[High Priority] - H0613 : [COVID-19] Considerations for Smoke Evacuation during Non-Deferrable Surgery [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

Published: Monday, May 18, 2020

UMDNS Terms:

- Electrodes, Electrosurgical, Active, Hand-Controlled, Smoke Evacuation [19327]
- Smoke Evacuation Systems, Surgical [16262]
- Smoke Evacuation Systems, Surgical, Mobile/Portable [18855]
- Smoke Evacuation Systems, Surgical, Stationary [18856]

Geographic Regions: Worldwide

Suggested Distribution: Anesthesia, Cardiology/Cardiac Catheterization Laboratory, Emergency/Outpatient Services, Infection Control, Nursing, Obstetrics/Gynecology/Labor and Delivery, Oncology, OR/Surgery, Risk Management/Continuous Quality Improvement, Urology, Gastroenterology, Dentistry/Oral Surgery, Otolaryngology, Staff Education, Materials Management

Problem:

1. Extensive community transmission of the SARS-CoV-2 virus has resulted in a patient surge and has altered care practices in many healthcare facilities.
2. While elective surgical procedures have been deferred, surgical teams may still need to perform procedures on high-acuity patients.
3. Healthcare personnel may be exposed to SARS-CoV-2 while performing non-elective/emergent surgery on a COVID-19 positive patient.
4. While there are no relevant clinical studies on the transmission effectiveness of the SARS-CoV-2 virus from surgical smoke, there is anecdotal evidence (see the Background section below) of similarly sized viral particles (0.06 to 0.14 mm in size) (1) transmitting disease to surgical staff via smoke plume, causing concern.
5. The lack of clinical evidence and concern for transmissivity of the virus warrants considering expanded use of surgical smoke evacuation.

Comment:

1. Many of the recommendations in this report are intended to place an emphasis on diligence and best surgical practices in any situation, regardless of the current pandemic.
2. Though increased diligence may increase overall operative and turnover times, ECRI believes the added benefit of staff and patient safety is paramount.
3. ECRI typically advocates for knowledge of the risks of surgical smoke and surgical smoke evacuation strategies to be made available to clinicians. For more information on the contents of surgical smoke, potential risks from chronic and acute exposure, a discussion on the current limited usage of smoke evacuation, and perspectives from other professional organizations, see ECRI's guidance " Clearing the Air around Surgical Smoke: Know the Risks " (2).
4. Recommendations that would represent a deviation from standard best practices in light of the COVID-19 pandemic are preceded by an asterisk (*).
5. ECRI's recommendations are not intended to endorse any particular product or manufacturer, but to review smoke evacuation options that are available to facilities.

ECRI Recommendations:

Surgical Staff

1. Follow ECRI's recommendations, including the minimization of the use of surgical smoke-generating devices (e.g., electrosurgery units [ESUs], lasers, ultrasonic scalpels), per Hazard Report H0614 "[COVID-19] Strategies to Minimize Surgical Staff Exposure to COVID-19" (3).
2. Use a form of active or passive surgical smoke evacuation with ULPA-level filtration efficiency, in conjunction with proper room ventilation and clinical team personal protective equipment (PPE).
    1. This recommendation is not only for surgical cases involving a known or suspected COVID-19 positive patient, but any procedure in which staff are concerned regarding the risks of surgical smoke, or as mandated by state legislature.
    2. *Note that even with smoke evacuation, appropriate ventilation, and PPE, the diameter of the SARS-CoV-2 virus may be smaller than a ULPA filter can effectively capture (see the Background section below for discussion). As such, none of these measures can truly eliminate the possibility of SARS-CoV-2 transmission during surgery.
3. When using surgical smoke evacuation technologies, consider which of the following best meets the needs of your facility:
    1. Open surgery with a portable smoke evacuator or suction/waste management system with ULPA-level filtration efficiency–capture tubing should be approximately 2 cm from the surgical site.
        1. Monopolar ESU pencils with integrated smoke evacuation tubing; these devices also have an option for automatic smoke evacuation when the pencil is active. Evacuation ceases a short amount of time after activation stops to minimize the noise of smoke evacuation during the procedure.
        2. Open smoke evacuation tubing
    2. Minimally invasive surgery

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1. Smoke evacuators with dedicated laparoscopic modes. The following systems both received a major advantage for prevention of gas leakage from the pneumoperitoneum and a minor advantage for laparoscopic evacuation efficiency in ECRI's 2019 Portable Surgical Smoke Evacuator evaluation.
    1. IC Medical Crystal Vision 450D
    2. Megadyne Mega Vac Plus (note, the standard Mega Vac does not have a dedicated laparoscopic mode).
2. Laparoscopic insufflators with an integrated smoke evacuation mode. Note, for supply chain management, that these devices typically require proprietary tubing for surgical smoke evacuation. Examples include:
    1. B Braun CO_2 Insufflator Flow 50 (this device is available only outside the U.S.)
    2. ConMed AirSeal iFS in AirSeal and Smoke Evacuation modes (see the Manufacturer's Recommendation section below)
    3. NTI Surgical Nebulae I
    4. Richard Wolf Insufflator High Flow 45 EVAC
    5. Stryker PneumoClear
3. Be alert to smoke evacuation systems that will require a separate ULPA-level filtration suction source. Examples include:
    1. Karl Storz S-Pilot
    2. Medtronic Valleylab Laparoscopic Smoke Evacuation System
        1. Note that this is a separate device from Medtronic's RapidVac Smoke Evacuator System, which does not have a dedicated laparoscopic mode.
4. Consider the use of passive ULPA smoke evacuation devices if active sources are unavailable. Examples include:
    1. Buffalo Filter PlumePort
    2. CooperSurgical PlumeAway

4. Refer to ECRI resources for smoke evacuation product specifications and manufacturers.
    1. Healthcare Product Comparison System (HPCS) for Surgical Smoke Evacuation Systems, including those with dedicated laparoscopic modes
    2. HPCS for Laparoscopic Insufflators , including those that have integrated smoke evacuation
    3. Health Devices' 2019 evaluation on Portable Surgical Smoke Evacuators
5. Dispose of and replace smoke evacuation ULPA filters when indicated or when a smoke odor is present in the OR during use, indicating diminished filtration efficiency.

Manufacturer's Recommendations:
Special considerations for ConMed AirSeal iFS in AirSeal mode

1. This system's AirSeal mode requires a proprietary trocar with a valveless design that prevents overinflation of the abdomen, and facilitates easy specimen removal. As a result of the valveless design, unfiltered air is vented to the OR through the open port.
2. *If your facility relies on the ConMed AirSeal iFS for smoke evacuation on a known or suspected COVID-19 positive patient, ConMed has outlined the following options (4):
    1. Use the Smoke Evacuation Mode, which requires proprietary tubing with a standard sealed trocar.
    2. Use the Standard Insufflation Mode with a suction source connected to a ULPA filter.
    3. In AirSeal mode, either:
        1. Connect a ULPA smoke evacuator to another port; replace the obturator during desufflation, or
        2. Connect a ULPA-filtered suction source to a separate port; replace the obturator during desufflation.

Background:

1. Smoke evacuation is intended to keep the surgical field clear, and to reduce irritants and odors for the surgical team via the capture of surgical plume, which may contain volatile chemical and/or biological components, such as viruses.
2. ECRI considers surgical smoke evacuation an example of an "engineering control" measure as defined by the CDC, intended to reduce COVID-19 exposures by shielding healthcare personnel (5).
3. SARS-CoV-2 is an RNA virus with a diameter of 0.06 to 0.14 mm (1). For reference, the human papillomavirus (HPV) is on the scale of 0.05 mm, whereas the flu virus may range from 10-70 mm (6).
4. As summarized in ECRI's guidance on surgical smoke [2]:
    1. Some animal studies have demonstrated viral transmission from surgical smoke; however, the infectiousness of that viral material has not been demonstrated (7).
    2. No studies have conclusively proven viral or cancer cell transmission to OR staff during ESU procedures (8).
    3. However, in a survey of 570 surgeons who use carbon dioxide lasers in the treatment of HPV (9):
        1. 5.4% of those surgeons (31 in total) reported developing viral warts after smoke exposure, in comparison with 4.9% of patients having viral warts.

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2. 13% of those 31 (4 in total) surgeons reported nasopharyngeal warts (i.e., via inhalation of smoke from laser-treated genital wart), which was a higher rate of occurrence than the control group (0.6% occurrence).

4. Additionally, there are case reports on HPV-positive gynecologists developing tonsillar squamous cell carcinoma from occupational exposure to the virus via surgical smoke (10).

5. For reference, here are the minimum required filtration efficiencies of some commonly used devices:
    1. An N95 filtering facepiece respirator filters out 95% of particles that are greater than or equal to 0.3 µm.
    2. HEPA (high efficiency particulate air) filters must demonstrate 99.997% efficiency for removing particles that are greater than or equal to 0.3 µm.
    3. ULPA (ultra-low particulate air) filters must demonstrate 99.999% efficiency for removing particles that are greater than or equal to 0.12 µm.
        1. ECRI recommends ULPA-level efficiency filtration for smoke evacuation.
        2. Note that as SARS-CoV-2 has a reported diameter of 0.06 to 0.14 µm, even a ULPA filter may not capture all viral particles.
        3. Some manufacturers may report ULPA level efficiency for particles smaller than 0.12 µm; because individual test set-ups may vary, ECRI does not have information to confirm these claims. However, a ULPA filter must perform at least at the efficiency listed above.

References:

1. Zhu N et al. "A Novel Coronavrius from Patients with Pneumonia in China, 2019." *N Engl J Med* 2020; 382:727-733. Available: https://www.nejm.org/doi/full/10.1056/NEJMoa2001017 .
2. "Clearing the Air around Surgical Smoke: Know the Risks." ECRI, 24 Jul 2019, https://www.ecri.org/components/HDJournal/Pages/Clearing-the-Air-around-Surgical-Smoke.aspx?tab=1 .
3. "[COVID-19] Strategies to Minimize Surgical Staff Exposure to COVID-19." ECRI, 2020 May 18. Accession no. H0614. https://www.ecri.orgwww.ecri.org/Components/Alerts/Pages/TrackingUser/AlertDisplay.aspx?AId=1643205
4. ConMed Corporation - "Insufflation Recommendations." ConMed, 2020. Available: Click here . "COVID-19 Insufflation Recommendations." Conmed, 2020. Available: Click here .
5. Centers for Disease Control and Prevention, U.S. Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings [online]. 2020 Mar 19. Available: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html .
6. "Resources for Smoke & Gas Evacuation during Open, Laparoscopic, and Endoscopic Procedures." Society of American Gastrointestinal and Endoscopic Surgeons, 29 Mar 2020, https://www.sages.org/resources-smoke-gas-evacuation-during-open-laparoscopic-endoscopic-procedures/ .
7. Neumann K, Cavalar M, Rody A, et al. Is surgical plume developing during routine LEEPs contaminated with high-risk HPV? a pilot series of experiments. *Arch Gyn Obstet* 2018 Feb;297(2):421-4.
8. Lindsey C, Hutchinson M, Mellor G. The nature and hazards of diathermy plumes: a review. *AORN J* 2015 Apr;101(4):428-42.
9. Gloster HM, Roenigk RK. Risk of acquiring human papillomavirus from the plume produced by the carbon dioxide laser in the treatment of warts. *J Am Acad Dermatol* 1995 Mar;32(3):436-41.
10. Rioux M, Garland A, Webster D, et al. HPV positive tonsillar cancer in two laser surgeons: case reports. *J Otolaryngol Head Neck Surg* 2013 Nov 18;42:54.

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 May 18. ECRI researched report

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