

An Ethical Framework for Head and Neck Cancer Care Impacted by COVID-19

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Abstract

The COVID-19 pandemic has upended head and neck cancer care delivery in ways unforeseen and unprecedented. The impact of these changes parallels other fields in oncology, but is disproportionate due to protective measures and limitations on potentially aerosolizing procedures and related interventions specific to the upper aerodigestive tract. The moral and professional dimensions of providing ethically appropriate and consistent care for our patients in the COVID-19 crisis are considered herein for head and neck oncology providers.

Introduction

The COVID-19 pandemic continues to evolve and commandeer all aspects of clinical management.¹¹Parodi SM, Liu VX. From Containment to Mitigation of COVID-19 in the US. *JAMA* 2020. The impact upon head and neck oncologic care might lead to delayed diagnoses, treatment, and surveillance in a manner that threatens optimal outcomes and survival for untold patients.²²Werner MT, Carey RM, Albergotti WG, Lukens JN, Brody RM. Impact of the COVID-19 Pandemic on the Management of Head and Neck Malignancies. *Otolaryngol Head Neck Surg* 2020 (Epub). How this will directly influence multidisciplinary care in widely divergent settings remains unknown and uncharted.³³De Felice F, Polimeni A, Valentini V. The impact of Coronavirus (COVID-19) on head and neck cancer patients' care. *Radiother Oncol.* 2020;147:84-85. Head and neck cancer providers will be constrained in their ability to provide vulnerable patients with the attention and care they require, and will likely experience moral distress when routine management is all but impossible. These feelings may be amplified by conflict between a duty to care for patients and a duty to protect others by avoiding high risk exposures. This article is designed to provide a guide to the ethical issues inherent to care delivery in the current COVID-19 era.

Conflicting Duties

One of the major challenges specific to head and neck cancer during this pandemic involves the significant risk associated with examination, biopsy and treatment of pathology arising in the upper aerodigestive tract. Health care workers constituted a large percentage of the first cohort of infected patients. Potential aerosolization of SARS-CoA-2 virions hinders our ability to conduct routine management and requires extra resources and time to perform what before were routine examinations, endoscopy, biopsy, and surgery. Recent publications echo and reinforce the related dimensions of infection control, safety, and resource stewardship.¹¹Givi B, Schiff BA, Chinn SB et al. Safety recommendations for evaluation and surgery of the head and neck during the COVID19 pandemic. *JAMA Otolaryngol Head Neck Surg* 2020 (In press). Airway management represents a discrete consideration in routine, urgent, and emergent settings, and newly published guides are also instructive.²²Balakrishnan K, Schechtman S, Hogikyan ND, Teoh AYB, McGrath B, Brenner MJ. COVID-19 Pandemic: What every Otolaryngologist – Head & Neck Surgeon Needs to Know for Safe Airway Management. *Otolaryngol Head Neck Surg* 2020 (Epub). All of these reaffirm the

importance of protecting patients as well as clinical staff from unnecessary exposure. Indeed, protection of the clinical workforce and public are fundamental ethical and professional responsibilities. However, the balance between our duty to care for patients with our duty to protect ourselves and our colleagues is not clear cut.

The American Head & Neck Society has a dynamic online resource for head and neck oncology providers.³³American Head & Neck Society COVID-19 Bulletin Board. <https://www.ahns.info/wp-content/uploads/2020/03/synthesized-physician-doc.pdf> (Accessed 6 April 2020). The American Academy of Otolaryngology – Head & Neck Surgery Foundation’s related position statement affirms the need to avoid all clinical interactions which are not urgent/emergent, but “recognizes that ‘time sensitivity’ and ‘urgency’ are determined by individual physician judgment and must always take into account each individual patient’s medical condition, social circumstances, and needs.”⁴⁴American Academy of Otolaryngology–Head and Neck Surgery. New Recommendations Regarding Urgent and Nonurgent Patient Care. <https://www.entnet.org/content/new-recommendations-regarding-urgent-and-nonurgent-patient-care> (Accessed 6 April 2020). Other societies have produced COVID-19 related resources and guidance that are also informative. The American College of Surgeons’ dedicated website clarifies the importance of delaying/deferring non-essential operations, and offers comprehensive support, including patient-facing messages which may be valuable to head and neck surgical oncology practices.⁵⁵American College of Surgeons COVID-19 and Surgery. <https://www.facs.org/covid-19> Accessed 6 April 2020. The Society for Surgical Oncology recommends that “urgent procedures... should be carefully considered for delay on a case-by case basis... and diagnoses which have equivalent results with radiation therapy and surgery should be considered for radiation therapy.”⁶⁶Society for Surgical Oncology Resource for Management Options of Endocrine/Head and Neck Cancer During COVID-19. <https://www.surgonc.org/wp-content/uploads/2020/03/Endocrine-Head-and-Neck-Resource-during-COVID-19-3.30.20.pdf> Accessed 6 April 2020. The American Society of Clinical Oncology has general guidance for cancer providers and patients to avoid in-person encounters whenever possible, but the organization does not offer guidance specific to management of specific cancers.⁷⁷American Society of Clinical Oncology COVID-19 Provider & Practice Information. <https://www.asco.org/asco-coronavirus-information/provider-practice-preparedness-covid-19> Accessed 6 April 2020.

Although the duty to the patient is a cornerstone of the medical profession, it should not trump our duty to care for ourselves and those around us. Head and neck cancer practitioners should recognize the stress of the current situation on themselves, practice diligent self-care, and liberally seek counsel among colleagues, loved ones, and professionals.

Individual vs. Population Interests

It is clear that we need to collectively limit face-to-face encounters, and do our part to flatten the epidemiological curve to protect our collective patient populations, providers and society at-large. Demonstrably worsened clinical outcomes among patients with cancer who contract COVID-19 underscore this risk.¹¹Liang W, Guan W, Chen R, et al. Cancer patients in SARS-CoV-2 infection: a 133 nationwide analysis in China. *Lancet Oncol.* 2020;21(3):335-337. We also know that delaying head and neck cancer evaluation and management will undoubtedly impact oncologic and functional outcomes, and patients and providers alike will bristle when facing such postponements.

The principles of medical ethics, broadly speaking, require us to consider patient preference, maximizing benefit, minimizing harm, and being deliberative and fair.²²Beauchamp and Childress, *Principles of Biomedical Ethics*, Fourth Edition. Oxford. 1994. The challenge of the current COVID-19 pandemic is that honoring these principles as resources become scarce or non-existent will lead to intrinsic conflict. There will be instances when we cannot grant specific individual requests or focus on a specific patient’s needs in a manner that supersedes the obligation to protect populations and to conserve resources necessary for others. This highlights the tension between “clinical ethics” and “public health ethics.”³³Kass NE. An ethics framework for public health. *Am J Public Health.* 2001; 91(11): 1776–1782. The former, which is familiar to most clinicians, focuses on the primacy of the doctor-patient relationship in formulating evidence-based and individualized treatment paradigms designed to maximize the best outcome for a specific patient. In contrast,

public health ethics concentrates on the needs and interests of populations, even if that might negatively impact specific individuals.

Such a paradigm shift might be difficult for individual head and neck cancer providers to accept, and explains the intense challenges facing us all. When we shift from a clinical ethics framework to a public health framework, it is important that we do not force individual clinicians to ration at the bedside, but rather, institutions that are charged with caring for communities must take the lead. Our oncology community will need to discern when the needs of populations outweigh the needs of individuals, potentially leading to treatment delays or non-standard treatment paradigms.

Since surgical manipulation of the upper aerodigestive tract now poses new risks and requires additional resources, the weighting of treatment choices will change. Specifically, when non-surgical modalities are superior to surgery, the choice is easy. In cases in which these choices are either neutral or preference-sensitive, non-surgical approaches should be recommended. However, for conditions in which surgery is clearly preferred or is the sole option, proceeding with an operation might carry considerably more risks and tradeoffs than in the pre-COVID-19 era. Relative urgency related to estimated tumor progression and risk of delay is another metric for triage. This is not to state that such tradeoffs cannot be justified, but rather than clinicians will need to recognize that choices for individual patients will be made based upon the needs of others in ways we do not normally consider. Complicating the situation, we will also need to factor in the finite availability of non-surgical resources and the limited number of skilled personnel necessary to deliver the selected care safely and appropriately. Non-surgical modalities also require repeated and uninterrupted visits over extended periods of time that serve as a potential vector to other populations of clinical staff and oncology patients seeking similar non-surgical therapies.

This does not obviate our ethical responsibility to our patients, though. Even though we might not be able to provide the same level of care or be able to see patients face-to-face, this does not prevent us from maintaining productive doctor-patient relationships. Patients and survivors are often intensely vulnerable and they deserve support, counseling and reassurance for cancer control and symptom management as much as ever. Utilization of virtual care can be invaluable to counsel our patients and ensure they do not feel abandoned.⁴⁴Shuman AG. Navigating the ethics of COVID-19 in otolaryngology. *Otolaryngol Head Neck Surg* 2020 (Epub).

Consistency as an Ethical Tenet

The multidisciplinary nature of head and neck cancer care is both an advantage and vulnerability in the COVID-19 era. Multiple treatment paradigms and the networks of clinicians create systemic redundancy and options, all of which are welcome. However, this also can create conflicting, disparate perspectives and approaches, both at societal/national levels and for individual care teams.

Major ethical concerns arise when dissimilar treatment approaches are offered to similar groups in different locations. Even if a provider or group is consistent in their practice and treatment algorithms for a specific, discrete population of patients, other providers might employ consistent but fundamentally different approaches, thus creating different care approaches that are inconsistent with ethical principles of justice and fairness.

The solution to this dilemma is to ensure consistent evidence-based approaches as best as possible, considering the systematic issues. Within our sphere of influence, it is essential that we form consensus approaches to head and neck cancer management. Also, given that resource allocation and safety will impact care decisions, these best consensus approaches may require revision. At the institutional level, this requires providers to collaborate and consider how best to maintain care paradigms. For example, it would be inappropriate for individual surgeons to decide to operate on all oropharyngeal cancers without proactively unifying the broad approach with radiation and medical oncology colleagues, whether they are part of the same institution or part of a broader referral network. Individual patients can and should still be discussed in multidisciplinary tumor boards, but this does not replace a more cogent and cohesive approach to disease management.

Limited capacity for treatment (regardless of modality) will also impact decisions. Scarce resource allocation with regard to ventilators and ICU beds for patients with COVID-19 is in the spotlight, but the principles similarly apply to cancer care resources if and when they are also insufficient.¹¹Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, Zhang C, Boyle C, Smith M, Phillips JP. Fair Allocation of Scarce Medical Resources in the Time of Covid-19. *N Engl J Med.* 2020 (Epub). The selection of ablative and reconstructive procedures that avoid the use of ICU beds is an example. In short, this requires explicit, consistent, evidence-based and objective standards, transparency, and involvement of all necessary stakeholders. Such protocols must responsibly utilize and preserve vital resources, and frame treatment that aligns as much as possible with current best practice.

Some populations have been victims of cultural, racial, geographic and economic discrimination for generations and societal stress points such as pandemics can worsen both explicit and implicit biases.²²Spector-Bagdady K, Lombardo PA. U.S. Public Health Service STD Experiments in Guatemala (1946-1948) and Their Aftermath. *Ethics Hum Res.* 2019; 41(2):29-34. Health care providers must deliberately partner with underrepresented groups to assure that the risks of care disparities are minimized in the face of crisis.

Clinical Research

Clinical oncology research trials in the era of COVID-19 can continue in some instances and ethical guidance is available.¹¹Shuman AG, Pentz RD. Cancer Research Ethics and COVID-19. *Oncologist.* 2020 (Epub). Trials can be stratified by trial phase, disease site/stage/histology, and treatment intent as well as how these options would compare with clinical care off-trial. Trials with a high likelihood of benefit should proceed although they may need modification after consideration of the added burdens, risks, and trial-specific testing and face-to-face interactions. For trials without clear benefits to the participant, continued enrollment into the trial is viewed in the context of the potential for generalizable knowledge afforded by the data generated. For head & neck cancer specifically – in everything from investigator-initiated to cooperative trials – risks, benefits and tradeoffs should be assessed, knowing that every intervention and instrumentation of the upper aerodigestive tract poses a risk to patients, subjects, and providers alike.

Regulatory and funding agencies have provided resources to assist. The NCI has issued specific guidance for federally funded cancer trials,²²NCI CIRB information about COVID-19. <https://www.ncicirb.org/content/nci-cirb-information-about-covid-19> Accessed 6 April 2020. and the NIH has broader resources available for clinical researchers.³³Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19. 2020. Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>. Accessed March 17, 2020. In addition, specific FDA guidance will be of value for those trials involving their regulatory oversight.⁴⁴FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. 2020. Available at https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/fda-guidance-conduct-clinical-trialsmedical-products-during-covid-19-pandemic?utm_source=&utm_medium=&utm_campaign=. Accessed March 17, 2020.

Conclusion

In summary, COVID-19 threatens the very essence of head and neck cancer care delivery and puts both patients and providers at significant risk for additional foreseen and unforeseen morbidities and mortality. This creates a significant and previously unknown barrier to care that must be acknowledged and addressed as an ethical challenge, both as we care for individuals and fulfill our responsibilities to society. The importance of open and honest communication, consistent multidisciplinary planning and messaging, and adoption of novel treatment approaches will be essential.

The practice of head and neck oncology has always been shaped by disease factors and the complex context in which our patients require care. Collectively, our diverse community can and will meet these new travails with the alacrity, creativity and commitment for which we pride ourselves.

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