

# Penn Medicine Head and Neck Cancer Service Line COVID-19 Management Guidelines

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## Abstract

**Introduction:** The COVID-19 pandemic caused by the SARS-CoV-2 virus has altered the healthcare environment for the management of head and neck cancers. The purpose of these guidelines is to provide direction during the pandemic for rational Head and Neck Cancer management in order to achieve a medically and ethically appropriate balance of risks and benefits.

**Methods:** Creation of consensus document.

**Results:** The process yielded a consensus statement among a wide range of practitioners involved in the management of head and neck cancer patients in a multi-hospital tertiary care health system.

**Conclusions:** These guidelines support an ethical approach for the management of head and neck cancers during the COVID-19 epidemic consistent with both the local standard of care as well as the head and neck oncological literature.

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#### *Introduction*

The individual cancer service lines at the Abramson Cancer Center at Penn Medicine were delegated the responsibility of creating treatment guidelines for the entire health system during the COVID-19 pandemic. The purpose of these guidelines is to provide direction during the pandemic for rational Head and Neck Cancer management and achieve a medically and ethically appropriate balance of risks and benefits. Our goal in sharing the guidelines are three-fold. First, it may be useful to share the process of developing the guidelines and achieving consensus in a multi-hospital tertiary care system. Second, we would like to share

our fundamental principles governing the guideline development process. Lastly, the guidelines themselves may be useful for Head and Neck Oncology services at other institutions to consider as they develop their own approaches.

### *Methods*

A core committee was created by the Director of the Head and Neck Cancer Service Line (GSW) including senior leadership from the surgical, medical oncology and radiation oncology services. The first draft was created by the core committee. All physicians and critical ancillary staff were sent a copy of the first draft of the guidelines via email and asked to review the document and make changes in track changes mode. In order to ensure an orderly process, the document was initially sent “Bcc” to the group to expedite individual responses that would then be trackable and avoid the ensuing cross chatter that occurs in groups when documents such as this are sent “Cc” and individuals send their response “Reply to All”. The entire group was assured that every recommended change would be reviewed by the core committee and their changes would either be adopted and if not there would be an explanation from the Director of the Head and Neck Service Line as to why their change was not included. This process allowed for an effective, efficient and timely turnaround in the development algorithm that was inclusive to all stakeholders.

### **Fundamental Principles Governing the Development of these Recommendations**

1. Alignment to the extent possible with our established multi-disciplinary practice approaches.
2. Adhere to the standard of care, and when this is not possible given the current health crisis, then supported to the extent possible by the existing medical literature.
3. Favor modalities and approaches that minimize the number of visits to PENN Medicine, while not compromising the opportunity for cure.
4. Favor modalities that minimize immune compromise during and after treatment.
5. Compliance with the evolving Center for Medicare Services (CMS) recommendations on medical and surgical triage during the COVID-19 pandemic.<sup>1</sup>
6. Avoid surgical treatment if patient is immunocompromised unless the risk of the cancer progressing outweighs the risk posed by their immunocompromised state.<sup>2</sup>
7. COVID 19 Thyroid Cancer Guidelines as well Skin Cancer Guidelines were created by separate respective Cancer Service Line and are not included in the Head and Neck Cancer COVID 19 guidelines reported herein.
8. COVID-19 Testing Principles for Patients with Head and Neck Tumors
9. All patients should undergo standard COVID-19 history taking by team members for possible active infection or exposure and referred for testing per hospital guidelines. The COVID -9 history should be taken at the time of the initial encounter and again the day before treatment begins and on the day of treatment.
10. Depending on availability, SARS-CoV-2 testing should be done preoperatively and prior to chemotherapy or radiation. It is recommended that this testing be done within 24 hours of starting cancer treatment during the surge and apogee of the COVID-19 curve and 72 hours prior to treatment initiation later in the disease pandemic curve.
11. Patients that have tested positive for SARS-CoV-2 or are a Patient Under Investigation (PUI) should, in general, have all treatment deferred until the patient is no longer ill or contagious confirmed by two negative tests a
12. Some patients that have tested positive for SARS-CoV-2 or are a PUI may start/continue radiation treatment; this recommendation is modality specific and has been defined in the general workflow created by the Department of Radiation Oncology for patients undergoing radiation therapy during the COVID-19 pandemic.
13. For patients who are COVID-19 positive, PUI or unable to determine and present with acute emergencies in need of immediate surgical intervention (e.g., bleeding or airway emergencies), the surgical team should don appropriate Personal Protective Equipment, which in our institution is an N95 face mask, goggles, double gown and gloves or a full Powered Air-Purifying Respirator (PAPR) if for that

individual the N95 mask is ill fitting.<sup>3,4</sup>

14. For patients who are neither COVID-19 positive or PUI the surgical team should don N95 masks, face shields, surgical gowns and gloves during patient assessment and treatment.

## Results

### *Penn Medicine Head and Neck Cancer Service Line COVID-19 Guidelines*

## Primary Treatment

### Surgical Treatment

#### Principles Concerning Operating Room Availability

- If there is a temporary inability to access operating rooms due to the COVID-19 pandemic, defer surgical treatment until a point in time when the operating rooms are re-opened.
- If treatment is delayed because of operating room capacity issues due to the pandemic, perform monthly CT or MRI scans to monitor growth of the tumor and consider primary radiation or chemoradiation for tumors with continued growth.

#### Masses and Lesions of Uncertain Behavior

- Needle biopsy for masses or biopsy of mucosal or skin lesions to rule out cancer can be done in the outpatient setting.
- If excision is thought to be the best way to determine the nature of the lesion, then perform incisional or excisional biopsy. We suggest the biopsy be done in the operating room with a justification of “rule out cancer”.

#### Definitively Benign Tumors and Masses Based on Biopsy Results.

Defer treatment until after the COVID-19 pandemic.

#### Salivary Malignancy

- Resect all high and intermediate grade cancers.<sup>5</sup>
- Defer treatment of low-grade carcinomas (e.g., low grade mucoepidermoid carcinoma, acinic cell carcinoma or polymorphous low-grade adenocarcinoma) until after the COVID-19 pandemic, per clinical judgement of the surgeon. In the interim, perform serial MRI or CT scans with contrast every two months to monitor growth of the tumor.

#### Asymptomatic Leukoplakia

- If this is the first patient visit for leukoplakia with no history of prior biopsy and no histologic diagnosis, we recommend the patient send pictures of the suspicious area(s) via our secure patient portal followed by a telehealth video visit<sup>6</sup> To avoid missing cancer, perform either incisional or excisional biopsy within 1 -6 weeks depending on the surgeon’s index of suspicion based on the pictures. The biopsy can be done in the outpatient setting or in the operating room depending on the preference of the clinician.
- If this is a long-standing patient with history of leukoplakia or a recent biopsy that shows premalignancy then have the patient submit a photo to your team and perform a telehealth video visit. If the lesion on the photo does not have high-risk features, then defer treatment until after the COVID-19 pandemic. If the lesion has high-risk features in the photo, then to avoid missing a cancer perform either incisional or excisional biopsy within 1 - 6 weeks depending on the surgeon’s index of suspicion based on the picture. The biopsy can be done in the outpatient setting or in the operating room depending on the preference of the clinician.

#### Mucosal Squamous Cell Carcinoma: p16 + and p16 -

- Perform surgery on all surgically resectable squamous cell carcinomas as soon as possible.
- The rationale is based on the following:

- Studies from Italy indicate delays in care may lead to increased cost of care and loss of life during the pandemic.<sup>7</sup>
  - The literature indicates that treatment delays in the 19-46 day range increase the risk of mortality.<sup>8,9</sup>
  - Treatment delays can result in upstaging of cancers.<sup>10</sup>
1. Choice of reconstructive approach should be based upon the defect as well as the preference of the reconstructive surgeon. We recommend the surgeon factor in time in the operating room and minimization of complications.<sup>11</sup>
  2. Prior to all transoral approaches, it is recommended that the nose and pharynx be irrigated with 1:4 solution of povidone iodine which has been shown to be virucidal for coronaviruses.<sup>12</sup>

#### Skull Base Malignancy

- Due to the potentially high COVID-19 viral load in the nasal mucosa, we suggest the guidelines in the section below for Office Procedures “Fiberoptic Laryngoscopy, Nasal Endoscopy, Transoral and Transnasal biopsies.”
- Unlike mucosal squamous cell carcinoma in which the recommendation is to perform surgery in all resectable cases as soon as possible, given the diverse biology of skull base tumors we recommend following the ICAR-Skull Base Tumors guideline to determine therapy after definitive biopsy is performed.<sup>13</sup>
- If a transnasal endoscopic surgery is needed, it is highly recommended that high speed drills be avoided and that the entire surgical, perioperative and anesthesia teams wear N95 masks, goggles and face shields for these cases for the duration of the COVID-19 pandemic.<sup>14,15</sup>

#### Adjuvant Radiation and Chemoradiation

1. All patients for which there are standard indications for postoperative radiation alone should proceed with treatment as per normal, without intentional delay.
2. Guidance for the use of Chemoradiation
  - Tier 1 – Patients over 70 years of age were underrepresented in the trials supporting the use of chemoradiotherapy. There is some evidence from meta-analyses that the addition of chemotherapy to radiation for patients over the age of 70 may confer minimal benefit or may even be detrimental.<sup>16</sup> Therefore, it is strongly encouraged that during the COVID19 pandemic, medical oncologists consider the omission of chemotherapy from the adjuvant treatment regimens for patients over 70.
  - Tier 2 – For pathological findings of microscopic extranodal extension (ENE) (< 1mm ENE) in patients with p16 + cancer there is retrospective evidence to support omitting chemotherapy without compromising oncologic outcomes. It is therefore reasonable to consider omitting chemotherapy with radiation during the COVID 19 pandemic.<sup>17,18</sup>
  - Tier 3 – In the following cases the recommendation is to proceed with chemoradiation with the caveat that there should be shared informed decision making between the clinician and the patient of the risks versus the benefits of adding cytotoxic chemotherapy to the treatment regimen during the COVID19 pandemic.
    - All p16- cancers with positive margins or any amount of ENE.
    - All p16 + cancers with positive margins or macroscopic (>1mm) ENE.

#### Primary Chemoradiation

1. Fundamental Principle is that all patients who are surgical candidates should undergo primary surgical resection as outlined above.
2. p16 Positive Squamous Cell Carcinoma of the Oropharynx

The recommendation is to proceed with standard cisplatin-based chemoradiation with the caveat that there should be shared informed decision-making between the clinician and the patient of the risks versus the benefits of adding cytotoxic chemotherapy to the treatment regimen during the COVID-19 pandemic.

p16 Negative Squamous Cell Carcinoma

The recommendation is to consider systemic-therapy sensitized radiation. Registry data indicate that cetuximab is inferior to cisplatin regardless of primary site, but this needs to be weighed against the desire to minimize the immunosuppression associated with cytotoxic chemotherapy.<sup>19</sup> There should thus be shared informed decision-making between the clinician and the patient of the risks versus the benefits of substituting cetuximab for cisplatin in the treatment regimen during the COVID-19 pandemic.

1. When Possible Avoid : TPF (docetaxel, cisplatin, and 5-fluorouracil) regimens for induction therapy, as they are associated with high rates of neutropenic fever and subsequent hospitalization.
2. When Possible Avoid : For chemoradiation patients, try to avoid high-dose cisplatin, which can result in higher rates of hospitalization and renal dysfunction. Instead, substitute weekly cisplatin at 40 mg/m<sup>2</sup>.<sup>20</sup>

## Outpatient Care

### General Principles

1. All patients will be advised prior to their visits that they must wear a mask at all times while in a Penn Medicine facility and if they do not have a mask one will be provided.
2. Patients will complete a COVID-19 questionnaire and undergo have their temperature and oximetry documented in the electronic medical record. All patients who qualify by Penn Medicine criteria will be instructed to go for immediate testing. Patients that have a minimum of one positive response on the questionnaire or an elevated temperature or decreased oxygenation will be escorted to a designated COVID 19 clinic room and be evaluated by a physician in consultation with infection control. This minimizes risk of exposure and maximizes safety for both patients and staff.
3. Known COVID-19 positive patients or PUI who are asymptomatic from the perspective of their Head and Neck Cancer should have follow-up visits delayed until they test negative for Sars-CoV-2.
4. During the surge leading up to and at the apogee of the COVID-19 incidence curve it is strongly encouraged that routine follow-up visits or visits for treatment-related symptoms be done via telehealth video visits whenever possible.
5. During the surge leading up to and at the apogee of the COVID-19 disease curve suspicious symptoms or radiologic evidence of mucosal disease should be assessed in the operating room under general anesthesia in order to optimize control of potentially infectious aerosolized secretions.
6. Known COVID-19 positive patients, or PUI with new head and neck symptoms that are potentially life threatening (e.g., bleeding, shortness of breath) should be seen in the emergency room by staff donning full protection, including PAPR.<sup>3</sup>
7. Later in the COVID-19 disease curve when routine office visits have resumed it is suggested that physicians wear N95 masks, goggles and gloves routinely given their proximity to patients and the potential exposure risks of aerosolizing procedures (e.g., fiberoptic laryngoscopy, nasal endoscopy, tracheostomy change). Support staff should not be in the patient examining room during aerosolizing procedures and therefore should only require and wear standard masks, goggles and gloves.<sup>21</sup>
8. Anesthetizing the nasal cavity with spray systems prior to scoping should be avoided until the COVID-19 pandemic is over.
9. It is recommended that throughout the COVID-19 pandemic that all outpatients have their temperature taken and have a COVID-19 history taken before they are seen and that all patients with either elevated temperatures or affirmative responses to the COVID-19 history be escorted to designated COVID-19 clinic rooms for further evaluation by providers and consultation with infection control for next steps.
10. Each department will create a phased plan to incrementally increase clinic volumes during this period with the goal of both avoiding exposure of staff, physicians and other patients to COVID-19 positive patients and creating a waiting room environment conducive with Social Distancing.

### Cancer Follow-up

1. During the surge leading up to and at the apogee of the COVID-19 incidence curve:

2. Routine follow-ups in asymptomatic patients should be delayed, including routine follow-up imaging.
3. Radiologic surveillance for patients who are cancer-free but are at risk for developing a cancer in the future should be delayed unless symptoms or signs are concerning.
4. Follow-up later in the COVID-19 pandemic when routine office visits have resumed:
5. Resume routine follow-ups in asymptomatic patients, including routine follow-up imaging
6. Since a third of asymptomatic COVID-19 patients have characteristic chest CT findings, all patients that undergo CT of the chest or total body PET/CT as part of their routine follow-imaging for their cancer and who have radiographic evidence suggesting viral infection should undergo SAR-CoV-2 testing.<sup>22</sup>

### **Postoperative Visits during the surge leading up to and at the apogee of COVID 19 disease incidence curve:**

When clinically appropriate it is recommended that all drains, tracheostomies and nasogastric tubes be removed during the hospital stay to allow for the maximum amount of postoperative care to be done via telehealth video visits. Visiting nurses in our community have also agreed to remove nasogastric tubes and drains to minimize visits to the medical center for removal.

### **Postoperative Visits later in the COVID 19 disease incidence curve when routine office visits have resumed**

1. Examine practices that were implemented during the COVID19 surge regarding hospital-based drain, tracheostomy and nasogastric tube removal and retain practices found to be safe and effective.
2. When removing nasogastric and tracheostomy tubes in the inpatient or outpatient setting it is recommended that N95 mask, goggles, gown and gloves be worn.

### **Office Procedures**

1. Fiberoptic Laryngoscopy, Nasal Endoscopy, Transoral and Transnasal biopsies.
2. During the surge leading up to and the apogee of the COVID-19 Disease Incidence Curve
3. If a staging laryngoscopy under anesthesia is planned and there is a question about the safety of standard intubation, it is suggested that the Fiberoptic Laryngoscopy be deferred and be done with the patient in the operating room just prior to anesthesia so that the surgical and anesthesia team can formulate an appropriate plan concerning safe intubation. For the duration of the COVID-19 pandemic we do not recommend screening bronchoscopy be performed at the time of staging endoscopy.
4. Later in the COVID-19 Disease Incidence Curve when Routine Office Visits have Resumed
5. Fiberoptic laryngoscopy and nasal endoscopy can be done at the discretion of the attending physician.
6. No anesthetizing the nasal or oral cavity with sprays.
7. Topical application of pledgets impregnated with Afrin and lidocaine may be used, instead.
8. Local anesthetic injection may be performed for transoral or transnasal biopsies.
9. The use of N95 mask, goggles, gloves and gown is required for all patients.
10. When testing is available, it is recommended that all patients undergoing potentially aerosol generating procedures (e.g. Fiberoptic laryngoscopy and Nasal Endoscopy) undergo COVID-19 testing within 72 hours of the procedure.
  1. Fine Needle Aspiration
  2. Standard garb including mask, goggles and gloves is suggested.

### **Palliative and End of Life Care**

- Patients with incurable disease undergoing palliative treatment such as chemotherapy or immunotherapy should be treated when significant extension of life (>6 months) and reduction of symptoms are reasonable expectations. Consideration should be given to alterations in treatment plans to reduce number and frequency of visits, including reduced frequency of imaging to re-assess disease if the state of disease can be assessed by other means.

- Consider a 4-6-week schedule for pembrolizumab for those patients who are clinically and radiographically stable or responding after 3-6 months of immunotherapy
- Consider discontinuation of immunotherapy for patients that are well into a complete response beyond one year.
- End of life patients should receive necessary care, much or all of which can be delivered at home via telehealth visits. Palliative care consultations at Penn Medicine are now being done entirely via telehealth visits. Goals of care (serious illness) conversations should occur early on to facilitate this approach.<sup>23</sup>

## Management of Complications

Patients with complications of care such as surgical site complications, neutropenic fever, etc., should be managed so as not to put the patient at increased risk for further complications or mortality, taking into consideration risk of COVID-19 infection with hospital visits. Low risk fever and neutropenia, for example, might be managed as an outpatient at home, for example, with appropriate monitoring by telehealth visits.

### *Discussion*

Our goal was to create effective and ethical cancer guidelines in an expeditious fashion to allow quick deployment during the COVID-19 epidemic. While a group consensus was both desired and required, time to completion was an important consideration which obligated the leadership to seek consensus individually rather than in a virtual group session. The result was a document agreed to by all which was completed within two weeks.

Our entire team agreed, that the primary treatment of choice during the COVID-19 epidemic was surgery in all surgically and medically resectable cases. Non-surgical options do exist utilizing radiation alone or chemoradiation. However, these options are fraught with increasing risks during this pandemic. In some cases, surgery results in a single day treatment that allows the patient with or without hospitalization to return home and avoid returning to the hospital. Radiation requires daily trips to the hospital for several weeks which puts both the patient and the radiation teams at risk of spread of SARS-CoV-2. Chemotherapy, when required, further immunocompromises the patient which makes them more susceptible to SARS-CoV-2 infection. Adjuvant radiation and chemotherapy can be done several weeks after surgery, safely and according to standard of care, and for many this will be after the peak of the virus spread in our community and when testing may be more readily available for screening patients.

A primary surgical approach for resectable cancers was seen as the safest pathway in cases where the pathology indicated that surgery was a standard of care option for a given anatomic site in the head and neck. For squamous cell carcinoma we made a distinction between P16+ and P16- cancers given how common oropharyngeal cancer is in our setting. Oropharyngeal cancers, in particular those which are P16+ and Human Papilloma Virus (HPV) associated, accounts for a significant percentage of the patients presenting to Head and Neck Surgeons in 2020. It has been estimated that by 2030 half of all head and neck cancers will be HPV related.<sup>24</sup> The Center for Disease Control (CDC) website notes that 70% of all oropharyngeal cancers are caused by HPV and account for 13,500 cases annually, making this the most common HPV related cancer in the United States, exceeding cervical cancer by almost 3000 cases.<sup>25</sup> Transoral Robotic Surgery (TORS) which was invented in 2005 and FDA cleared in 2009 has emerged as the most common surgical treatment of HPV related oropharyngeal cancer.<sup>26,27</sup> The most frequent alternative non-surgical treatment for the management of HPV related oropharyngeal cancer is cisplatin-based chemoradiation which is associated with significant acute and chronic toxicity, including acute compromise of the immune system and significant acute and late risk of treatment related death and gastrostomy tube dependence.<sup>28</sup> The standard of care for the treatment of oral cavity cancer worldwide is primary surgery with or without adjuvant radiation or chemoradiation.<sup>29</sup> The standard of care requires that many laryngeal cancers be offered the option of surgery as the primary modality for organ preservation.<sup>30</sup>

The major concerns for Head and Neck Surgeons for the safety of all members of the surgical, perioperative and anesthesia teams are related to numerous factors. It is well established that large viral load of SARS-

CoV-2 reside in nasal cavity and all levels of the mucosa between the nasopharynx and trachea. In addition, histological evaluation, in the primate model, of the SARS-CoV-1, a similar corona virus, indicates large viral load with the cells of the head and neck mucosa.<sup>31,32</sup> Experimental evidence from the University of Pennsylvania indicates that appropriate surgical masks, even when virus is present in the electrocautery plume, do prevent passage of viral particles in electrocautery plume to the wearer.<sup>33</sup> The aerosolized virus particles from SARS-CoV-2 remain viable for at least 3 hours.<sup>34</sup> An article in Science estimates that 86% of SARS-CoV-2 infections in China were undocumented prior to the January 23, 2020 travel ban and that undocumented infections were likely responsible for spreading the disease to 79% of documented cases.<sup>35</sup> Initially in the COVID-19 pandemic Personal Protective Equipment (PPE) and patient testing were in short supply or unavailable. Early on in the pandemic our team successfully negotiated with our hospital executives to ensure that for all head and neck cancer cases involving transection of mucosa the entire staff in the operating room would be issued N95 masks and all patients would undergo SARS-CoV-2 testing within 24 hours of the procedure. The fundamental premise of our negotiations were based on the idea that “the goal is to flatten the disease curve, not the personnel curve.”<sup>36</sup>

Preoperative testing of patients for SARS-CoV-2 may be critical for patient and staff safety. Xia et al. published a paper in which asymptomatic patients underwent a variety of surgical procedures throughout the body, including one laryngeal surgery. Thirty-four patients developed COVID-19 during the postoperative period and the mortality rate for this group was 20.5%. We recommend based on this study that asymptomatic patients who test SARS-CoV-2 positive prior to any treatment delay such treatment until they have had two negative tests within 24 hours.<sup>37</sup>

Our guidelines include a discussion of the management of routine cancer follow-up during the apogee of the COVID-19 disease incidence curve as well as during the reopening process of face-to face visits in the outpatient clinics. The pillars upon which our plan is built are: (1) multilevel triage approach to minimize the risk of COVID-19 PUI or positive patients encountering multiple personnel, (2) special precautions when performing potentially aerosolizing procedures (e.g., fiberoptic laryngoscopy and nasal endoscopy) in clinic, (3) appropriate workflow and PPE use by staff, physicians and patients so that if an unexpected exposure to COVID-19 does occur the need for quarantine of staff or physicians is either minimized or non-existent, (4) added cleaning measures to sanitize patient exam and treatment rooms and (5) plan for clinic re-opening that ensures appropriate social distancing in the waiting room.<sup>38</sup>

### Conclusions

The COVID-19 pandemic has created significant constraints within the healthcare environment and it is important that each cancer management team work together to create efficient and ethical care guidelines to which all team members agree. It is important to consider the concerns of all subspecialties involved in patient care while also moving forward with publishing guidelines in a timely fashion. Given the rapid changes in our knowledge about this novel corona virus it is understood by all involved that these guidelines are in a state of constant revision to allow for adaptability in a quickly changing environment. Our goal was to share process, fundamental principles and our internal guidelines with the intent of information sharing for other institutions that are in the process of creating their own management algorithms during this pandemic.

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