in the previous 10-years and therefore had no recommendations to make. This would indicate that several large NHS Trusts in England are not following the Health and Safety Executive guidance on diathermy and surgical smoke. Worryingly, the largest NHS contacted expressly stated that there was no requirement to conduct a risk assessment for surgical smoke under COSHH (2002) or any Health and Safety legislation.

Employers already have well established legal obligations to protect their employees from harm under the Health and Safety at Work Act 1974 and The Management of Health and Safety at Work Regulations 1999, and where practicable should take measures to protect their employees. However, the available evidence suggests this is largely still not happening with respect to surgical smoke. Despite being available for several years, surgical smoke evacuation device use remains the exception rather than the rule – in a survey of 98 surgeons in England, only 3 reported using a smoke evacuation system.<sup>27</sup> However, more recent evidence has shown that because of concerns about the transmission of COVID-19 in surgical smoke there has been a marked increase in the use of smoke evacuation devices in some specialties. Before the COVID-19 pandemic compared with during the January 2021 lockdown the use of surgical smoke evacuation devices increased from 38% to 56% in British orthopaedic trauma units.<sup>28</sup> This indicates that the COVID-19 pandemic has helped to normalise the use of surgical smoke evacuation devices in certain surgical contexts, despite no evidence that transmission can occur. Standard wall-mounted suction is frequently the most common method used to

remove surgical smoke despite not being designed to do so and the absence of evidence to support its efficacy.<sup>27</sup>

## Principlism

Principlism describes four ethical principles – nonmaleficence, beneficence, respect for autonomy and justice – that have become a mainstay of medical ethics since Tom Beauchamp and James Childress first published their book *Principles of Biomedical Ethics* in 1979. Principlism is by no means the only ethical framework that can be used to assess ethical issues in healthcare – and is not without its critics<sup>29</sup> – but it does have the benefit of being accessible and culturally neutral; this can be useful when first considering an ethical problem to weigh any salient competing ethical concerns. The four principles are *prima facie*, which means that no one principle is more important than the other and are therefore non-hierarchical. However, when a conflict of principles becomes apparent it may become necessary to balance the reasons to prioritise one principle over another.<sup>30</sup> For example, respecting a patient's autonomy to refuse a life-saving allogeneic blood transfusion against the principle of nonmaleficence. Principlism is usually applied to ethical issues in healthcare involving patients, but they are equally applicable to those involving healthcare professionals.

## Nonmaleficence

Nonmaleficence can be understood as the obligation to avoid causing unnecessary harm. Harm describes thwarting, defeating, or setting back of some party's interests through an act of commission or omission. Any harm must therefore be sufficiently justified and where it can be prevented without causing additional harm it should be. Nonmaleficence is concerned with preventing harm through inaction, by avoiding taking actions that can cause unnecessary harm. An obvious action would be to simply stop using heat generating devices like diathermy and laser; however, that is not possible given the significant surgical and patient benefits they provide, without which some kinds of surgery would not be possible or safe. Consequently, the production of surgical smoke is a necessary hazard of surgery that cannot be avoided; however, the level of exposure *can* be significantly reduced by using surgical smoke evacuation.<sup>24</sup> Therefore, the failure to use smoke evacuation devices is therefore a failure to uphold the principle of nonmaleficence, since the inaction of healthcare organisations and responsible individuals *is* leading to preventable harm that may be compromising the health of perioperative staff. This failure can be partly explained by variations in the knowledge of the risks posed by surgical smoke, and the available technology across all perioperative staff groups.<sup>11,27,31</sup> However, this is something that can be improved through interdisciplinary

education<sup>32</sup> and healthcare organisations investing in the available technology and responsible individuals using it when indicated. Despite uncertainty about the degree of harm that exposure can cause, there is enough evidence to support limiting exposure.

## Beneficence

Beneficence is closely related to nonmaleficence and describes the *prima facie* duty to act for the benefit of another – to maximise their wellbeing. The primary goal of a beneficent intervention is to produce the best outcomes for all those involved, usually by removing or preventing possible harms and producing more good than the alternative. The principle of beneficence places a positive obligation on healthcare organisations to act to protect the wellbeing of their employees and patients. Consequently, the beneficent act would be to mandate and normalise the use of smoke evacuation systems in the operating theatre when indicated.

The compulsory use of smoke evacuation systems may also provide additional benefits for patients and have further cost saving implications for healthcare organisations. It has been posited that because viable bacterial and virus particles<sup>33,34</sup> can be present in surgical smoke then its removal at the site of surgery could lead to a reduction of surgical site infection (SSI). It is at least theoretically possible that smoke evacuation use could be associated with a reduction in the rate of SSIs. However, thus far no statistically significant difference has been identified between SSI rates with or without smoke evacuation device use<sup>35</sup> and more research is required to explore this relationship.

An illustrative example of the principle of beneficence being applied in the perioperative setting is through the ethical and legal obligation healthcare organisations have to reduce occupational exposure to waste anaesthetic gases by using anaesthetic gas scavenging systems. This is because there is evidence that chronic exposure to unscavened nitrous oxide can increase the risk of spontaneous abortion<sup>36</sup> and possibly reduce fertility in female staff.<sup>37</sup> Therefore – because it is a hazardous substance – it is justifiably covered by COSHH in the UK and so employers are legally required to ensure that recommended exposure levels are not exceeded. Similarly, as noted earlier, there are hazardous substances in surgical smoke that are known to be potentially carcinogenic, mutagenic and teratogenic and there is emerging evidence that surgical smoke could also be contributing to adverse pregnancy outcomes and increased rates of infertility in female surgeons.<sup>38</sup> Ultimately, there is an absence of *definitive* evidence and in this case must be inferred from animal studies and its effects in other contexts. Nevertheless, it remains plausible that chronic exposure to surgical smoke that is not evacuated at the operative site could contribute to female

infertility and pregnancy complications. Healthcare organisations must take these kinds of risks seriously considering the legal requirements imposed by COSHH until they have been ruled out.

The low rate of smoke evacuation use in clinical practice may indicate either a lack of awareness of the potential health risks and/or an unwillingness to invest in the necessary equipment to protect their employees. If perioperative staff and patients are routinely being exposed to potentially harmful substances, then action should be taken to prevent or minimise it unless there are overriding reasons to the contrary. The principle of beneficence demands that action is taken to remove the harmful conditions and to promote the good of perioperative staff and patients – by using smoke evacuation systems.

### Respect for autonomy

Respect for autonomy means acknowledging a competent individual's right to make choices based on their personal values and beliefs. There is commonly symmetry between beneficence and respect for autonomy because individuals usually want what is in their best interests. However, in the case of surgical smoke exposure, the potential harms are not widely understood, and this can undermine individual autonomy. Given that the available evidence indicates that health benefits could be accrued by surgeons and the perioperative team, it is in their best interests to limit their exposure to surgical smoke. The single most effective method of doing so would be to mandate the use of smoke evacuation devices where it is safe to do so. Where it is not possible to use such a device then alternative measures should be taken to limit exposure that might include the use of high filtration masks.<sup>32</sup>

Because the use of smoke evacuation devices is only recommended and not compulsory, one could argue that surgeon preference should dictate whether they choose to use it or not. However, this conclusion is open to several objections because respect for autonomy is *prima facie* and there are at least two good reasons that may support overriding surgeon preference in this case.

First, there is evidence that surgeons as a group are uncertain and perhaps not well enough informed about the potential harm posed by surgical smoke exposure. In one study only 51% of consultants felt that surgical smoke was harmful and even when smoke was cleared it was not always motivated by safety concerns, for example, to optimise the view during laparoscopic surgery.<sup>27</sup> It follows that the decision not to routinely use smoke evacuation devices may not be rooted in an informed evidence-based perspective.

Second, respect for autonomy can be restricted if there is a risk of harm to others and themselves. By failing to utilise smoke evacuation systems, surgeons are exposing themselves, the other members of the perioperative team and patients to preventable harm. It follows that respect for a

surgeon's autonomous choice in this instance is not ethically justified once balanced against the potential for wider harm. This is because the surgeon's decision does not only impact themselves but has wider implications for the entire perioperative team. However, as already noted, if surgeons are not sufficiently informed about the risk of harm surgical smoke poses then the decision not to use smoke evacuation may itself not always be an informed choice. Advances in health and safety can be met with resistance, which is paradoxically a common phenomenon among healthcare professionals and is often an attempt to preserve professional autonomy.<sup>39</sup>

### Justice

The principle of justice means that any benefits and risks should be fairly distributed; it entails treating equals equally and unequals unequally. Justice seems relevant to the problem of surgical smoke and the distribution and use of smoke evacuation devices. For example, smoke evacuation systems are used routinely by some surgeons – but not by others – and available in some operating departments but not at others. This means that the health benefits that accrue by limiting exposure to surgical smoke are not being fairly distributed between perioperative staff, even within the same department. It does not seem fair that merely being allocated to work with a certain surgeon requires exposing oneself to avoidable risks.

To further complicate matters, many staff may feel they lack the agency or authority to ask a surgeon to use an available surgical smoke evacuation device, or to even request that their department acquire the necessary equipment. This is compounded by the well documented steep hierarchical climate present in the operating department that can make challenging authority and speaking up especially challenging.<sup>40</sup> This problem is multifactorial, but the hierarchical climate can contribute to an unequal distribution of benefits and risks, meaning that those that perceive themselves as being lower in the hierarchy may be bearing the burden of risk. Healthcare organisations also contribute to this unequal distribution by failing to invest in surgical smoke evacuation devices, especially in light of their responsibilities to ensure the safety of all of their employees. Not doing so in this case places the burden of risk on the individuals themselves. Healthcare organisations can address this by conducting risk assessments, educating all employees about the potential risks associated with surgical smoke exposure, and investing in the technology to minimise exposure.

The application of justice to this issue means that no member of the perioperative team should be routinely exposed to the hazardous substances in surgical smoke where this is preventable. Unless there are good reasons to justify the unequal distribution of benefits and risks then justice would demand that efforts are made to intentionally limit everyone's exposure. This apparent unfairness

provides prima facie support for making surgical smoke evacuation systems compulsory.

### Objections to surgical smoke evacuation systems use

There are usually two common objections raised against the use of surgical smoke evacuation systems.<sup>28</sup> First, that they are expensive and would incur a significant initial investment and an ongoing cost for consumables that might redirect resources away from patient care. Improving safety usually comes at a cost and if the preponderance of evidence indicates that smoke evacuation systems reduce the risk of harm for staff then the justification for not doing so must be significant. However, by taking a preventative approach it is possible to reduce long-term costs which would be compensated for by fewer staff sick days, increased staff retention, and possibly fewer SSI, all of which could have significant economic benefits. Furthermore, preventative measures could help to avoid the legal costs that could materialise in the future following definitive evidence of occupational harm posed by surgical smoke exposure. This cost would primarily fall on healthcare organisations who failed to protect their employees from surgical smoke exposure by not conducting risk assessments or using smoke evacuation systems if indicated.

Second, smoke evacuation systems have been described as cumbersome, bulky, noisy, and can potentially act as a distraction during surgery.<sup>9,28</sup> These are legitimate concerns that entail that surgeons may be less likely to use a smoke evacuation device. Assuming that smoke evacuation systems do have some limitations then this must also be factored into the case for their compulsory use. It is true that many of the early smoke evacuation devices could be accurately described in such negative terms, but in recent years the technology has become significantly more advanced, compact, and user friendly. This does not mean there are no longer any limitations, but it does mean that this is now a less persuasive justification for not using a device. These improvements have been brought about in large part by user feedback and may be further improved by continued collaborative work between surgeons, engineers, and manufacturers to overcome any remaining limitations (e.g. noise) and to produce a more user-friendly product. Furthermore, there is no evidence that the use of surgical smoke evacuation devices is associated with an increased rate of surgical error. One of the other disadvantages of surgical smoke is that it can significantly impair vision of the surgical field during some open and laparoscopic surgery.<sup>41,42</sup> Importantly, smoke evacuation devices help to reduce the time that vision of the surgical field is impaired and may reduce the overall operating time. Consequently, these objections are not sufficient to outweigh the short- and long-term benefits that could be accrued by pre-emptively and effectively removing surgical smoke at the site of surgery.

### Conclusion

Perioperative staff – and patients – are routinely exposed to avoidable harm in the form of surgical smoke. This harm can be mitigated by employing surgical smoke evacuation systems that can significantly reduce the levels of exposure. Having considered the issue through a principlist lens I have shown that there is no sufficiently strong justification for maintaining the status quo and that surgical smoke evacuation systems should be made compulsory. Merely recommending their use has proved insufficient since the available evidence indicates that it is rarely followed in practice and so compulsory use may be the only effective means of ensuring perioperative staff are protected from prolonged surgical smoke exposure. In a minority of cases, it may not be appropriate to use smoke evacuation and in such instances other measures should be used to minimise exposure. I have also briefly considered some of the common objections to the utilisation of smoke evacuation systems and have found them wanting. Therefore, on balance there is a strong ethical case in support of compulsory surgical smoke evacuation until safe levels of exposure have been established.

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