What’s New: Clarified guidance on source control for those wearing respirators with exhalation valves or PAPR.

Background

It is important for every ministry to plan for surgical care of those with confirmed COVID-19, PUI, or others in our communities who need urgent or emergent operative or other invasive procedures in a restricted area. Work practices need to include (but not be limited to):

- preoperative screening and testing (if turnaround of results can be available prior to procedure);
- appropriate use of and inclusion of PPE prior to and during time out;
- logistics of transport of the patient to the Surgery Suite or procedure room;
- precautions during aerosol generating procedures (AGP); and
- recovery.

As the number of cases of COVID-19 continue to grow use the principles below to inform planning and preparation at the ministry – including strategies aimed at protecting personnel during aerosol generating procedures.

Planning and Preparation Guidelines for Procedures Involving COVID-19 Patients

Refer to PPE booklet guide for overall requirements for PPE for healthcare personnel caring for Persons Under Investigation (PUI) or COVID-19+ patients.

Elements of planning and provision of surgical procedures in anticipation of PUIs or those with COVID-19 need to include, but are not be limited to the following:

☐ Establish a Surgical Review Committee, composed of surgery, anesthesiology, and nursing personnel to provide defined, transparent, and responsive oversight of assessment of urgency of surgery for PUI or patient with COVID-19.
  o This committee can develop and implement a process for prompt review and oversee application of infection prevention and control work practices to assure safety of patients and personnel.
  o PPE considerations may be made during this time given the uniqueness of the procedure being undertaken.

☐ Screening of patients prior to/after admission who have been identified as needing surgical procedures, for symptoms and use of testing for SARS-CoV-2, if available in a timely manner. If not available – assume the patient is a PUI.
  o Patients should receive appropriate and timely surgical care, including operative management, based on sound surgical judgment and availability of resources.
  o Consider nonoperative management whenever it is clinically appropriate for the patient.
Avoid emergency surgical procedures at night when possible due to limited team staffing.

Aerosol generating procedures (AGPs) increase risk to the healthcare personnel but may not be avoidable. For patients who are or may be infected, AGPs should only be performed while wearing full PPE including gown, gloves and one of the following:

- A surgical N95 respirator and eye protection,
- A non-surgical N95 respirator (without an exhalation valve) and a face shield, or
- Powered air purifying respirator (PAPR), if no N95s available.

Important - use of PAPRs or Elastomeric Respirators with unfiltered exhalation valves by the Surgical Team prior to and throughout the surgical procedure:

- Elastomeric respirators, some models of PAPRs (tight fitting) and loose fitting PAPRs (involves a loose-fitting hood or helmet worn over the head) may allow unfiltered air exhaled by the wearer to escape. Therefore, these don't provide source control of the wearer's exhalation. To provide source control:
  - For elastomeric respirators or tight fitting PAPRs, wear a surgical or procedure mask over the exterior of the exhalation valve
  - For loose fitting PAPR, wear a surgical or procedure mask under the PAPR hood or helmet.
- The CDC’s National Institute of Occupational Safety & Health (NIOSH) has determined that Powered Air-Purifying Respirator (PAPR) and elastomeric respirators with unfiltered exhalation valves are not recommended for use in the Operating Room (OR) due to a lack of scientific evidence to support safe usage of this type of device, and the possible impact (contamination of wearer's exhaled, unfiltered air) onto the sterile field. AORN’s recommended practice, due to the lack of evidence, is to use a fit tested NIOSH-approved N95 respirator without an exhalation valve.
- There is recent, in-vitro evidence using air samplers and settle plates involving the impact of PAPR compared to standard surgical mask worn by volunteers in an OR on contamination of the surgical field.\(^1\) Surgical masks and the 2 PAPRs studied all drastically reduced aerosolized droplet contamination. Surgical masks reduced contamination by 98.48%, and both PAPRs reduced contamination by 100%. This is one investigation but may assist leaders in responding to instance when a member(s) of the surgical team requires use of a PAPR.
- Any member of the team providing the surgery, e.g. surgeon/perioperative nurse or technician / or anesthesia provider that cannot successfully complete a fit test or achieve a fit seal for available N95 respirator, must:
  - Leave the OR just prior to beginning the procedure, doff the PAPR, and don standard surgical attire – if the procedure does not involve an AGP.
  - If the procedure will involve an AGP – identify alternative personnel that have been successfully been fitted to a N95 to participate in the procedure.
  - Exceptions to the requirements above will need to be approved by leaders of Surgery Services, Anesthesia and Chief of Surgery or their designee. Exceptions cannot generally be granted (see note below) for the use of an elastomeric respirator with an unfiltered exhalation valve due to the inability to direct the exhaust away from the sterile field.

**NOTE:** If there is a situation where there is no option but to use an elastomeric respirator with exhalation valve by a member of the perioperative team, they are to wear a surgical mask on the outside of the elastomeric respirator over the exhalation valve. This option, as with PAPR, needs to be pre-approval by Surgery leadership team.

**Safe Use of the PAPR intraoperatively – for situation when PAPR use is approved:**

- Determine the type of PAPR that will be worn- Review how the wearer's exhalation of respiration differs by model as part of product selection.
  - For both source control and protection of the sterile field(s):
    - For loose fitting models, wear a surgical or procedure mask underneath the PAPR hood or helmet
    - For tight fitting PAPRs, wear a surgical or procedure mask over the exterior of the exhalation valve
- Direct exhaust and configure room set up – Direct blower exhaust away from the sterile field & consider repositioning of the sterile field and the location of the wearer to decrease exposure to the PAPR blower
- Protect the sterile field- Consider covering areas of the sterile field that are not in immediate use to prevent settling of any contaminants

Examples of known and possible AGPs include:

- Intubation, extubation, bag masking, bronchoscopy, insertion of chest tubes
- High frequency oscillating ventilation (HFOV), BiPap, high flow nasal cannula oxygen
- Other procedures requiring instrumentation of the upper respiratory tract or chest cavity
□ Presence and concentration of SARS-CoV-2 is highest in the upper respiratory tract followed by lower respiratory tract. Investigations, albeit limited to date, have detected highest concentration of virus in the respiratory tract. Viremia is likely short-lived and therefore logical that tissue would also have little viable virus. The studies below provide a basis for this assessment. SARS-CoV-2 has been detected in the gastrointestinal tract but the concentration is much less than in respiratory tract and the epidemiology to date continues to demonstrate most transmission between persons is from contaminated droplets.

□ Repeated testing of the first patient in the U.S. did not detect viral RNA in serum but was found in a patient in China. Viral RNA was detected in stool of the U.S. case but not in urine. Extrapulmonary detection of viral RNA does not necessarily mean that infectious virus is present, and the clinical significance of the detection of viral RNA outside the respiratory tract is unknown at this time.²

□ Posterior oropharyngeal saliva samples and serum antibody responses, dated by symptom onset and correlated with clinical findings. Salivary viral load was highest during the first week after symptom onset and subsequently declined with time.³

□ No positive results were found in blood or urine. The positive rate of sputum samples was significantly higher than that of throat swabs and nasal swabs.⁴

□ There are insufficient data to recommend for/against an open versus laparoscopy approach; however, the surgical team should choose an approach that minimizes OR time and maximizes safety for both patients and healthcare staff.⁵

Note: surgeons and perioperative care teams should monitor the peer reviewed literature for new evidence and experience with surgical care of the PUI or patient with COVID-19. The American College of Surgeons has been facilitating awareness of these and links are available from this link: https://www.facs.org/covid-19/publications

Precautions for Surgical and Other Invasive Procedures⁶

□ Transport the patient directly to the operating room or invasive procedure room.
  o During transport have the patient wear a surgical mask and continue this for post procedure transport.

□ Identify the room in which AGPs are needed
  o If no AGP is required, e.g. interventional cardiology or radiology follow routine pre-, intra- and post procedure care processes and standard precautions
    □ Standard precautions for insertion of a central line, for example include the following:
      • Maximal barrier precautions wherein a fenestrated, full body drape is placed over the patient. Ask the patient to keep their mask on during this process
      • Personnel will wear face mask and eye protection, Sterile gown & gloves

  o If an AGP is needed, e.g. tracheal intubation, use the following process for all patients:
    □ Do not alter the HVAC system's normal, positive pressure operating mode for the ORs, C section room, or invasive procedure rooms
      • Check to assure there is no equipment or furniture obstructing the return air grills in the OR or other procedure room being used.
      • Contaminated respiratory secretions containing the virus only travel for short distances of up to 6 feet, even during an AGP.

□ Place the patient in the OR or procedure room. If available, consider use of a separate OR for intubation and extubation as a process to mitigate the need for the waiting period. For example, intubate in a designated OR – transfer patient to another OR for the procedure - then return to the designated OR for extubation. The surgical team can proceed with the procedure as soon as the patient arrives in the OR identified for surgery. Air in the OR used for intubation will have been cleared by the time the patient is returned for extubation.

□ Use a transparent barrier drape or shield during intubation and extubation.
  • Many ministries have identified drapes or shields that have been approved for use by the Surgery Services and Infection Prevention and Control (IPC) leaders. Others with interest can contact System Office Director of Perioperative Care for details on available options. This engineering control needs to be reviewed and approved by Surgery Services and
IPC before their use.

- Limit number of anesthesia personnel needed to safely perform intubation, e.g., an anesthesiologist and CRNA. All anesthesia providers need to wear a N95 respirator and eye protection OR a PAPR as well as gown and gloves during intubation and extubation.

- After intubation, the surgeon and other members of the perioperative team will wait for 20 minutes before entering the OR. This wait time will clear any particles generated by the intubation.
  - NOTE: for emergent surgery or procedure, e.g. emergency C-section all members of the care team inside the OR or procedure room will wear full PPE; N95 respirator and eye protection, gown and gloves

- For procedures that require instrumentation of the upper respiratory tract or lungs or the surgical team anticipates an AGP will be needed during the invasive or surgical procedure. All personnel in the OR or procedure room are to wear full PPE as described for intubation.

- Use smoke evacuation practices to contain and evacuate all surgical smoke (plume). Surgical smoke is a dangerous byproduct or energy producing devices used in the surgical setting. Generation of surgical smoke is not considered an aerosol generating procedure and does not require an N95. In addition, it is unlikely that SARS-CoV-2 would survive in surgical smoke generated during electrocautery albeit scientific studies of this have not been published.

- After completion of the procedure, the surgeon and members of the perioperative team will leave the OR.

- The anesthesia providers will extubate and recover the patient in the OR. Wait at least 20 minutes after extubation before transporting the patient out of the OR.

- Transport the patient back to their inpatient room or, if possible, continue recovery in a private room in PACU or an airborne infection isolation room.

- Surgical instruments and other reusable devices should be decontaminated and processed using standard practices following device manufacturer instructions for use and applicable ministry policies.

- Laryngoscope handle and blade should either be single use or reprocessed using routine procedure in Sterile Processing Department (SPD).
  - Perform routine between case cleaning and disinfection – paying attention to surfaces that are touched with high frequency – especially those near the head of the patient where the AGP was performed.

**Invasive procedure:** A procedure that is performed in an aseptic surgical field and penetrates the protective surfaces of a patient’s body (e.g., subcutaneous tissue, mucous membranes, cornea). An invasive procedure may fall into one or more of the following categories:

- Requires entry into or opening of a sterile body cavity (i.e., cranium, chest, abdomen, pelvis, joint spaces)
- Involves insertion of an indwelling foreign body
- Includes excision and grafting of burns that cover more than 20 percent of total body area
- Does not begin as an open procedure but has a recognized measurable risk of requiring conversion to an open procedure

*Note:* Invasive procedures are performed in locations suitable to the technical requirements of the procedure with consideration of infection control and anesthetic risks and goals. Accepted standards of patient care are used to determine where an invasive procedure is performed. “Invasive procedure” is a broad term commonly used to describe procedures ranging from a simple injection to a major surgical procedure. For the purposes of this document, the term is limited to the above description. The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included in this definition. – SOURCE: FGI 2018 Guidelines for Design & Construction of Hospitals.
References


