



RRH Safe Tracheostomy Procedure Protocol

Indication and Multidisciplinary Decision

- Review indications for tracheostomy in the patient
- Review timing and prognosis of the patient
 - No earlier than 2 weeks from day of intubation, prefer 3 weeks
 - Patient is progressing towards improvement and is in a stable medical state and the major issue is inability to get the patient off the ventilator.
 - Patient's hemodynamic and respiratory status must be stable and/or improving for at least 48 hours. If on any blood pressure support it should be minimal and stable pressor support.
 - PEEP<12, FiO2<60%, Vent settings such that patient can be taken off the vent for 1-2 minutes at a time.
 - Any patient on ECMO should have a tracheostomy placed prior to decannulation. We can stop the ventilation completely in these patients or if there is a loss of airway it's not nearly as dangerous. Much better way to manage the patient and decrease risk of exposure to the team.
 - **Decision case-by-case basis. Individual cases/extenuating circumstances will be discussed.**
- Contraindications
 - Prior neck radiation or neck surgery, unable to palpate surface neck anatomy, unable to extend the neck
 - Uncorrected coagulopathy
 - Relative contraindication is acute multi-organ system failure.
- Consultation from palliative care team
 - No heroic measures if severe complications occur, such as tracheoinnominate fistula or intraoperative great vessel injury
- Approval from Multidisciplinary Team (At least three services agree to proceed from the list below)

- Critical Care
- Cardiothoracic surgery
- Anesthesia
- Acute Care Surgery
- Otolaryngology
- Procedure type (Percutaneous vs Open) will be the judgment of the surgeon and is consistent with what the surgeon feels the most comfortable and safe to perform.
- Code Discussion should take place prior to starting the procedure between the ICU team and the surgical team. Discussion about code status and who is running a code. Make sure code cart is available as well as **PPE for people responding**.
- Medical clearance (cardiac, renal and hepatic function, INR<1.7)
 - Ideally single-organ failure, but decision made on case-by-case basis

Timing

- Elective, during a week day
- Planned date and time when all members of the designated team are present
- Ideally the patient has 2 negative COVID-19 tests. These should be greater than or equal to 24 hours apart. If the patient remains COVID positive it is **not** a contraindication to proceeding with the tracheostomy. Even if patient tests COVID negative the procedure and protocols are followed as if they were COVID positive.

Location of Procedure

- 3 way communication system between the room, anteroom, and people outside of the room. Need effective verbal communication within the room and to the support team outside of the room.
- Bedside in the ICU with negative pressure room with antechamber is preferred over the OR, to avoid transportation and contamination of wider range of environment with COVID. There is some difference in opinion and again it should be performed where the surgeon feels it is safest for the patient and operative team to perform the procedure.
- No opening or closing the door unless absolutely necessary during the procedure
- Prior to exiting the room after procedure completion, communicate to Outside Room Runners for them to leave the antechamber while the in room surgical team enters the anteroom and takes off contaminated PPE.

Equipment Outside the Room

- Cardiac arrest cart
- Airway bougie
- Difficult airway equipment (glidescope)
- Full selection of cuffed, non-fenestrated tracheostomy tubes
 - Sizes 6-8 regular trachs

- Sizes 6-8 proximal and distal XLT trachs, surgeon will ask for sizes he/she would like in the room and opened.
- Nursing team to check availability of equipment, take note of what has been used and the need for re-stocking
- Tracheostomy tray
- Extra percutaneous tracheostomy kit or extra tracheostomy tray depending on procedure type chosen.

Equipment Inside the Room

- 3 wet towels
 - One for the mouth
 - One to cover the bronchoscope suction button
 - One for back up
- Percutaneous tracheostomy kit or open tracheostomy tray
- One selected trach size
- A selection of Manometer to measure cuff pressure in order to minimize leaks and risk of aerosolization
- Macintosh laryngoscope
- Disposable Bronchoscope
- Yankauer Suction

Designated team consists of one surgeon and one anesthesiologist in the room during the procedure, one OR nurse outside the room, and one surgeon or surgical PA/NP inside or outside the room

- Surgeon as the Airway Operator
 - Adept at percutaneous and open tracheostomy placement
 - One designated surgeon, with prepared list of replacements from different surgical subspecialties. The purpose is to avoid exposing multiple surgeons of the same specialty and potentially paralyzing one particular surgical service should infection occur
 - Consider ranking the list by age and comorbid status if skill levels are equal
- Anesthesia as the Endoscopist and Airway Assistant
 - Adept at flexible bronchoscopy, difficult airway management
 - One designated anesthesiologist, with prepared list of replacements
 - Consider ranking the list by age and comorbid status if skill levels are equal
- Nursing team as the Outside Room Runner
 - Experience in upper air way cases, endoscopy, and tracheostomy cases
 - One designated OR nurse, with prepared list of replacements
 - Staying outside the COVID room
- Physician Assistant or Nurse practitioner in the room to assist or as the Outside Room Runner (If assisting in the room a second PA or NP outside the room as a runner).
 - Experience in upper airway cases, endoscopy and tracheostomy cases

- One designated PA with prepared list of replacements

Personal Protective Equipment

- Infection Prevention Team should be present to observe for breaches of technique and minimize self contamination.
- In-Room Airway Operator and Airway Assistant: PAPR (if available), double-layer of gloves, double-layer disposable gowns, surgical mask, goggles, single-use OR hat, blue towel to cinch around the neck with securement, surgical disposable shoe covers, and surgical boot covering up to knees. If PAPR not available, preference is to delay case until a PAPR can be made available. An N-95 and face-shield could be used, if PAPR will not be available.
- Outside Room Runner Surgical PA/NP: same outfit as In-Room Personnel in case of intraoperative emergency
- Outside Room Runner OR Nurse: They are required to wear N95 mask, face shield cover, single-use OR hat, surgical gown, double-layer gloves, and shoe covers.
- Perform “buddy-check” before entering the room
- No personnel are to enter the room where an aerosol generating procedure is being performed unless they are in appropriate PPE
- Ensure anteroom is ready for doffing PPE for when procedure is complete (need trash can, hand gel, and gloves available)

Sedation Management

- Given by anesthesiologist
- Full paralysis needed throughout the procedure to reduce risk of cough
- Paralytic choice depending on supply

Surgical Pause Outside the Room Prior to Donning PPEs

- Staff present: in-room personnel, outside room runners
- Go over steps of the procedure with the opened test kit
- Go over intraoperative emergencies
 - Accidental extubation before tracheostomy tube is in place
 - Anesthesiologist to reinbuate
 - Bleeding:
 - Airway operator: leave wire and extended catheter in the distal airway, digital pressure on the bleeder
 - Airway endoscopist: re-advance ETT, flush bronchoscope port and suction out blood
 - Anesthesiologist: pre-oxygenate with 100% FiO₂, more sedation and paralytics as needed, optimize hemodynamic
 - If innominate vein/artery injury, abort procedure

- If skin or subcutaneous venous branch bleeding, second attempt after bleeding stops
- Cardiac arrest:
 - Place wet gauze over the trach incision, and wet towel in the mouth, close the ETT opening
 - C-armor sheet to cover face and neck
 - Airway operator to initiate CPR
 - Anesthesiologist to administer medications
 - Outside room runners who are already in appropriate PPEs can come into room with code cart

Completely Percutaneous Tracheostomy Insertion Using Blue Rhino Kit

- Surgical Time out/Pause – Time out to occur outside the room and the pause within the room.
 - Confirm paralysis and sedation
 - Pre-oxygenate with PEEP
 - Surgeon and anesthesiologist verbally go over the steps of the procedure
 - Confirm proper position with neck extension
- Sedation
 - Give sedation medications
- Make the skin incision
 - if bleeding occurs in skin and subcutaneous tissue, hold pressure
 - If patient reacts to the incision, additional sedation is given
- Paralysis
 - Once deep sedation is confirmed, and no surgical site bleeding, proceed with paralysis
- Bronchoscopy
 - Moistened towel or other occlusion over bronchoscopy port and within the patient's mouth to minimize aerosol generation
 - Avoid suctioning if possible
- Hold ventilation
- Keep ETT cuff inflated, pull back under bronchoscopic view
- Place finder needle below the second or third tracheal ring, aimed caudally
- Make a horizontal skin incision 2-3cm in length, Kelly clamp to bluntly dissect the soft tissue
- Replace finder needle with Introducer Needle with catheter, then followed by guidewire
- Remove catheter and leave wire in place
- Serially dilate the track
- Tracheostomy tube with inner trocar is cannulated into trachea over the extended catheter
- Bronchoscope through the tracheostomy tube to confirm placement
- Inflate trach balloon, Remove ETT, resume ventilation through trach
- secure trach to skin with sutures and tape

Open Tracheostomy Insertion Technique

- Disposable bronchoscope in room in case needed
- One moistened towel within the patient's mouth
- Adequate lighting, head light, open trach tray
- Surgeon and anesthesiologist verbally go over the steps of the procedure
- Neck extension
- Surgical exposure of trachea by surgeon
- Confirm paralysis and adequacy of pre-oxygenation
- Stop ventilation and turn off flow, allow time for passive expiration
- Clamp ETT, then advance cuff beyond planned site of the tracheal window
- Hyperinflate cuff and re-establish oxygenation with PEEP
- Pre-oxygenate again, confirm paralysis
- Stop ventilation and flow again, allow time for passive expiration
- Incise the trachea to make the tracheal window
- Deflate ETT cuff, draw back proximal to the tracheal window under direct vision
- Insert cuffed tracheostomy tube
- Inflate trach tube cuff
- Place non-fenestrated inner tube and HME
- Prompt attachment of circuit
- Confirm placement via ETCO₂ only
- Withdraw the clamped ETT
- secure trach to skin with sutures and tape

Removal of PPE

- Remove outer pair of gloves, gown, and booties in the patient room
- Use hand gel on inner gloves
- Remove second layer of booties, gloves, and gown in anteroom nearest the ICU door, upon exiting
- Perform hand hygiene, don new gloves, and remove PAPR
- Perform hand hygiene and exit anteroom still wearing surgical mask
- Outside Room Runner wearing the appropriate PPE may need to assist with PPE removal and also serve as an observer for proper PPE removal
- All disposable PPEs immediately removed and placed within a biohazard bag as quickly as possible
- Cover bronchoscopy tower with disposable plastic or drape
- In-Room Personnel full body shower, then change to new scrubs

Room Decontamination

- The ventilator and other parts of the room must be thoroughly cleaned and disinfected
- Air turnover times to allow clearance of aerosol generated COVID must be maintained
- The ICU negative pressure room will have a high level of surface contamination. Therefore, if possible the patient should be moved to a different room so the room where the procedure was performed can be terminally cleaned.
- The anteroom will also be terminally cleaned after enough time has elapsed for air turnover

Post-Tracheostomy ICU Care

- HME only
- Only use in-line closed suction circuits at all times
- Periodic check of cuff pressure with manometer
- Cuff should be inflated at all times
- Do not change trach dressing unless frank signs of infection
- Delay first tube change, clearly label with tape no trach change until COVID-19 negative
- When performing first tube change, use the same PPEs and precautions as in tracheostomy tube insertion
- When patient is placed on trach collar and the system is no longer closed the patient continues to be treated as COVID positive with caregivers wearing N-95 masks and face shields. Pt is considered as in an aerosolizing state and that protocol is followed.
- If patient is tested negative for COVID on two occasions, may consider readiness for cuffless trach and decannulation. Patient continues to be treated as COVID positive with caregivers wearing N-95 masks and face shields. Pt is considered as in an aerosolizing state and that protocol is followed.

- Tpiece



Intraoperative Complications

- Code status remains in effect for the procedure however a code discussion should take place prior to starting the procedure between the ICU team and the surgical team. Discussion about code status and who is running a code.
 - Make sure code cart is available as well as **PPE for people responding**.
 - The code captain should incorporate/consider the risk to the staff as well as the potential for recovery of the patient in determining the length of the code. At least one round should be performed. CPR is considered a high exposure procedure.
- Tracheoesophageal puncture and or posterior membranous airway injury

- Immediate consult to thoracic surgery
- Abort tracheostomy
- Endotracheal intubation from above, bronchoscopic guidance of the balloon of the ETT below the injury site
- Further management as per thoracic surgery
- Great vessel injury, e.g. innominate artery
 - Immediate consult to cardiac surgery
 - Abort tracheostomy
 - Endotracheal intubation from above, digital compression to obtain hemostasis
 - Further management as per cardiac surgery

Data Collection

- Name, date, MRN
- Indications, days since intubation, vent setting the day prior and the day after trach placement
- Prior failed extubation attempt
- Location of procedure, technique, number of team member in room
- Sedation
- Paralysis
- Complications
- Date of first trach change
- Date of completely weaned off ventilator
- Date of change to cuffless trach
- Date of decannulation
- Date of first swallow
- Date of Death

References: There are many in the literature used for this protocol and there are an ongoing changes based on evolving information and experiences obtained in caring for these patients.

Background

Upper respiratory surgery present a high likelihood of viral dispersion and aerosolization. Experience in Asia and Europe has shown that transmission of this virus is not adequately prevented by surgical masks, and not even by N-95 masks alone. At the Zhongnan Hospital of Wuhan University in Wuhan, China, the records of 138 consecutive hospitalized patients with COVID infection were reviewed. Thirty-six patients (26%) were transferred to the ICU because of ARDS, arrhythmia and shock. Seventeen patients received mechanical ventilation, four switched to ECMO. Six patients died (overall mortality 4.3%).¹ The benefit of tracheostomy is the potential to reduce duration of mechanical ventilation, wean sedation, and shorter ICU stays; however, its effect on incidence of ventilator-associated pneumonia and overall mortality are not clear.² The American Academy of Otolaryngology-Head and Neck Surgery did not identify an optimal timing for tracheostomy insertion. From the SARS epidemic experience, they noted that the mean time from onset to death was 23.7 days, and they suggest low potential benefit for tracheostomy prior to this time.² Although clinical decision should be made on an individual basis, their recommendation is tracheostomy should not take place sooner than 2-3 weeks from intubation.

The recommendation is that we should use powered air-purifying respirator; however, it is not available to healthcare providers at most institutions. The table below is a summary table from Lessons learned from the SARS Outbreak by Tay et al. This study showed that these PPE measures were effective that all members of the tracheostomy teams remained healthy after a total of 23 tracheostomies across institutions.³

Table. Case Series of Open Tracheostomies Performed During the Severe Acute Respiratory Syndrome (SARS) Outbreak

Characteristic	Case series		
	Chee et al ⁵	Tien et al ⁶	Wei et al ⁷
Institution	Tan Tock Seng Hospital, Singapore	Sunnybrook and Women's College Health Sciences Centre, Toronto, Ontario, Canada	Queen Mary Hospital, Hong Kong SAR, China
No. of tracheostomies performed	15	3	3
Barrier precautions during surgery	Standard PPE, ^a shoe covers, and powered air-purifying respirator system	Standard PPE ^a and Stryker T4 Protection System	Standard PPE, ^a shoe covers, and additional plastic face shield worn outside goggles
Setting of surgery	Negative-pressure room in ICU	Negative-pressure room in ICU	Negative-pressure room in ICU or operating room
Intraoperative steps to reduce aerosolization	Complete paralysis of the patient, mechanical ventilation stopped before tracheotomy, limited suction used during the procedure, no specific avoidance of diathermy other than during tracheotomy ^b	Complete paralysis of the patient, mechanical ventilation stopped before tracheotomy, no suction used after trachea was entered, diathermy avoided when possible	Complete paralysis of the patient, mechanical ventilation stopped before tracheotomy, no suction used throughout the procedure, diathermy avoided as much as possible
Surgical team members	Single dedicated team performing all tracheostomies: experienced surgeon, experienced anesthesiologist, 1 scrub nurse, and 1 surgical assistant ^b	Senior attending trauma surgeon and most senior surgical staff member available, attending ICU anesthetist, and no circulating nurse or scrub nurse	Single surgeon, 1 intensive care specialist, and 1 standby medical or nursing staff member

Abbreviations: ICU, intensive care unit; PPE, personal protective equipment.

^a Standard PPE consists of an N95 mask, surgical cap, goggles, surgical gown, and gloves.

^b Personal experience from Mark Li-Chung Khoo, MBBS (February 23, 2020), surgical lead for tracheostomies at Tan Tock Seng Hospital during the SARS outbreak.

Based on the consensus statement of safe airway society principles of airway management specific to the COVID-19 patients in from Australia, disposable equipments are preferred over reusable equipment, alternative is to have dedicated re-usable items for COVID patients. When assembling an airway team, they also recommend limiting the number of staff in the room, excluding staff who are vulnerable to

infection (over age of 60, immunocompromised, pregnant or serious comorbidities). The guideline also has a team composition recommendation, of airway operator, airway assistant, team leader, optional in-room runner, door runner, outside room runner.⁴

The ENT UK's Framework for open tracheostomy guideline stated that the aerosol-generating ability of a percutaneous or open tracheostomy approach is debatable. The Lessons learned from SARS Outbreak by Tay et al. argues that open tracheostomy is preferred as it does not involve serial airway dilations during tracheal entry and no repeated connection and disconnection from the ventilator circuit, compared to a percutaneous tracheostomy. However, the authors did note that the technique for percutaneous trach has improved since then, and the experience of the team can play a role.³ The ENT UK published a step-by-step flowchart for tracheostomy procedure, which will be modified and incorporated in our institutional safety protocol below.⁵

References

1. Wang D, Hu B, Hu C, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China. *JAMA* 2020; **323**(11): 1061-9.
2. Surgery AaSCotAAoO-HaN. Tracheostomy recommendations during the COVID-19 Pandemic. <https://www.entnet.org/content/tracheotomy-recommendations-during-covid-19-pandemic>.
3. Tay JK, Khoo ML-C, Loh WS. Surgical Considerations for Tracheostomy During the COVID-19 Pandemic: Lessons Learned From the Severe Acute Respiratory Syndrome Outbreak. *JAMA Otolaryngology–Head & Neck Surgery* 2020.
4. Brewster DJ, Chrimes NC, Do T, Fraser K, Groombridge C, Higgs Aea. Consensus statement: safe airway society principles of airway management and tracheal intubation specific to the COVID-19 adult patient group. *The Medical Journal of Australia* 2020.
5. UK E. Tracheostomy guidance during the COVID-19 Pandemic. 2020.