The State of Surgical Smoke Evacuation at Oregon Health and Science University Hospital

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Abstract

Surgical smoke (SS) is a byproduct of tissue pyrolysis that pollutes the operating room (OR) atmosphere, and its inhalation constitutes an occupational risk for all OR personnel. Research strongly suggests that SS is a chemical, mutagenic, carcinogenic, and biologic hazard. Smoke evacuation devices (SEDs) constitute the most effective means of SS removal, but they are not routinely employed nationwide despite recommendations from professional and government agencies. This quality improvement project's goal was to generate a descriptive analysis regarding the state of SS evacuation and SED use at Oregon Health & Science University South ORs and identify perceived barriers to SED utilization during a recent one-year period beginning November 1, 2019. This analysis relied on Roger's Diffusion of Innovation Theory, the Institute for Healthcare Improvement's Model for Improvement, surveys, targeted interviews, and OR record review. Based on supply utilization, OHSU surgeons used SEDs in approximately 30.8% of surgical cases, with the primary barriers being surgeon refusal due to inconvenience, device bulkiness, and impaired visualization. Approximately half of the surgeons reported no education regarding SS, and these findings suggest that surgeons may adopt more widespread SED use if education and these perceived barriers are addressed. Most survey participants recognized SS as a health hazard and were concerned about their exposure to SS, and most non-surgeons agreed that SEDs should be incorporated into all SS-generating procedures. Registered nurses and certified surgical technologists were most likely to encourage SED use, whereas only 6% of anesthesia providers chose to do so.

Keywords: surgical smoke, smoke evacuation devices, operating room, occupational hazard, quality improvement, survey

Introduction

Problem Description

Surgical smoke (SS) poses physical, chemical, and biological hazards to operating room (OR) personnel (Karjalainen et al., 2018; Swerdlow, 2020a). Generated by electrosurgical units (ESUs), lasers, and ultrasonic scalpels, SS consists of 95% water vapor and 5% cells and cellular debris (Hill et al., 2012). Inhalation of SS results in the dispersion of particulate matter (PM) into airways; acute and chronic surgical staff exposure to volatile organic compounds (VOCs) with an irritant, mutagenic, and carcinogenic potential; and transmission of active biological agents. Standard surgical masks are inadequate to filter these products of pyrolysis (Liu et al., 2019). However, smoke evacuation devices (SEDs) effectively remove SS from the OR when utilized during surgeries (Liu et al., 2019). Unfortunately, numerous studies show that these devices are underutilized despite their efficacy and multiple professional and regulatory organizations' recommendations (Limchantra et al., 2019). A detailed evaluation of the SS evacuation practices at Oregon Health & Science University (OHSU) may reveal modifiable factors to improve OR air quality and protect OR personnel's health.

Available Knowledge

The quantity of SS generated by tissue pyrolysis depends on the type of surgery, the diathermy power employed in the process, the duration of diathermy, and the characteristics of the OR ventilation system (Barrett & Garber, 2003; Swerdlow, 2020a). Thus, while the quantity of SS available for inhalation represents one crucial consideration regarding its potential occupational hazard, SS's precise composition poses equally salient concerns.

Particulate matter (PM) from tissue pyrolysis deposits in pulmonary tissue and reproducibly results in inflammatory changes (Limchantra et al., 2019; Board on Population,

2016). This process can cause acute and chronic pulmonary injury. The propensity for such adverse events relates to PM size since smaller particles can travel more distally in airways. PM size depends upon the SS source. Only electrosurgical units (ESUs), and to a limited extent, laser devices, generate ultrafine PM (UFPM) with a maximum diameter ≤ 0.1 micrometers (μm). UFPM poses unique problems because it can penetrate standard OR personal protective equipment (PPE) such as surgical masks and N-95 respirators (Brook et al., 2010; Ling, 2009).

Surgical smoke contains 150–600 volatile organic compounds (VOC) that penetrate all respiratory PPE without charcoal filters (Pierce et al., 2011). OR concentrations of SS VOCs often exceed recommended levels, and inhalation of these substances correlates with multiple adverse events (Swerdlow, 2020a). In addition to immediate noxious effects, chronic exposure to these compounds can cause heart, lung, reproductive, and neurologic disease and may relate to the increased prevalence of respiratory ailments in OR personnel (nearly twice as high as the general population) (Limchantra et al., 2019; Board on Population, 2016; Ball, 2010). These VOCs have significant mutagenic effects with *in vitro* Ames testing (Sisler et al., 2018). In a study of SS generated during plastic surgery procedures, passive inhalation of 1g of pyrolyzed tissue was shown to have the equivalent mutagenic effect of six unfiltered cigarettes (Yoshifumi et al., 1981). While no long-term studies link lung cancer incidence to SS, many VOCs in surgical plumes possess known carcinogenic properties (Karjalainen et al., 2018; Liu et al., 2019).

In addition, SS transmits active biological agents. Bacteria, including mycobacterium tuberculosis, have been cultured from plumes (Garden et al., 1988; Pollock, 2007; Georgesen & Lipner, 2018). Furthermore, multiple viral entities from SS have been isolated from SS, including human papillomavirus, hepatitis B virus, human immunodeficiency virus, and

poliovirus, and many of these viral entities remain pathogenic for days or longer on OR surfaces (Liu et al., 2019; Board on Population, 2016). At least three nosocomial diseases result from SS transmission of HPV in humans: oropharyngeal warts, laryngeal papillomatosis (and likely pulmonary papillomatosis), and tonsillar cancer (Lui et al., 2019; Hallmo & Naess, 1991; Calero & Brusis, 2003). Multiple reports have linked serologies of HPV in SS with identical viral entities from the nasopharynx of inadequately protected OR personnel (Swerdlow, 2020a). Similarly, case reports of laryngeal papillomatosis and tonsillar carcinomas associate these nosocomial diseases with HPV SS transmission (Hallmo & Naess, 1991; Calero & Brusis, 2003).

Considering these hazards associated with SS inhalation, routine methods to mitigate SS exposure, including OR ventilation, improved respiratory PPE, and wall suction, provide inadequate protection for OR staff (Swerdlow, 2020; Romano et al., 2017). Standard surgical masks filter PM with maximum diameters larger than 5-15 μm, and N-95 respirators filter particles larger than 0.3 μm (Swerdlow, 2020a). However, SS routinely contains much smaller pathogenic material, including bacteria and viruses as small as 0.3 μm and 0.01 μm, respectively, and PM that are potentially less than 0.1μm in maximum diameter (Liu et al., 2019). In addition, improper N-95 mask fit and staff non-compliance interfere with effective PPE use (Ball, 2010; Pollock, 2007; Swerdlow, 2020a). Lastly, wall suction produces an inadequate vacuum to address SS evacuation (Swerdlow, 2020a).

On the other hand, SEDs routinely provide effective evacuation of SS. Through a combination of adequate suction and effective filtration, SEDs eliminate nearly all SS elements larger than 0.1 μm and result in markedly reduced UFPM concentrations (Swerdlow, 2020a). SS removed in this manner passes through either high-efficiency particulate air (HEPA) filters or ultra-low particulate air (ULPA) filters, and SS contents are not recycled into the OR atmosphere

(Limchantra et al., 2018; Swerdlow, 2020a). Common reasons for lack of routine SED use include a lack of protocols, a reluctance by OR personnel to acknowledge SS hazards, excessive noise, the bulkiness of equipment, and lack of accessibility; however, the most cited reason for SED under-use remains surgeon refusal for unspecified reasons (Edwards, 2008; Steege et al., 2016).

Despite multiple professional organizations recommending routine use of SEDs, a national survey of OR nursing staff revealed that only 14% of all surgeries with ESU devices routinely employed SEDs (OSHA, n.d.; AORN, 2017; Limchantra, 2019). Although four states (Rhode Island, Colorado, Kentucky, and Oregon) recently have mandated SED use, at present, there is no federal regulation of SS evacuation (AORN, 2021; Senate HB 2622, 2021). Thus, smoke evacuation often becomes relegated to institutional discretion (Limchantra et al., 2019).

Rationale

Despite current evidence demonstrating harm from SS exposure, practitioners commonly overlook its effective removal via SEDs. This project defined the extent of SED use at OHSU by utilizing Roger's Diffusion of Innovation (DOI) Theory and the Institute for Healthcare Improvement's (IHI) Model for Improvement. DOI identifies five stages associated with an individual's adoption of innovation (knowledge, persuasion, decision, implementation, and confirmation), and describes what factors influence adoption or rejection of an innovation. Additionally, a core principle of DOI theory is that innovation follows a predictable adoption pattern through a cumulative effect from early and late adopters. Initially, early adopters and "innovators" accept innovation, and through sociocultural pressure, late adopters and "laggards" eventually come to accept the innovation (Greenhalgh et al., 2007). DOI theory enhanced survey development and served as a guide during interviews. The IHI Model for Improvement acted as

the project's methodologic framework, and it included Plan-Do-Study-Act (PDSA) cycles to optimize survey development and distribution (IHI, 2020).

Specific Aim

The specific aims of this study were (1) to describe the current nature of SED use at OHSU's South OR (S-OR) from November 1, 2019, through October 31, 2020, and (2) to identify the barriers to the more widespread use of SEDs in the S-OR. Surveys with S-OR personnel including surgical attendings and surgical residents (hereafter "surgeons"), anesthesia attendings, residents, certified registered nurse anesthetists (CRNAs) (hereafter "anesthesia providers"), registered nurses (RNs), and certified surgical technicians (CSTs); face-to-face interviews; and OR records review provided the primary sources for data.

Methods

Context

OHSU Hospital is a 576-bed tertiary care center that serves the Portland, Oregon, metropolitan area. From November 1, 2019, through October 31, 2020, over 13,000 surgical procedures were performed in the hospital's S-OR. During the study period, OHSU employed 129 surgical attendings, 141 anesthesia providers, 124 OR nurses, and 46 CSTs in the S-OR. The Center of Health and Healing (CHH) is OHSU's ambulatory surgical center, and it represents the only OHSU site to embrace an SS-free OR. In 2018, CHH received an Association of periOperative Registered Nurses (AORN) Go Clear Award for ensuring a smoke-free environment. Since, S-OR leadership has attempted to reproduce CHH's success through staff education and addressing SED use barriers, but they thus far have been mostly unsuccessful. Although current OHSU policy recommends SEDs during smoke-generating procedures, there is no institutional mandate concerning SED use. The choice of whether to use

SEDs remains exclusively with the surgeons. In 2018, Occupational Safety and Health Administration (OSHA) received two formal complaints regarding SS evacuation in S-OR. However, a subsequent investigation by the organization found that staff exposure to VOCs was within acceptable limits.

OHSU has integrated SEDs into every S-OR suite to facilitate SED utilization as both built-in and stand-alone units (Buffalo Filter Visiclear), and surgeons can select additional surgery-specific SED supplies. However, while S-OR leadership has fashioned an environment that promotes easy access to SEDs, the frequency of SED utilization in their ORs remains unknown due to obscurity in the record keeping.

Interventions

Data related to the study period of November 1, 2019, through October 31, 2020, was gathered using a combination of record reviews, surveys, and interviews. Records provided quantitative SED utilization information. Specific records considered for this purpose included reports of surgical volume, surgical procedure cards containing SED requests (subdivided by specialty), and SED supply utilization reports.

Surveys were created to gather additional information not found in the records review. Using Roger's DOI Theory as the theoretical basis for survey development, survey questions addressed the characteristics of the individual adopter and the cultural norms of SS evacuation at OHSU S-OR. Questions were tailored to each type of provider. The survey design included Likert scale questions, multiple-choice questions, select all that apply questions, and questions with free-text answers to allow quantitative and qualitative data collection. Survey length was minimized to reduce burden and encourage participation. Recipients received email reminders to complete the survey for two consecutive weeks. A timeline of data collection is in Appendix A.

Following the IHI's Model for Improvement Methodology, this quality improvement (QI) project utilized two PDSA cycles. The pilot cycle involved a sample of five OR personnel to provide an opportunity for survey design feedback through a section embedded in the survey. OHSU's Operating Room Executive Medical Group (EMG) reviewed the second survey iteration before distribution to a larger volume of S-OR personnel. PDSA cycle 2 provided the bulk of survey data collection and was distributed to all S-OR surgeons, anesthesia providers, RNs, and CSTs.

Interviews served as the third method of data collection. Interviewees represented key stakeholders: department managers, SS evacuation "champions" (employees that advocate for SED use), early adopters, and SED non-users, who provided organization-specific, unpublished information. These individuals were identified and selected for an interview in conjunction with the operating room management committee consisting of surgeons, anesthesiologists, CSTs, and OR nurses.

Measures

This study analyzed outcome measures, process measures, and balancing measures (Appendix D). Our team chose outcome measures to address the project's specific aim of quantifying SED use and describing its perceived benefits and barriers to its use. Process measures described the steps taken to quantify these outcomes. Balancing measures monitored any external influence that may have altered outcomes or results.

Analysis

Qualtrics XM and Microsoft Excel served as software for data processing. Information gleaned from procedure card, supply utilization, and case volume reports quantified aspects of SED use and is organized in tabular form. We analyzed survey responses by provider type,

professional demographics, source of education related to SS, and perceived benefits of and barriers to SED use. Interviews and survey free-text responses provided common themes pertaining to SEDs.

Ethical Considerations

The study was reviewed by the university institutional review board and was considered exempt (Appendix L). All data collected was anonymous, encrypted, password-protected, and required two-factor authorization to access. The authors report no conflicts of interest.

Results

Methods of Data Collection

Record Review

Results are presented in Appendix I. During the study time interval, a total of 13,376 surgical cases in the S-OR were recorded. The total number of SEDs utilized during this period (based upon supply records which assumes used SEDS are replaced on a 1:1 basis) was 4,122. Therefore, the S-OR utilized SEDs in 30.8% of cases. Nearly all surgeries performed in the S-OR generate some quantity of SS, so the denominator of 13,376 cases is appropriate. The PlumePen®, an electrocautery pencil with a SED built-in, was the most utilized SED unit (n= 3,159, 77.8% of the 4,122 times SEDs were used). The least requested SED unit was the laparoscopic SED attachment (n= 603, 14.8% of the 4,122 times SEDs were used).

Procedure cards provided information related to surgeon requests rather than SED utilization. For this reason, SED purchase data was employed to estimate SED usage (Table 3I). Thus, to the extent that SEDs are ordered and not utilized, 30.8% represents an upper limit for the frequency of SED use. The same limitations apply to surgical subspecialty fractional utilizations in Table 1I.

Surveys

Survey data are in Appendix F. A total of 491 surveys were distributed, and 196 survey responses were received, yielding an overall survey response rate of 39.9%. Response rates broken down by provider were as follows: 56.6% (73/129) of surgeons, 33.9% of anesthesia providers (65/192), 36.3% of RNs (45/124), and 28.3% of CSTs (13/46). Surgeons responded the most frequently, and CSTs responded the least frequently. Additionally, surgeons with more than ten years of experience were the most likely group of surgeons to respond to this survey (65.8%, n= 31), while RNs with less than five years of experience were most likely group of RNs to respond to this survey (68.9%, n= 31).

The most prevalent method of SS education reported across all professions was non-industry sponsored material, such as journal articles and colleague presentations (49.1%, n=115). RNs (100%, n= 65) and CSTs (94.4%, n= 18) reported receiving the most education. In contrast, few anesthesia providers and surgeons had received any SS education (38.6%, n= 27 and 33.3%, n=27 respectively).

Most respondents (79%, n= 155), including surgeons, agreed, or strongly agreed that they are regularly exposed to SS. Likewise, the majority of RN (84.5%, n= 38) and CST (84.6%, n= 11) respondents agreed or strongly agreed that SS is a health hazard, as did most surgeons and anesthesia providers (52%, n= 38 and 67%, n= 43, respectively).

Surgeons were more likely to respond that they agreed or strongly agreed that they are not concerned about the hazards of SS (31.5%, n= 23), compared to RNs (8.8%, n= 4) and CSTs (7.6%, n= 1). Conversely, most RN and CST respondents also agreed that an SED should always be used in a SS generating procedure (89% and 76.9%, n= 50, respectively). In addition, approximately half of the CST and RN staff reported suggesting SED use to surgeons, whereas

only 6.2% (n= 4) of anesthesia providers reported participating in such discussions (see Table 5F).

Regarding perceived SED utilization rates, 68.5% of surgeons believed that they utilized SEDs greater than half the time in their procedures, with 21.9% of surgeons reporting use "all of the time." This response rate contrasts with the views of RNs (n= 21, 44.4%) and CSTs (n= 3, 23%) who believed SEDs use occurred less than half the time, and it also is inconsistent with the calculated SED use rate of 30.8% based on utilization data. Interestingly, 58.3% of surgeons who did not view SS as a health hazard reported using SEDs less than half of the time (compared with 31.5% of surveyed surgeons in general), and 17.4% of the same subset of surgeons reported never using SEDs (compared with 11.1% of surgeons who viewed SS as a health hazard).

The most frequently cited perceived barrier by RN, CST, and anesthesia providers to SED utilization was surgeon preference for no identifiable reason (44.4%, n= 87). Based on surgeon response, the three most common reasons surgeons opted not to use SEDs included “inconvenience” (32.7%, n= 37), “impaired surgical field visualization” (18.6%, n= 21), and “surgical smoke evacuation is not necessary” (11.5%, n= 13). Some surgeons expanded on "inconvenience" in the free-text submission to include improper RN and CST training on SED set-up, and devices not being readily available in the OHSU S-ORs. Of note, however, only one RN and no CSTs believed set-up was a barrier to SED use. In total, only 16 out of 196 respondents disagreed with SEDs being necessary—with 13 out of the 16 respondents being surgeons.

Interviews

A total of 13 individuals were interviewed, including two surgeons, one anesthesia provider, three RNs, two CSTs, and five OR managers. We organized responses by nine primary

themes (see Appendix H): (1) perceptions of SS hazards; (2) education surrounding SS/SEDs; (3) appropriateness of current SED utilization; (4) perceived benefits of SED use; (5) perceived barriers to SED use; (6) opposing viewpoints of SED users and non-users; (7) overall opinions regarding SED use; (8) passive/active roles of various OR personnel; and (9) suggestions for future changes regarding SED use.

Most interviewees believed SS was hazardous and thought SEDs were currently underutilized at the OHSU S-ORs. All provider types reported receiving education on SS/SEDs from in-services, professional organizations, colleagues, or self-guided research, except for the anesthesia provider, who reported never receiving education on the matter. Perceived benefits of SED use included patient safety and OR personnel safety, while perceived barriers included impaired visualization and noise. Interviewees identified that orthopedics and spine procedures frequently utilized SEDs, while plastics, urology, and neurosurgery cases were least likely. Nearly all interviewees commented on the current opposing opinions surrounding SED use in the OR, with frustrations expressed by surgeons, RNs, CSTs, and OR management. One surgeon described frustration with the lack of standardization of SED use at OHSU in all smoke-generating procedures, while another expressed the opposing belief that there is no explicit evidence to support SED use. RNs, CSTs, and OR management all expressed frustrations with a lack of legislative or institutional policy mandating SED use for smoke-generating procedures. Several groups commented on the passive role of anesthesia providers in issues related to SS evacuation. Suggestions for future changes regarding SED use at OHSU primarily focused on legislative and institutional policy, educational efforts, and modifications to S-OR cultural norms.

Discussion

Summary

The most salient findings of this descriptive study regarding SED use in the S-OR for the one-year period beginning November 1, 2019, and ending October 31, 2020, include:

1. Based on supply utilization reports and surgical case volume, these results indicate that S-OR utilizes SEDs in slightly less than one-third of all surgeries during the study period. Since SS generating procedures are common in the S-OR, SEDs are likely underutilized.

2. Surgeon preference without an expressed rationale was the most cited reason by RN, CST, and anesthesia providers for lack of SED use.

3. Surgeons reported that the most common reasons they opted not to use SEDs were inconvenience (including bulkiness), impaired surgical visualization, and the belief that SEDs are unnecessary.

4. Most surgeons recognized that they had significant occupational exposure to SS and believed that SS was a health hazard. Additionally, more than half of them (52%) were concerned about their exposure to SS. This finding suggests that addressing issues related to surgeon preference may facilitate more robust SED use amongst surgeons.

5. The overwhelming majority of non-surgeon OR staff view SS exposure as harmful and concerning, and they believe that surgeons should employ SEDs for all SS generating procedures. Further, RNs and CSTs were most likely to discuss SS evacuation with surgeons, and anesthesia providers are least likely to engage in this discussion with surgeons.

6. Individuals who believed SS to be a health hazard were more likely to be concerned about their exposure to SS.

7. Although anesthesia providers overwhelmingly believed that SEDs should be used with any SS generating procedure (80%), only 6.2% routinely suggest that the devices be used. This is a striking and anomalous finding that needs explanation.

8. At OHSU S-OR, plastic surgery procedure packs contain an SED and as such plastic surgeons represent the only specialty where a surgeon must opt-out, rather than opt-in, when choosing SED equipment.

Interpretation

The overall use of SEDs in the OHSU S-OR as estimated by utilization data (30.8%) is significantly higher than the most recent national data, based on an OR RN survey (14%) (Limchantra, 2019). On the other hand, the present study survey data suggests that OHSU RNs believe that SEDs are employed routinely in only 4% of cases (Table 3F). There are multiple potential reasons for these differences. First, approximately ten months of the study occurred during the 2019 coronavirus pandemic (COVID-19) when concerns for transmission of infectious virus by SS were greatest (Swerdlow, 2020b). This latter consideration likely increased SED utilization at many facilities, including OHSU. Second, published estimates of SED use are based on survey information, whereas the current study provides data based on utilization as approximated by purchase data. If SED units were replaced in excess of a one unit per surgery, then such purchase data overestimated usage. In contrast, survey numbers skewed by RN responder bias may have underestimated usage. Furthermore, record review and SED utilization requests indicate that there is significant variation in SED use among surgical specialties. This variation may stem from technical difficulties incorporating SEDs into specific surgical approaches and techniques, which this QI project did not explore.

Bias concerning the extent of perceived SED use may stem from differing levels of education among OR staff. This study shows that about 40% of surgeons and one-third of anesthesia providers at OHSU have received no education concerning SS, compared with RNs who uniformly received such education. Based on Roger's DOI Theory, survey and interview responses indicate that RNs and CSTs will likely be early adopters of any future SS evacuation innovation, whereas surgeon and anesthesia providers are more likely to be late adopters. Furthermore, this gap in education among surgeons may relate to the fact that only 52% of surgeons believed that exposure to SS constituted a health hazard (compared with 85% of RNs). These descriptive findings suggest that better education of surgeons may alter their perception of SS hazards and encourage more widespread use of SEDs consistent with other survey studies (Liu, 2019; Chavis, 2016). The Association of Operating Room Nurses strongly advocates for this approach (York, 2019).

On the other hand, even though two-thirds of anesthesia providers agreed that SS is a health hazard, and four-fifths of them believed that surgeons should use SEDs with any SS generating procedure, and only 6% routinely advocated for the use of these devices. This finding is striking, and it raises the question of why it has not been previously reported. This functional apathy on the part of anesthesia providers is also consistent with the near-complete lack of discussion of SS in the anesthesia literature, and it represents a striking inconsistency worthy of explanation (Swerdlow 2020a). Given the strong biases and comparably strong emotions concerning routine SED use among surgeons, it is possible that anesthesia providers choose not to address this issue due to fears of economic and political reprisal, or perhaps simply because they understand the critical importance of a mutually supportive surgeon-anesthesia relationship in patient care (Edwards, 2012; May, 2000). This lack of support of anesthesia providers for SED

use represents a significant deviation from their traditional role as unrelenting safety advocates. Regardless of the reasons, the fact that such a small fraction of anesthesia providers advocated for SED use is a unique finding of this QI project; and it is a potential source for problem remediation and represents opportunity for future studies.

Many findings of this study are consistent with previous investigations. For example, although the precise numbers may vary, SEDs were relatively underutilized in the OHSU operating rooms compared with their potential for use during SS generating procedures, a widespread observation (Limchantra, 2019). In addition to a limited education of surgeons, surgical attitudes toward SS as identified by the current study agree with past surveys: reasons suggested by surgeons herein and elsewhere for their reluctance to use SEDs include impaired visualization of the surgical field and noise (Swerdlow, 2020a; Edwards, 2012). In the current investigation, some surgeons expressed the opinion that wall suction is adequate for SS evacuation, a belief that is not supported with current evidence (Swerdlow, 2020a). Furthermore, perioperative nurses reported frustration concerning what they perceive as disregard for physical safety and wellness, a theme outlined in several other SS studies (Lindsey, 2015; Spearman, 2007).

Some of the findings of this study may have been affected by survey response rates. Although the overall response rate to this study's online survey was 39.9%, consistent with an expected value of 37%, the extent of such responses varied considerably between professional groups (Geyer et al., 2020). For example, the response rate for surgeons was 56.6%, a relatively high number, can be attributed to a concern that this QI analysis could potentially mandate future surgeon practices. On the other hand, CSTs had comparatively low response rates (28.3%), possibly related to a sense of futility associated with a history of failed CST-led QI attempts at

addressing SS evacuation at OHSU, including a recent occupational hazard complaint filed with OSHA with no beneficial outcome (Kahn, D., 2020, April 24).

Strengths & Limitations

A major strength of this study includes its use of multiple sources for data collection, including review of OR purchase records, case volume reports, survey data, and interview data. For example, the current investigation employed utilization data (derived from purchase records) rather than solely survey responses to quantitate SED use, and the higher figure (30.8%) reported herein may be related to this relatively novel methodology. In addition, the overall survey response rate suggests an accurate sampling of OHSU perioperative staff. Furthermore, the study was conducted in a prospective fashion that reduces biases compared with retrospective investigations.

There are some unique contextual elements to this QI project that may limit its general applicability. These include: (1) A significant portion of the one-year study period overlapped with the COVID-19 pandemic, which likely positively influenced SED use: and (2) OSHA recently investigated OHSU in response to a complaint regarding SS evacuation. Also, this study addresses overall SED use, not whether SEDs are appropriately used; and whether proper techniques of SS evacuation are employed, including effective capture device use, filter rotation, and other technical aspects of SED function that affect efficacy.

In addition to limits on the application and details of the results, several sources of bias exist that may influence the interpretation of this study's findings. Interviewees were identified by OR management to participate in this study, and as such, their opinions may reflect management perspectives regarding SS evacuation. Additionally, a separate OR committee screened survey questions in an alleged effort to avoid controversial and emotionally charged

issues related to SED use. Both these processes may have influenced study outcomes. Efforts to minimize these limitations included employing large survey sample sizes, interviewing individuals with opposing views on SS evacuation, and collecting data from multiple sources. For example, survey responses were compared to objective data points such as SED utilization data as a balancing measure to account for outlier opinions. Despite these efforts, there was an unexpectedly marginal survey response rate from CSTs and low response rates from RNs and anesthesia providers. Efforts made to improve response rates included a low survey burden and email reminders.

Conclusions

This quality improvement project provided a descriptive analysis of the state of surgical smoke evacuation and perceived barriers to SED use at OHSU during a recent one-year period that partially coincided with the COVID-19 pandemic. As such, this project may provide a framework for similar endeavors at other facilities that seek to perform similar observational studies. Furthermore, within the limitations of the current investigation, the perceived barriers of SED utilization at OHSU hospital may be extrapolated to other institutions where the same or similar operative conditions exist, and this information may guide future studies as technological advances (such as noise reduction and improved ergonomics) address some of these issues.

Oregon state law soon will mandate universal use of SEDs (Senate HB 2622, 2021), but this does not change the importance of questions raised by this study that relate to operating room personnel and their behavior. Among these findings is the notable gap of SS education among surgeons related to this health hazard; and the observation that only 6% of anesthesia providers routinely advocated for the use of these devices despite strongly agreeing with routine SED use. Although anesthesia providers are advocates of health, patient safety, and leaders in the

operating room, they have self-reported a laissez-faire approach to promoting SED use despite considering their use necessary for OR personnel safety. In this manner, the current study highlights areas with significant QI implications that warrant further investigation regardless of the future status of SED use during surgery.

References

AORN. (2017). Guideline summary: Surgical smoke safety. *AORN J, 105*(5), 498-500. doi:10.1016/j.aorn.2017.02.008

AORN. (2021). *Kentucky secures third place in states' race to go smoke free - health policy news - aorn*. AORN. https://www.aorn.org/about-aorn/aorn-newsroom/health-policy-news/2021-health-policy-news/kentucky-passes-smoke-bill

Ball, K. (2010). Compliance with surgical smoke evacuation guidelines: implications for practice. *AORN J, 92*(2), 142-149. doi:10.1016/j.aorn.2010.06.002

Barrett, W. L., & Garber, S. M. (2003). Surgical smoke: a review of the literature. Is this just a lot of hot air? *Surg Endosc, 17*(6), 979-987. doi:10.1007/s00464-002-8584-5

Baruch, Y. (1999). Response rate in academic studies-A comparative analysis. *Human Relations*, *52*(4), 421-438.

Board on Population. (2016). *Health risks of indoor exposure to particulate matter: Workshop summary*. National Academies Press. https://doi.org/10.17226/23531

Brook, R. D., Rajagopalan, S., Pope, r. C. A., Brook, J. R., Bhatnagar, A., Diez-Roux, A. V., Holguin, F., Hong, Y., Luepker, R. V., Mittleman, M. A., Peters, A., Siscovick, D., Smith, J. S. C., Whitsel, L., & Kaufman, J. D. (2010). Particulate matter air pollution and cardiovascular disease: An update to the scientific statement from the American Heart Association. *Circulation (New York, N.Y.), 121*(21), 2331-2378. https://doi.org/10.1161/CIR.0b013e3181dbece1

Calero, L., & Brusis, T. (2003). Laryngeal papillomatosis - First recognition in Germany as an occupational disease in an operating room nurse. *Laryngo-Rhino-Otologie*, *82*(11), 790–793. https://doi.org/10.1055/s-2003-44546

Chavis, S., Wagner V., Becker M., Bowerman, M. I., & Jamais M. S. (2016). Clearing the air about surgical smoke : An education program. *AORN J, 103,* 289-296.

Cho, Y. I., Johnson, T. P., & Vangeest, J. B. (2013). Enhancing surveys of health care professionals: A meta-analysis of techniques to improve response. *Evaluation & the Health Professions*, *36*(3), 382-407. https://doi.org/10.1177/01632787134964

Dearing, J. W., & Cox, J. G. (2018). Diffusion of innovations theory, principles, and practice. *Health Affairs*, *37*(2), 183-190. https://doi.org/10.1377/hlthaff.2017.1104

Doyle, C. (2020). *Surgical smoke: A risk too real to ignore*. OR Management News. https://www.ormanagement.net/Article/PrintArticle?articleID=59416

Edwards, B. E., & Reiman, R. E. (2012). Comparison of current and past surgical smoke control practices. *AORN J, 95*(3), 337-350. doi:10.1016/j.aorn.2011.07.019

Garden, J. M., O'Banion, M. K., Shelnitz, L. S., Pinski, K. S., Bakus, A. D., Reichmann, M. E., & Sundberg, J. P. (1988). Papillomavirus in the vapor of carbon dioxide laser-treated verrucae. *JAMA, 259*(8), 1199-1202. https://doi.org/10.1001/jama.1988.03720080033024

Greenhalgh, T., Robert, G., Bate, P., Macfarlane, F., & Kyriakidou, O. (2007). Diffusion of innovations in health service organizations: A systematic literature review. ProQuest Ebook Central. https://ebookcentral.proquest.com

Georgesen, C., & Lipner, S. R. (2018). Surgical smoke: Risk assessment and mitigation strategies. *Journal of the American Academy of Dermatology, 79*(4), 746-755. https://doi.org/10.1016/j.jaad.2018.06.003

Hallmo, P., & Naess, O. (1991). Laryngeal papillomatosis with human papillomavirus DNA contracted by a laser surgeon. *European Archives of Oto-Rhino-Laryngology*, *248*(7), 425–427. https://doi.org/10.1007/bf01463570

H.B 2622, 2021 Annual, 2021 Reg. Sess. (2021). https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/HB2622

Hill, D. S., O'Neill, J. K., Powell, R. J., & Oliver, D. W. (2012). Surgical smoke – A health hazard in the operating theatre: A study to quantify exposure and a survey of the use of smoke extractor systems in UK plastic surgery units. *Journal of plastic, reconstructive & aesthetic surgery, 65*(7), 911-916. doi:10.1016/j.bjps.2012.02.012

Institute for Healthcare Improvement. (2020). *How to improve.* http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

Kahn, D. (2020, April 24). *Exposure assessment of surgical smoke: OHSU.* Forensic Analytical Consulting Services: FACS Project #PJ45826. https://www.forensicanalytical.com

Karjalainen, M., Kontunen, A., Saari, S., Rönkkö, T., Lekkala, J., Roine, A., & Oksala, N. (2018). The characterization of surgical smoke from various tissues and its implications for occupational safety. *PLOS ONE*, *13*(4), e0195274. https://doi.org/10.1371/journal.pone.0195274

Limchantra, I. V., Fong, Y., & Melstrom, K. A. (2019). Surgical smoke exposure in operating room personnel: A review. *JAMA surgery, 154*(10), 960. doi:10.1001/jamasurg.2019.2515

Lindsey, C., Hutchinson, M., & Mellor, G. (2015). The nature and hazards of diathermy plume: A review. *AORN J, 101,* 428-442

Ling, S. (2009). Particulate matter air pollution exposure: role in the development and exacerbation of chronic obstructive pulmonary disease. *International Journal of Chronic Obstructive Pulmonary Disease*, 233. https://doi.org/10.2147/copd.s5098

Liu, Y., Song, Y., Hu, X., Yan, L., & Zhu, X. (2019). Awareness of surgical smoke hazards and enhancement of surgical smoke prevention among the gynecologists. *Journal of Cancer, 10*(12), 2788-2799. https://doi.org/10.7150/jca.31464

May, S. L., Dupuis, G., Harel, F., Taillefer, M., Dubé, S., & Hardy, J. (2000). Clinimetric scale to measure surgeons' satisfaction with anesthesia services. *Canadian Journal of Anesthesia*, *47*(5), 398–405. https://doi.org/10.1007/BF03018967

Occupational Safety and Health Administration. (n.d.). *Laser/Electrosurgery Plume*. https://www.osha.gov/SLTC/laserelectrosurgeryplume/

Oregon Health & Science University. (2020). *Factbook 2019*. https://www.ohsu.edu/sites/default/files/2020-02/Fact Book 2019 for web.pdf

Pierce, J. S., Lacey, S. E., Lippert, J. F., Lopez, R., & Franke, J. E. (2011). Laser-generated air contaminants from medical laser applications: A state-of-the-science review of exposure characterization, health effects, and control. *Journal of Occupational and Environmental Hygiene, 8*(7), 447-466. https://doi.org/10.1080/15459624.2011.585888

Pollock, L. (2007). Hazards of electrosurgical smoke. *Perioperative Nursing Clinics, 2*(2), 127-138. https://doi.org/10.1016/j.cpen.2007.03.002

Romano, F., Gusten, J., De Antonellis, S., & Joppolo, C. M. (2017). Electrosurgical smoke: Ultrafine particle measurements and work environment quality in different operating theatres. *Int J Environ Res Public Health, 14*(2). doi:10.3390/ijerph14020137

Spearman, J., Tsavellas, G., & Nichols P. (2007). Current attitudes and practices towards diathermy smoke. *Ann R Coll Surg Engl., 89,* 162-165

Steege, A. L., Boiano, J. M., & Sweeney, M. H. (2016). Secondhand smoke in the operating room? Precautionary practices lacking for surgical smoke. *American Journal of Industrial Medicine*, *59*(11), 1020–1031. https://doi.org/10.1002/ajim.22614

Swerdlow, B. N. (2020a). Surgical smoke and the anesthesia provider. *Journal of Anesthesia*, *34*(4), 575–584. https://doi.org/10.1007/s00540-020-02775-x

Swerdlow, B. (2020b). Surgical smoke and SARS-CoV-2 transmission. *Journal of Clinical Anesthesia and Intensive Care*(1).

Van Mol, C. (2017). Improving web survey efficiency: The impact of an extra reminder and reminder content on web survey response. *International Journal of Social Research Methodology*, *20*. (4), 317-327. https://doi.org/10.1080/13645579.2016.1185255

York, K., & Mandy, A. (2018). Surgical smoke: Putting the pieces together to become smoke-free. *AORN J, 107,* 127-138.

Yoshifumi, T., Shigenobu, M., Kazuto, N., Setsuo, U., Masakazu, F., Minoru, H., & Tomio, H. (1981). Mutagenicity of smoke condensates induced by CO2-laser irradiation and electrocauterization. *Mutation Research/Genetic Toxicology, 89*(2), 145-149. https://doi.org/10.1016/0165-1218(81)90120-8

Appendix A

Project Timeline

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Finalize Project Design (703A)	X								
IRB Determination (703B)	X								
PDSA Cycle 1 (703B)		X							
PDSA Cycle 2 (703B)			X	X					
Final Data Analysis (703B)				X	X				
Write Sections 13-17 (703B)						X	X		
Prepare for project dissemination (703B)							X	X	X

Intervention	Date Performed
Compiled procedure card data	November 24, 2020
Submitted survey questions to OHSU's EMG	January 5, 2021
Distributed PDSA cycle 1	February 4, 2021
Sent reminder emails to PDSA cycle 1 recipients	February 11, 2021 February 18, 2021
Deadline for PDSA cycle 1 responses	February 19, 2021
Distributed PDSA cycle 2	March 10, 2021
Sent reminder emails to PDSA cycle 2 recipients	March 17, 2021 March 24, 2021
Deadline for PDSA cycle 2 responses	March 26, 2021
Conducted targeted interviews	April 19, 2021 – April 30, 2021

Appendix B

Members of the QI Project Team

OHSU Nurse Anesthesia DNP Students

- William Meyer, RN, BSN
    - DNP student
    - Project Author
- Nathan Isbell, RN, BSN
    - DNP student
    - Project Author

OHSU Nurse Anesthesia Program Faculty

- Dr. Barry Swerdlow, MD, FASA
    - DNP Project Chair
    - Assistant Professor – Nurse Anesthesia Program
- Dr. Julie Soelberg, Ph.D., CRNA
    - DNP Project Consultant
    - Assistant Professor – Nurse Anesthesia Program

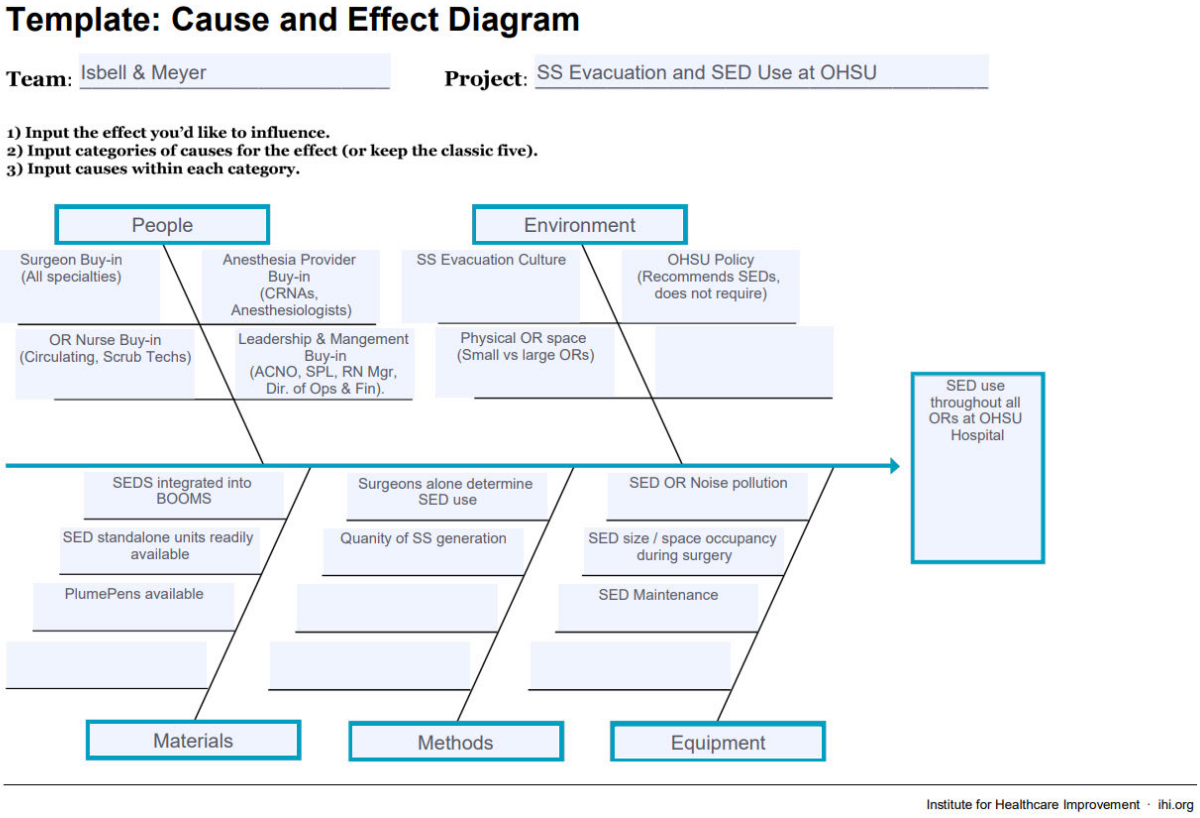
OHSU Perioperative Management and Leadership

- Dio Sumagaysay, RN, MS
    - Associate Chief Nursing Officer (ACNO), Perioperative & Procedural Services
- Jamie Harrell
    - OHSU Director of Perioperative Operations and Finance
- Anna McAllister, RN, BSN, CNOR
    - OHSU Procedure Card Specialist

- Haley Sands, RN, BSN
    - OR Nurse Manager
- Brian Droege, RN
    - Specialty Practice Leader
- April Jenkins,
    - Program Technician

Appendix C

Cause and Effect Diagram



Appendix D

Measures

Measure	Type	Definition	Data Collection
Percentage of cases utilizing SEDs	Outcome measure	Total number of surgical cases using SEDs / Total number of surgical cases	Procedure card and surgical case volume records
Identify surgical specialties who utilize SEDs most frequently/infrequently	Outcome measure	• Cardiovascular • ENT • Dental / Oral • General surgery • Gynecology • Hepatobiliary • Neurosurgery • Ophthalmology • Orthopedic surgery • Otolaryngology • Plastic surgery • Surgical oncology • Urology • Vascular	Procedure card and surgical case volume records
Identify perceived barriers to SED use	Outcome measure	Barriers of SED use identified by OR personnel	Survey and targeted interview responses
Number of procedure cards that request SEDs	Process measure	The total number of procedure cards that list SED equipment	Procedure card records
Number of cases performed at OHSU	Process measure	Total number of cases performed at DCH from November 1, 2019, through October 31, 2020	Surgical case volume records
Number of available SEDs at OHSU S-OR	Process measure	Total number of stationary and portable SEDs available at OHSU S-OR	Targeted interview responses
Feedback from the sample after initial PDSA cycle	Process measure	Comments received from the initial provider sample regarding survey length, clarity of questions, the function of survey question format, and identification of unintended effects	Targeted interview responses from the initial provider sample
Percent response rate after final PDSA cycle	Process measure	The number of completed surveys divided by the total number of surveys distributed	Survey responses
Survey burden	Balancing measure	Provider perception of excessive survey length	Targeted interview responses from the initial provider sample
Change in SED use or SED perception as a result of survey distribution during second PDSA cycle	Balancing measure	Alterations in SED use or SED perception attributed to the distribution of the survey	Targeted interview responses from OHSU S-OR management

Appendix E

Survey

Qualtrics Survey

Surgeon	OR Staff	Anesthesia Provider
1. What surgical specialty/specialties do you work in? *(select all that apply)* i. Cardiothoracic ii. Dental iii. Otolaryngology iv. General Surgery v. Gynecology vi. Ophthalmology vii. Neurosurgery viii. Orthopedics ix. Podiatry x. Plastic Surgery xi. Urology xii. Vascular xiii. Other: _____	1. What is your role in the operating room? (*select all that apply)** i. Scrub nurse/perioperative nurse ii. Circulating nurse iii. Registered Nurse First Assistant	1. What is your role in the operating room? i. Certified Registered Nurse Anesthetist ii. Anesthesiologist
2. How many years have you worked in an operating room environment? *(select one)* i. < 5 years ii. 5-10 years iii. 10-15 years iv. > 15 years	2. What surgical specialty/specialties do you work in? *(select all that apply)* i. Cardiothoracic ii. Dental iii. Otolaryngology iv. General Surgery v. Gynecology vi. Ophthalmology vii. Neurosurgery viii. Orthopedics ix. Podiatry x. Plastic Surgery xi. Urology xii. Vascular xiii. I work with all surgical specialties xiv. Other: _____	2. How many years have you worked in an operating room environment? *(select one)* i. < 5 years ii. 5-10 years iii. 10-15 years iv. > 15 years
3. I have received education about surgical smoke from: *(select all that apply)* i. Journal articles ii. Seminars iii. Continuing medical education (CME) courses iv. Colleagues v. Other: _____ vi. I have not received education regarding surgical smoke	3. How many years have you worked in an operating room environment? *(select one)* i. < 5 years ii. 5-10 years iii. 10-15 years iv. > 15 years	3. I have received adequate education about surgical smoke from: *(select all that apply)* i. Journal articles ii. Seminars iii. Continuing education (CME/CE) courses iv. Colleagues v. Other: _____ vi. I have not received education regarding surgical smoke
4. On a scale of 1-5 (1 = strongly disagree, 3 = neutral, and 5 = strongly agree) please rate the following: i. I am exposed to a significant amount of surgical smoke in the operating room ii. I believe that surgical smoke is hazardous to my health iii. I feel my colleagues don't use smoke evacuation devices as often as I do	4. I have received education about surgical smoke from: *(select all that apply)* i. Journal articles ii. Seminars iii. Continuing education (CE) courses iv. Colleagues v. Other: _____ vi. I have not received education regarding surgical smoke	4. On a scale of 1-5 (1 = strongly disagree, 3 = neutral, and 5 = strongly agree) please rate the following: i. I am exposed to a significant amount of surgical smoke in the operating room ii. I believe that surgical smoke is hazardous to my health iii. Surgical smoke evacuation devices should always be used during any surgical smoke generating procedure iv. I often suggest that a smoke evacuation device be used during a procedure v. I desire more input into the decision whether to employ smoke evacuation devices in cases I am involved in
5. Circle the best answer: i. I use surgical smoke evacuation device for open and minimally invasive cases that generate surgical smoke is: *(select one)*	5. On a scale of 1-5 (1 = strongly disagree, 3 = neutral, and 5 = strongly agree) please rate the following: i. I am exposed to a significant amount of surgical smoke in the operating room ii. I believe that surgical smoke is hazardous to my health iii. Surgical smoke evacuation devices should always be used during any surgical smoke generating procedure iv. I often suggest that a smoke evacuation device be used during a	5. Circle the best answer: i. The primary reason smoke evacuation devices are not utilized more often in the OR is: *(select one)* a. Too noisy

a. All the time
b. More than half the time
c. About half the time
d. Less than half the time
e. Never

ii. Use of smoke evacuation devices is problematic for me due to: (circle all that apply)
a. Surgical smoke evacuation is unnecessary
b. Too noisy
c. Inconvenience (including bulkiness of the device)
d. Impaired surgical field visualization
e. Surgical smoke evacuation devices are ineffective for evacuation of smoke

iii. When I choose <u>not</u> to use a surgical smoke evacuation device, the primary reason is: *(select ONE)*
a. Surgical smoke evacuation is unnecessary
b. Too noisy
c. Inconvenience (including bulkiness of the device)
d. Impaired surgical field visualization
e. Surgical smoke evacuation devices are ineffective for evacuation of smoke
f There is no surgical smoke generated with the surgery

iv. I use smoke evacuation devices more often with: *(select one)*
a. Open procedures
b. Minimally invasive procedures
c. Equally with open and minimally invasive procedures

procedure

v. I desire more input into the decision whether to employ smoke evacuation devices in cases I am involved in

6. Circle the best answer:
i. The primary reason smoke evacuation devices are not utilized more often in the OR is: *(select one)*
a. Too noisy
b. Inconvenience including bulkiness of device
c. Impaired surgical field visualization
d. Surgical smoke evacuation is unnecessary
e. Surgical smoke evacuation devices are ineffective for evacuation of surgical smoke
f Smoke evacuation devices are difficult to set up

ii. In my practice, use of surgical smoke evacuation devices for cases that generate smoke occurs approximately: *(select one)*
a. All the time
b. More than half the time
c. About half the time
d. Less than half the time
e. Never

b. Inconvenience including bulkiness of device
c. Impaired surgical field visualization
d. Surgical smoke evacuation is unnecessary
e. Surgical smoke evacuation devices are ineffective for evacuation of surgical smoke
f Smoke evacuation devices are difficult to set up

ii. In my practice, use of surgical smoke evacuation devices for open and minimally invasive cases that generate smoke occurs approximately: *(select one)*
a. All the time
b. More than half the time
c. About half the time
d. Less than half the time
e. Never

*This question only pertains to OR nursing staff, and it was not included in surveys distributed to CST. The remainder of the survey was identical for all professional groups.
Note: This table includes three variations of the survey that were delivered to OR staff. The intent of these variations were to address the unique perspective of OR personnel related to SS evacuation.

Appendix F

Survey Results

Figure 1F: Provider Experience

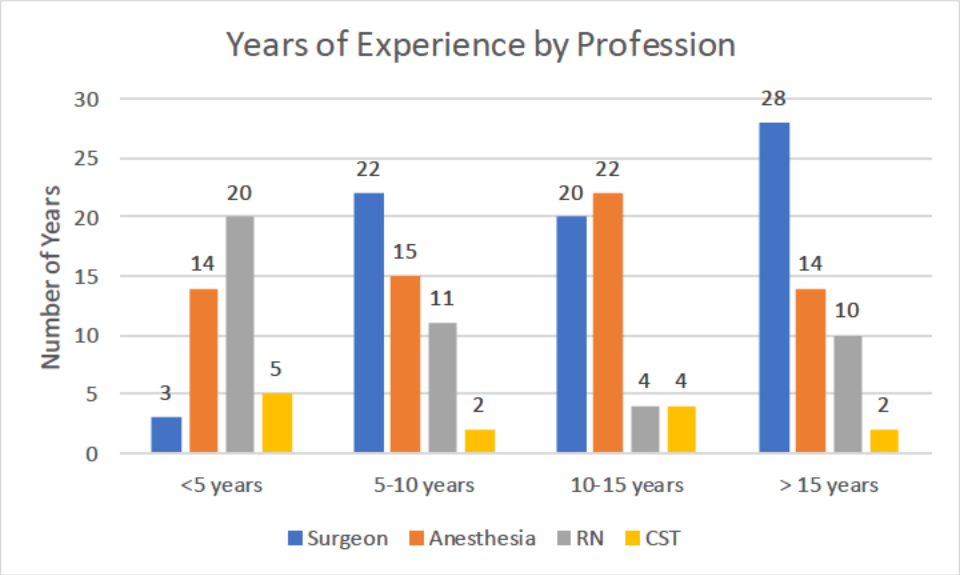


Figure 2F: Self-Reported SED Utilization Across All Professions

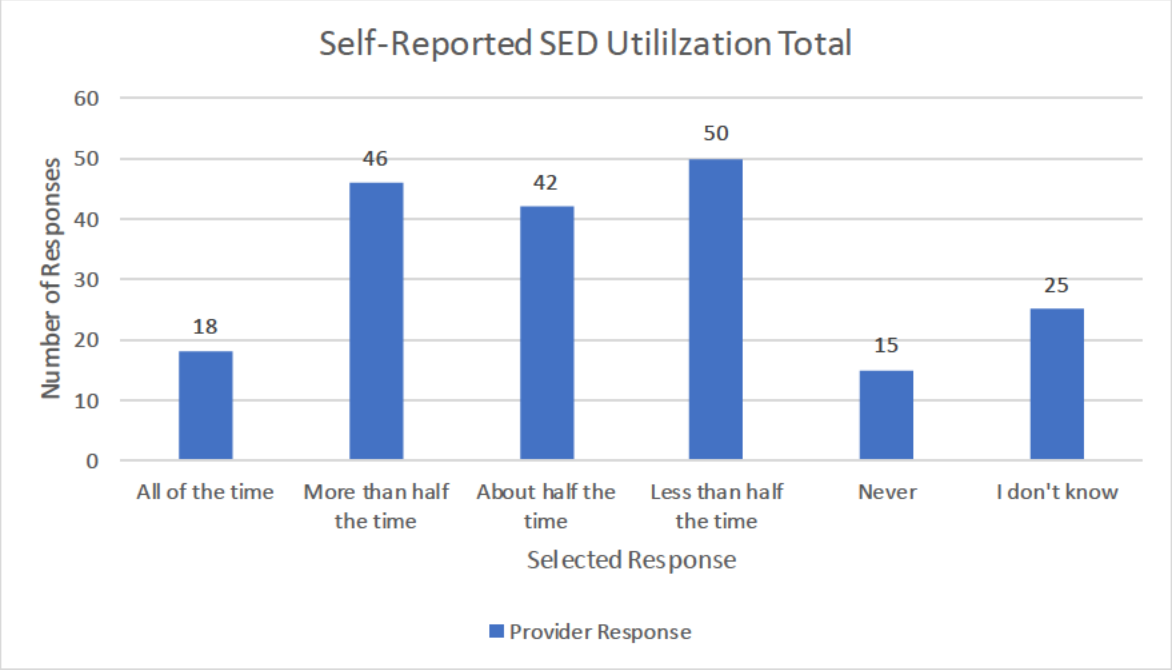


Figure 3F: Perceived Hazards of SS Among Professions

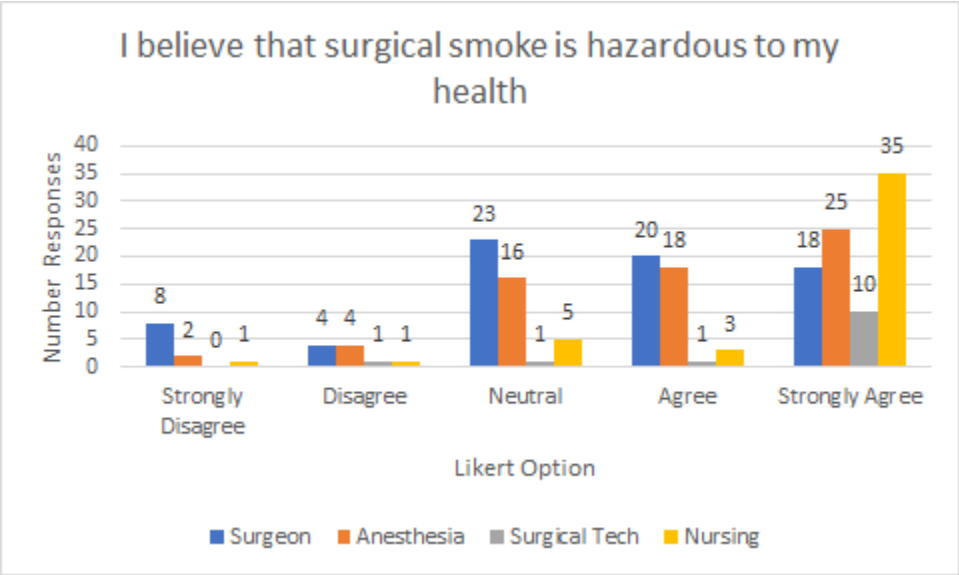


Figure 4F: Concern of Occupational Exposure of SS Among Professions

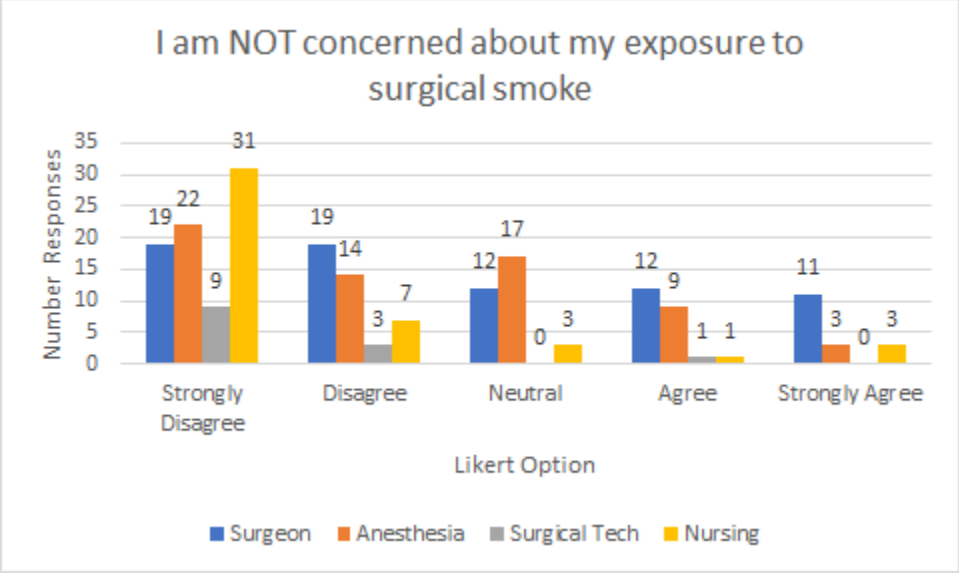


Figure 5F: Necessity of SEDs During SS Generating Procedures by Profession

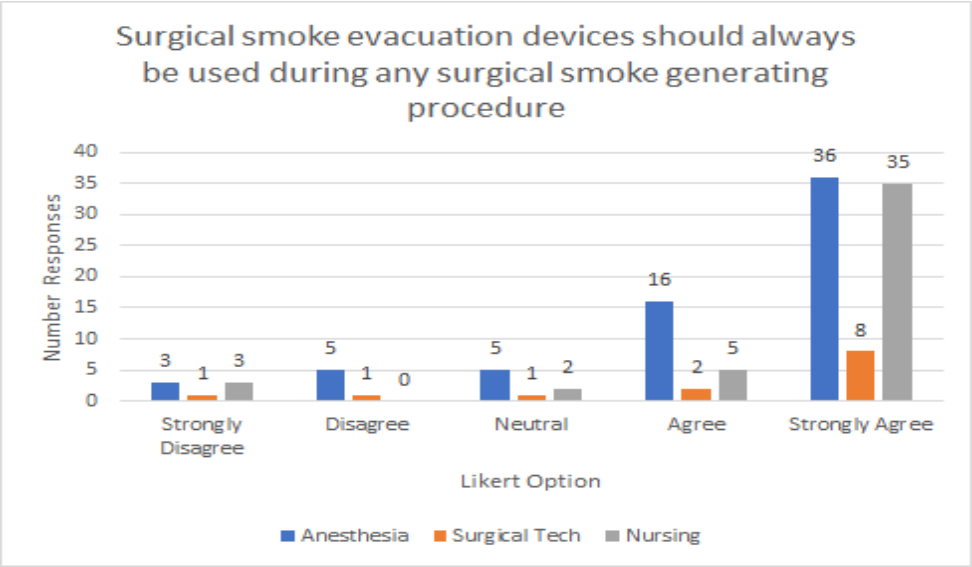


Table 1F: Response Rates

Provider	Responses	Surveys Delivered	Reponses Rate
Surgeon	73	129	56.58%
ST Staff	13	46	28.26%
RN Staff	45	124	36.29%
Anesthesia	65	192	33.85%
Total	196	491	39.92%

Table 2F: Provider Specialty

What surgical specialty/specialties do you work in? (Select all that apply)	Count	%
General Surgery	19	23.75%
Orthopedics	13	16.25%
Other	12	15.00%
Gynecology	9	11.25%
Otolaryngology	5	6.25%
Vascular	5	6.25%
Urology	5	6.25%
Plastic Surgery	5	6.25%
Ophthalmology	2	2.50%
Cardiothoracic	2	2.50%
Neurosurgery	2	2.50%
Dental	1	1.25%
Podiatry	0	0.00%
Total	80	100%

Table 3F: Nursing, Anesthesia, and Surgical Technologist Perception of SED Utilization

Question *In my practice, use of surgical smoke evacuation devices for cases that generate smoke occurs approximately (select one)*

Answer	Nursing		Anesthesia		CST	
	n	%	n	%	n	%
All of the time	2	4.44	0	0	0	0
More than half the time	11	24.44	9	13.85	2	15.38
About half the time	10	22.22	14	21.54	8	61.54
Less than half the time	19	42.22	15	23.08	3	23.08
Never	2	4.44	3	4.62	0	0
I don't know	1	2.22	24	36.92	0	0
Total	45	100	65	100	13	100

Question The reasons surgical smoke evacuation devices are not utilized more often in the OR are (select all that apply)

Answer	Nursing		Anesthesia		CST	
	n	%	n	%	n	%
Too noisy	13	11.02	7	8.75	3	10.00
Inconvenience including bulkiness of the device	30	25.42	18	22.50	7	23.33
Impaired surgical field visualization	29	24.58	12	15.00	5	16.67
Surgical smoke evacuation is unnecessary	0	0.00	2	2.50	1	3.33
Surgical smoke evacuation devices are ineffective for evacuation of smoke	3	2.54	4	5.00	1	3.33
Smoke evacuation devices are difficult to set up	1	0.85	5	6.25	0	0.00
Surgeon choice	42	35.59	32	40.00	13	43.33
Total	118	100	80	100	30	100

Table 4F: Surgeon Self-Reported SED Utilization

Question: *I use surgical smoke evacuation device for open and minimally invasive cases that generate surgical smoke is (select one)*		
Answer	n	%
All the time	16	21.92%
More than half the time	24	32.88%
About half the time	10	13.70%
Less than half the time	13	17.81%
Never	10	13.70%
Total	73	100%

Question: *I use smoke evacuation devices more often with (select one)*		
Answer	Count	%
Open procedures	32	49.23%
Minimally invasive procedures	14	21.54%
Equally with open and minimally invasive procedures	19	29.23%
Total	65	100%

Table 5F: Perceived Barriers to SED Utilization – Nursing, Anesthesia, and Surgical Tech

Question: *The primary reason smoke evacuation devices are not utilized more often in the OR is (select one)*	Nursing		Anesthesia		CSTs	
Answer	n	%	n	%	n	%
Too noisy	13	11.02%	7	8.75%	3	10.00%
Inconvenience including bulkiness of the device	30	25.42%	18	22.50%	7	23.33%
Impaired surgical field visualization	29	24.58%	12	15.00%	5	16.67%
Surgical smoke evacuation is unnecessary	0	0.00%	2	2.50%	1	3.33%
Surgical smoke evacuation devices are ineffective for evacuation of smoke	3	2.54%	4	5.00%	1	3.33%
Smoke evacuation devices are difficult to set up	1	0.85%	5	6.25%	0	0.00%
Surgeon choice	42	35.59%	32	40.00%	13	43.33%
Total	118	100%	80	100%	30	100%

Table 6F: Perceived Barriers to SED Utilization – Surgeons

Question Use of surgical smoke evacuation devices is problematic for me due to (select all that apply)		
Answer	Surgeon	
	n	%
Surgical smoke evacuation is unnecessary	13	11.50
Too noisy	10	8.85
Inconvenience (including bulkiness of the device)	37	32.74
Impaired surgical field visualization	21	18.58
Surgical smoke evacuation devices are ineffective for evacuation of smoke	10	8.85
There is no surgical smoke generated with the surgery	12	10.62
Loss of haptics/ tactile feedback	10	8.85
Total	113	100

Table 7F: Likert Scale Questions

Provider	Question	1		2		3		4		5	
		n	%	n	%	n	%	n	%	n	%
Surgeon	I am exposed to surgical smoke in the operating room	1	1.37	7	9.59	8	10.96	14	19.18	43	58.90
	I believe that surgical smoke is hazardous to my health	8	10.96	4	5.48	23	31.51	20	27.40	18	24.66
	I feel my colleagues don't use smoke evacuation devices as often as I do	14	19.18	19	26.03	22	30.14	9	12.33	9	12.33
	I am not concerned about my exposure to surgical smoke	19	26.03	19	26.03	12	16.44	12	16.44	11	15.07
		1		2		3		4		5	
Anesthesia	I am exposed to surgical smoke in the operating room	0	0.00	6	9.23	11	16.92	25	38.46	23	35.38
	I believe that surgical smoke is hazardous to my health	2	3.08	4	6.15	16	24.62	18	27.69	25	38.46
	Surgical smoke evacuation devices should always be used during any surgical smoke generating procedure	3	4.62	5	7.69	5	7.69	16	24.62	36	55.38
	I often suggest that a smoke evacuation be used during a procedure	27	41.54	16	24.62	18	27.69	4	6.15	0	0.00
	I am NOT concerned about my exposure to surgical smoke	22	33.85	14	21.54	17	26.15	9	13.85	3	4.62
		1		2		3		4		5	
CST	I am exposed to surgical smoke in the operating room	0	0.00	0	0.00	4	30.77	0	0.00	9	69.23
	I believe that surgical smoke is hazardous to my health	0	0.00	1	7.69	1	7.69	1	7.69	10	76.92
	Surgical smoke evacuation devices should always be used during any surgical smoke generating procedure	1	7.69	1	7.69	1	7.69	2	15.38	8	61.54
	I often suggest that a smoke evacuation be used during a procedure	0	0.00	2	15.38	4	30.77	1	7.69	6	46.15
	I am NOT concerned about my exposure to surgical smoke	9	69.23	3	23.08	0	0.00	1	7.69	0	0.00
		1		2		3		4		5	
Nursing	I am exposed to surgical smoke in the operating room	0	0.00	1	2.22	3	6.67	12	26.67	29	64.44
	I believe that surgical smoke is hazardous to my health	1	2.22	1	2.22	5	11.11	3	6.67	35	77.78
	Surgical smoke evacuation devices should always be used during any surgical smoke generating procedure	3	6.67	0	0.00	2	4.44	5	11.11	35	77.78
	I often suggest that a smoke evacuation device be used during a procedure	6	13.33	3	6.67	13	28.89	11	24.44	12	26.67
	I am NOT concerned about my exposure to surgical smoke	31	68.89	7	15.56	3	6.67	1	2.22	3	6.67

Note: Column headings 1 through 5 represent Likert scale responses: 1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree.

Appendix G

Standardized Interview Questions by Provider

Anesthesia Provider	1. Do you believe surgical smoke (SS) is harmful? Why or why not? 2. Where have you received information concerning SS? 3. In your opinion, which surgical specialty utilizes smoke evacuation devices (SEDs) most often and why? Which specialty utilizes SEDs least often and why? 4. In your opinion, is SS evacuation underutilized, overutilized, or utilized appropriately at OHSU? Why do you think that is? 5. Which cases are you regularly involved in that generate the most SS? 6. What, if any, changes would you like to see at your facility regarding SS evacuation? 7. Compared to other professional organizations, there is little writing in the anesthesia literature or from anesthesia organizations concerning surgical smoke. Why do you believe this is the case? 8. What do you think are the responsibilities of anesthesia providers with respect to smoke exposure of operating personnel? 9. Are there any steps you feel that the anesthesiology department or the individual could take to promote a safe OR environment with regards to SS? 10. Are there barriers that have prevented any of these steps from being taken previously?
Surgeons	1. Do you believe surgical smoke (SS) is harmful? Why or why not? 2. Where have you received information concerning SS? 3. In your opinion, is SS evacuation underutilized, overutilized, or utilized appropriately at your facility? Why? 4. Could you describe your own personal experiences with smoke evacuation devices (SEDs)? 5. Can you discuss the precise aspects of SEDs that potentially interfere with your surgeries? For example: a. Do they impair visibility? b. Do they add to the complexity of an already complex care situation? c. Does the noise interfere with communication among operating room staff? d. Are the pencil devices awkward to hold? 6. What can your institution do to make SEDs more user-friendly and less problematic for surgeons? 7. Are there any other changes you would like to see at your facility regarding SS evacuation?
Registered Nurses & Certified Surgical Technologists	1. Do you believe surgical smoke (SS) is harmful? Why or why not? 2. Where have you received information concerning SS? 3. In your opinion, which surgical specialty utilizes smoke evacuation devices (SEDs) most often and why? Which specialty utilizes SEDs least often and why? 4. In your opinion, is SS evacuation underutilized, over-utilized, or utilized appropriately at your facility? Why? 5. Which cases are you regularly involved in that generate the most SS? 6. What, if any, changes would you like to see at your facility regarding SS evacuation? 7. How could the institution optimize communication and discussion about surgical smoke evacuation among staff? 8. Does SED setup interfere with operating room workflow? a. If so, what adjustments have been made in the past, and what adjustments could be made in the future, to preserve workflow that would still allow SED use in each case?
OR Management	1. Do you believe surgical smoke (SS) is harmful? Why or why not? 2. Where have you received information concerning SS? 0 3. In your opinion, which surgical specialty utilizes smoke evacuation devices (SEDs) most often and why? Which specialty utilizes SEDs least often and why? 4. In your opinion, is SS evacuation underutilized, over-utilized, or utilized appropriately at your facility? Why? 5. What, if any, changes would you like to see at your facility regarding SS evacuation? 6. What are the major impediments (institutional or otherwise) to implementation of an effective smoke evacuation program at OHSU? 7. What are the practice differences between CHH and OHSU/DCH pertaining to surgical smoke evacuation? Why do these practice differences exist?

Appendix H

Interview Themes

Themes Derived from Targeted Interviews

Themes	Coding Phrases	Examples by Provider Type
Perceptions of SS Hazards	Believes SS is hazardous	• Surgeon = Underwent a lung operation for a benign tumor in the lung, believes it to be related to SS exposure • RN = Referenced statistic regarding ablation of one gram of tissue to be equivalent in carcinogenicity to six cigarettes • CST = Stated particles in SS smaller than 0.1 microns can become entrapped within the respiratory tract and have been shown to be harmful • OR Management = Has known three people who have been diagnosed with oral cancer and has attributed it to SS exposure
	Does not believe SS is hazardous	• Anesthesia = Does not believe there is conclusive evidence that SS is harmful • Surgeon = Believes there hasn't been a study to show OR personnel dying from smoke-related diseases
Education Surrounding SS/SED	Self-taught	• Surgeon = Felt SED companies were "fear-mongering", examined scientific literature, and did not find any data showing cause and effect between SS and illness • Surgeon = Conducted own literature search • CST = Researched current available evidence, undertook it as a project, and presented it to staff
	In-services	• Surgeon = Mentioned SED company in-service was the first exposure to the topic • RN = Referenced SED company in-service • CST = Stated SED company in-service prompted further exploration
	Professional organizations	• RN = Discussed AORN resources • CST = Mentioned AST conferences and journal articles • OR Management = Referenced AORN and emails from state legislature
	Colleagues	• RN = Credited colleagues who are passionate about SEDs with bringing awareness to the topic • OR Management = Credited former employee with bringing awareness to the topic

	No education	• Anesthesia = Stated there had not been any education on the matter
Appropriateness of Current SED Utilization	Believes SEDs are underutilized	• Surgeon = Stated SEDs are underutilized, because it is not yet a standard practice • RN = Stated SEDs are underutilized, since only two services at DCH use it routinely • OR Management = Stated SEDs are heavily underutilized, due to lack of full buy-in at DCH • OR Management = Stated underutilization was primarily a result of surgeon preference • OR Management = Stated SEDs are underutilized, and encounters the common argument of "show me the causative data", but felt there is a lack of understanding that RCTs cannot be performed to obtain this kind of data • OR Management = Stated SEDs are underutilized, as they should be utilized for all cases to mitigate any potential risk, which they currently are not • CST = Stated SEDs are underutilized at an institutional level, but more surgeons have increased their SED use in recent years • RN = Stated "appropriate" utilization would be 100% of cases
	Unsure if SEDs are utilized appropriately	• Surgeon = Described not feeling sure if SEDs are utilized appropriately. Stated they probably have a role in some cases, but would need to do more research. However, described willingness to adopt SED use if evidence supported it • OR Management = Referenced the fact that utilization is dependent upon the site. Described appropriate utilization at CHH, but underutilization in S-OR
Perceived Benefits of SED Use	OR personnel safety	• Surgeon = Believes SED use should be mandated for OR personnel safety as a part of OSHA • OR Management = Emphasized that SEDs keep everyone in the OR safe • CST = Compared SS safety to fire safety, and encouraged annual education regarding SS • RN = Referenced frequent headaches from smoke inhalation and fear of impact on health
	Patient safety	• CST = Stated SS has been shown to be harmful to patients and SEDs should be used routinely for patient safety
	SED technology has greatly improved	• Surgeon = Found current SED technology to be reliable and a significant improvement from prior models, with no issues regarding loss of haptics
Perceived Barriers to SED Use	Impaired visualization	• Surgeon = Stated handheld devices are cumbersome and difficult to see around • Anesthesia = Discussed overhearing surgeons say SEDs are bulky and impair visualization

		• CST = Believes small size of pediatric patients can make visualization difficult with SEDs
	Noise	• Surgeon = Described noise from SEDs to be distracting to the flow of the case • CST = Stated they are noisy systems
	Loss of haptics / tactile feedback	• Surgeon = Emphasized that SEDs interfere with tactile feedback while ablating tissue
	Setup Time	• Surgeon = Mentioned the fact that some circulators are not as comfortable with the setup, so it takes time
	Patient safety	• Surgeon = Believes loss of haptics with handheld device impacts patient safety by making it more difficult to assess tissue and increases risk of complications
SED Users / Non-Users	Users	• RN = Referenced orthopedics and spine cases as users at DCH • OR Management = Referenced plastics as users at OHSU • RN = Referenced plastics, ENT, and general surgery as users at OHSU
	Non-users	• RN = Referenced urology, plastics, and neurosurgery as non-users at DCH • CST = Referenced neurosurgery and orthopedics as non-users at OHSU • OR Management = Referenced surgical oncology and spine cases as non-users at OHSU
Opposing Opinions Regarding SED Use	Surgeons feeling frustrated	• Surgeon = Described an adversarial culture surrounding SED use in the OR. Desires a way to address the issue in a rational way. Believes that if SEDs can't be used in a particular case, then those who are uncomfortable with that can scrub into another room
	RNs and CSTs feeling frustrated	• OR Management = Believes the issue is placing stress on interpersonal relationships in the OR, and expresses desire for OHSU to move beyond surgeons being the sole decision maker for everyone's health and safety • OR Management = Described the discussion surrounding SEDs as becoming increasingly more adversarial, causing significant division among staff • CST = Referenced a distinct hierarchy in the OR, with some surgeons being more intimidating and adversarial than others, but others being fairly open to a discussion regarding SED use • RN = Expressed frustration that OHSU as an institution is about "bettering the health of all

		Oregonians", but surgeons won't use SEDs for the health of their colleagues
Passive and Active Roles of OR Personnel	Passive role of anesthesia department	• OR Management = Described the anesthesia department as appearing indifferent on the issue, but believes this may be because they don't want to be in the middle of their surgical and nursing colleagues • Anesthesia = Believes it is possible that data has not been presented to anesthesia providers, or that anesthesia groups are less impressed by the data • RN = Believes there is a lack of education among anesthesia providers, similar to most other provider groups
	Active / influential role of CSTs	• RN = Emphasizes that CSTs have a very influential role in SED use, as they are opening up the supplies for the procedure
Suggestions for Future Changes Regarding SED Use	Standardized policy for SED use	• Surgeon = Would like to see an institutional mandate for SED use for OR personnel safety • OR Management = Would like to see a change in the language used in the OHSU SED policy so that SED use is not up to provider preference • OR Management = Would like to see the institution push surgeons to challenge their own habits • CST = Would like to see replacement of Bovies with PlumePens® in all packs
	State legislative changes	• OR Management = Looking forward to passage of Oregon bill to mandate SED use, which would completely change the discussion around SED use
	Increased buy-in from surgeons	• RN = Expressed frustration with setting up an SED for a case, only to have a surgeon say they don't use that • CST = Would like to see surgeons try various SEDs to find one they feel comfortable using
	Change in culture	• Surgeon = Would like to create a culture where everyone feels comfortable asking if SEDs are being used • CST = Would like to create a culture where SED use is automatic • OR Management = Feels a small team would be needed to champion this initiative in order for it to be as successful as it was at CHH
	Increased education	• Surgeon = Would like to see consistent training regarding SED use for all OR personnel • CST = Would like to create annual continuing education courses regarding hazards of SS

		• OR Management = Would like to increase education and familiarity with SEDs in the hopes of adopting consistent SED use prior to state mandate
	Encouraging further conversation	• Surgeon = Would like to get to a place where everyone is comfortable talking about SS and having a difference in opinion
	No suggestions for future changes	• Anesthesia = Stated no opinion on future changes, does not feel there is enough evidence of harm and hears reports from surgeons that SEDs are substandard

Appendix I

Procedure Card, Supply Utilization, and Case Volume Report Results

Table 1I: Surgical Volume by Service in S-OR

Service	Surgical Volume	Percentage of Total Cases
Orthopedics	2,793	21%
General Surgery	1,610	12%
Neurosurgery	1,607	12%
Trauma	1,199	9%
Cardio Thoracic Surgery	1,032	8%
Otolaryngology	916	7%
Vascular	814	6%
Urology	748	6%
Oral & Maxillofacial	452	3%
Gynecology	430	3%
Plastics	424	3%
Abdominal Tx	349	3%
Surgical Oncology	337	3%
Bariatrics	294	2%
Medical Surgical	263	2%
Endoscopy, GI	67	1%
Ophthalmology	29	<1%
Other	10	<1%
Peds General Surgery	2	<1%
Dermatology	0	0%
Total	13,376	100

Data represent surgical volume from November 1st, 2019, through October 31st, 2020

Table 2I: Card Data

Surgical Specialty	Total Cards	Total Number of SEDs Requested	Types of SEDs Requested	
All Cards[2]	2,605	1,422	Buffalo Equipment	453
			PlumePen®	665
			Plastics Pack (includes PlumePen®)	109
			PlumePort ActiV ®	195
Cardiothoracic	72	5	Buffalo Equipment	1
			PlumePen®	2
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	2
Dental / Oral	88	71	Buffalo Equipment	34
			PlumePen®	37
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0
General Surgery	410	359	Buffalo Equipment	104
			PlumePen®	68
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	187
Gynecology	225	60	Buffalo Equipment	11
			PlumePen®	17
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	32
Hepatobiliary	67	23	Buffalo Equipment	3
			PlumePen®	9
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	11
Neurosurgery	410	26	Buffalo Equipment	13
			PlumePen®	13

			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0
Ophthalmology	34	7	Buffalo Equipment	5
			PlumePen®	2
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0
Orthopedics	456	272	Buffalo Equipment	95
			PlumePen®	177
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0
Otolaryngology	232	123	Buffalo Equipment	34
			PlumePen®	89
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0
Plastics	245	270	Buffalo Equipment	55
			PlumePen®	110
			Plastics Pack (includes PlumePen®)	105
			PlumePort ActiV ®	0
Surgical Oncology	140	118	Buffalo Equipment	42
			PlumePen®	61
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	15
Urology	235	176	Buffalo Equipment	77
			PlumePen®	91
			Plastics Pack (includes PlumePen®)	4
			PlumePort ActiV ®	4
Vascular	88	16	Buffalo Equipment	7
			PlumePen®	9
			Plastics Pack (includes PlumePen®)	0

			PlumePort ActiV ®	0
Service Not Indicated	2	0	Buffalo Equipment	0
			PlumePen®	0
			Plastics Pack (includes PlumePen®)	0
			PlumePort ActiV ®	0

Table 3I: Percentage of Cases Utilizing SEDs

SED Type	Number of Cases Utilizing	Percentage of Total Cases
PenAdapt	3	0.01%
Plumepen in pack	295	7.27%
Plumepen	3,159	77.81%
Plumeport SEO	8	0.20%
Plumeport Active	595	14.66%
Total	4,060	1.00%

Appendix J

Data Management

Data Management
1. Data Processing
1.1. Data Entry
1.1.1. Method of data entry will include split-screen verification and electronic data capture (*Qualtrics* software) to ensure accuracy and reliability.
1.1.2. All data will be compiled onto a Microsoft Excel spreadsheet (See *3.2*). The spreadsheet can be modified through either web-browser, downloading file and editing the document on a personal computer, and uploading updated document onto server.
1.2. Data Error Correction
1.2.1. Two-person verification of data entry to ensure accuracy and reliability of data.
2. Data Security
2.1. Electronic data will be password protected and require two-factor authentication to access.
2.2. Electronic data will be stored on an encrypted OHSU server under *The Box* service.
2.3. OHSU OR operation records will be delivered securely through OHSU email and stored onto *The Box* service.
2.4. Data will not include protected health information.
2.5. Data will be anonymous.

Appendix K

IRB Application for Determination

Request for Determination Form

Research Integrity Office
Mail Code L106-RI
Portland, Oregon 97239-3098
Phone: 503.494.7887
Fax: 503.346.6808

Version 1.1
Updated 5.28.2019

PI Name Barry Swerdlow, Julie Soelberg eIRB
Project Title The State of Surgical Smoke Evacuation at Oregon Health & Science University Hospital

INSTRUCTIONS

Use this form when:

- *You are not sure if your project requires IRB oversight, or*
- *You would like a formal determination from the IRB as to whether the project requires IRB oversight, or*
- *You are conducting research with samples or data that are not individually identifiable to the research team, but the project involves genetic research.*

Complete the entire form unless your response to a particular question instructs you to skip ahead.

Upload the form to the eIRB in place of, or in addition to, a protocol.

If your project meets the definition of Research (Section 1), includes Human Subjects (Section 2), and OHSU is Engaged in the research (Section 3), you should submit a new study with a full protocol instead of submitting this form.

ection One – Research

esearch is a **systematic investigation**, including research development, testing and evaluation, designed to evelop or contribute to **generalizable knowledge**.

☐ This project is research. → **Skip to Section Two**.

☒ I don't think this project is research, or I am not sure. → **Answer the questions below:**

1.1. Is this a case study of a single patient or a case series of three or fewer patients? If so, describe.
Note: Inclusion of more than three patients is generally considered research.

1.1.1. *No.*

1.1.2. If yes, will it involve testing of biological specimens for non-clinical purposes? If so, describe.

1.2. Is this a quality improvement/quality assurance, program evaluation, or public health project? If so, explain. (*These types of activities may not meet the definition of research. See the Quality Improvement or Research? Quick Guide on the IRB Policies and Forms web page for more information.*)

1.2.1.1. This project's aim is to generate a descriptive analysis regarding the state of surgical smoke evacuation at OHSU Hospitals operating rooms and degree smoke evacuation devices (SEDs) are employed. This will be accomplished through face-to-face interviews with key individuals (management, leadership, and other OR employees), anonymous staff surveys, and record review of OR operations that pertain to SED utilization, surgeon procedure cards, and OR case volume.

1.3. Will individuals, groups, or institutions/organizations be randomized or otherwise designated to receive different interventions that will be compared? If so, explain. *Note: Randomization or comparison against a control tends to indicate a systematic investigation, which may be research.*

1.3.1. *No.*

1.4. What are you hoping to learn from this project? Will the knowledge you gain be generalizable to other contexts or situations?

1.4.1. *We are hoping to understand the sociocultral context at OHSU hospital as well as the perceived barriers and benefits of SED-use. Roger's Diffusion of Innovation (DOI) theory describes the characteristics and attributes to why an individual adopts or rejects an innovation. We will address each of DOI's five stages (Knowledge, Persuasion, Determination, Implementation, Confirmation), which should give us a comprehensive understanding of SS evacuation at OHSU. With these stages defined, future local interventions may possibly address any gap in SED. The knowledge we gain will not be generalizable.*

1.5. What will you do with the results? *Note: Whether you intend to publish does not itself determine whether your project is research.*

1.5.1. *These results will be available for future Nurse Anesthesia classes to utilize and implement future interventions to address this gap. If this project is high-yield and of exceptional quality, we will submit it to be published.*

ection Two – Human Subjects

human subject is a **living individual** about whom an investigator conducting research obtains:
Data through **intervention** or **interaction** with the individual, or
Identifiable private information (*information is identifiable if the identities of the subjects are **readily ascertainable** to the investigator, either directly or indirectly through a coding system*)

☐ This project involves human subjects. → **Skip to Section Three.**

☒ This project is not research. → **Skip to Section Five.**

☐ This project is or may be research, but I don't think it involves human subjects, or I am not sure. → **Answer the questions below:**

2.1. Are all of the subjects in the research known to be deceased? *Note: Decedents are not considered human subjects.*

2.2. Describe the data and/or specimens to be used for the project.

2.3. Are all of the data and/or specimens pre-existing or going to be collected for some purpose other than this project?

If yes:

2.3.1. What is the original source of the data and/or specimens? How will they be provided to the investigators?

2.3 2. Are all of the data and/or specimens de-identified such that none of the investigators working on the project could readily ascertain the identities of the subjects, either directly or indirectly through a coding system? Explain. *Note: If investigators have a way of identifying individual subjects, the project likely involves human subjects.*

If no:

2.3.3. How will the investigators (at OHSU or another institution) collect the data and/or specimens? *Note: If investigators will intervene (including both physical procedures and manipulations of the subject or subject's environment) or interact (including all forms of communication or interpersonal contact) with individuals in order to collect information about them, this project likely involves human subjects.*

ection Three – Engagement in Research

HSU is **engaged** in a research project if **OHSU employees, students, or other agents** do any of the following:
Intervene or interact with human subjects for the research,
Obtain **individually identifiable private information** about human subjects for the research, or
Obtain the **informed consent** of individuals for participation in the research.

here are exceptions for certain recruitment activities and for performance of some protocol-required ocedures as a commercial service or on an emergency or temporary basis.

☐ This project is research and OHSU is engaged in the research project. → **Skip to Section Four. If the project also involves human subjects, STOP and complete a new study submission.**

☐ This project is not research, or it is research that does not involve human subjects. → **Skip to Section Four.**

☐ This project is or may be human research, but I don't think OHSU is engaged in the project, or I am not sure. → **Answer the questions below:**

3.1. Describe OHSU's and any other institutions' roles in the research, including which investigators will interact with human subjects, obtain subjects' identifiable private information, or obtain informed consent for the research. *Note: If OHSU investigators will do any of these things, OHSU is probably engaged in the research.*

3.2. Will OHSU employees, students, or agents obtain ***only de-identified data or specimens*** (that is, the data/specimens are completely anonymous or the data/specimens are coded and OHSU investigators will not have access to the key to the code)? *If so, OHSU is probably not engaged in the research.*

3.3. Will OHSU employees, students, or agents ***only release pre-existing data or specimens*** to investigators at another institution (that is, OHSU investigators will have no part in testing of specimens or data analysis)? *If so, OHSU is probably not engaged in the research.*

ection Four – Oregon Genetic Privacy Law

enetic Research is research using human DNA samples, genetic testing, or genetic information. **Genetic formation** is information about an individual or the individual's blood relatives obtained from a genetic test. or more details, see our Genetic Research web page.

☐ This project does not involve genetic research. → **Skip to Section Five.**

☐ This project involves genetic research. → **Answer the questions below:**

4.1. The specimens/data are (check one):

☐ Anonymous (meaning the identity of the individuals or their blood relatives cannot be determined by anyone, including through a code or other means of linking the information to a specific individual)
☐ Coded (meaning that some link exists that would allow re-identification of the data/specimens, even if the OHSU investigators will not have access to it)

NOTE: If the specimens or data are individually identifiable, you are likely conducting human research. ***STOP and complete a new study submission.***

4.2. For coded data/specimens, describe the method of coding and steps you will take to ensure data security. (See HRP-461 WORKSHEET – Oregon Genetic Research – Anon-Coded on the IRB Policies and Forms web page for specific criteria regarding coded genetic research.)

4.3. In Oregon, the individuals who originally provided the data/specimens must have consented to genetic research, or you must verify that the individuals have not "opted out" of genetic research at OHSU (see our Genetic Research web page for more information). Indicate how your project complies with this requirement (check one):

☐ Subjects consented for this project specifically
☐ Subjects consented for future genetic research generally
☐ Subjects did not consent, but we will exclude any subjects who opted out of coded/anonymous genetic research – Describe your plan to verify opt-out status:

☐ None of the specimens/data are from subjects in Oregon
☐ Other – Describe:

ection Five – HIPAA

rotected Health Information (PHI) = health information + one or more of the 18 identifiers. See our HIPAA and esearch web page for more details.

ven if your project is not human research or OHSU is not engaged in the research, you may have requirements nder HIPAA if you are using, obtaining, or releasing/disclosing PHI.

l HIPAA forms linked below are available on the IRB Policies and Forms web page. Upload them on the ***ecruitment, Consent and Authorization*** page of the IRQ.

☒ This project does not collect any health information. → **Stop here, no HIPAA requirements.**

☐ This project collects health information, but does not involve access to or recording of any of the 18 individual identifiers, and therefore does not involve PHI. → **Stop here, no HIPAA requirements.**

☐ Investigators on this project will only have access to data/specimens already at OHSU and that meet the definition of a Limited Data Set *(no direct identifiers such as name, MRN, initials, or street address, but*

may include dates and geographic subdivisions smaller than a state), and the Limited Data Set will NOT be sent outside OHSU. → **Stop here, no additional HIPAA requirements.**

☐ PHI will be accessed, used, and/or sent outside OHSU, but not for research purposes (examples: case reports, QA projects, public health reporting). → **Stop here, comply with OHSU HIPAA policies for non-research activities.**

Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (contains any of the 18 individual identifiers, photos or illustrations that contain identifiable features such as pictures of a patient's face or tattoos), must first obtain each patient's authorization. In the case of deceased individuals, consent might be obtained from the next of kin.

Authorization to Use and Disclose Protected Health Information Form

☐ PHI will be accessed only for purposes preparatory to research, such as preparing a protocol or compiling a recruitment list, and the PHI will not be released outside OHSU. → Prep to Research **form required.**

☐ This project is research and will collect and use PHI, but all subjects are known to be deceased. → Decedents Representation **form required.**

☐ This project is research and will collect PHI, but only for the purpose of preparing a Limited Data Set to send outside OHSU. → Data Use Agreement **required.**

☐ This project is research and OHSU will receive a Limited Data Set from another institution for this project. → **Data Use Agreement may be required by the other institution. If so, submit DUA for review and signature to the office that handled the contract for the project (if there was one, or to OPAM if there was no contract). DUAs for OPAM should be directed to Contract-triage@ohsu.edu.**

☐ This project is research, PHI will be accessed, used, and/or sent outside OHSU for purposes of this study, and none of the above options apply. → **You most likely need a** Waiver or Alteration of Authorization**. Any disclosures outside OHSU must be tracked in the** Accounting of Disclosures System**.**

☐ Other – Explain:

Appendix L

Letter of Support from OHSU

Letter of Support from Clinical Agency

Date: *12/10/2020*

Dear *Nate Isbell & William Meyer*,

This letter confirms that I, *Dio Sumagaysay*, allow *Nate Isbell & William Meyer* (OHSU Doctor of Nursing Practice Student) access to complete his/her DNP Final Project at our clinical site. The project will take place from approximately *01/03/2021* to *05/31/2021*.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

Project Site(s):
Oregon Health and Science University (OHSU) Hospital
Perioperative Services
3181 SW Sam Jackson Park Road
Portland, Oregon 97239

Project Plan:
Surgical smoke (SS) poses a potential health hazard to OR personnel that can be mitigated by utilizing smoke evacuation devices (SED), yet the state of SS evacuation and SED-use at OHSU Hospital is not well-defined. The specific aim of this quality improvement (QI) project is to generate a descriptive analysis of the state of SS evacuation for the one-year period from November 1, 2019 through October 31, 2020, as well as the current perceived and actual barriers to SED use. We will acquire data through targeted OR staff interviews, record reviews, and OR staff surveys. Roger's Diffusion of Innovation (DOI) theory describes the process an individual undergoes to accept or reject an innovation, and it will guide our survey development to create a questionnaire to comprehensively address the characteristics of an innovation, adopter, and organization. The Institute for Healthcare Improvement's (IHI) Model for Improvement will function as the methodological framework, and Plan-Do-Study-Act (PDSA) cycles will allow refinement of survey questions and survey length.

This QI project seeks to complete targeted interviews, record reviews, and staff surveys by May 31st, 2021, and have approximately 50% survey response rate. The survey will be uploaded to Qualtrics software and delivered via email to select OR registered nurses, surgeons, and anesthesia providers. Targeted interviews will be completed through Webex videoconferencing. These interviews will involve OR management, known surgeon SED users (relative), known surgeon SED non-users (relative), and smoke evacuation advocates. Records that will be reviewed include surgeon procedure card reports, supply utilization reports, and case volume reports from November 1st, 2019 through October 31st, 2020. Outcome measures (SED utilization rate by specialty, perceived and actual barriers to SED use), process measures (PDSA cycles, survey response rate), and balancing measures (survey burden, local policy state legislation concerning SS), will be analyzed throughout this project.

This project will manage its data in Microsoft Excel. It will be encrypted, password protected, and require two-factor verification to access. The data collected will be anonymous, and it will not have any patient identifiers. OHSU perioperative management and leadership will facilitate this process by identifying key individuals and stakeholders, assist with survey distribution, and provide record reports.

During the project implementation and evaluation, *Nate Isbell & William Meyer* will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact *Nate Isbell & William Meyer* and *Dr. Barry Swerdlow & Dr. Julie Soelberg* (student's DNP Project Chairperson).

Regards,

DNP Project Preceptor / Job Title — Date Signed: 12/14/2020

Signature — Date Signed: 12/14/2020

Signature — Date Signed