

Improving the Quality of Head and Neck Cancer Care

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The 2001 report by the Institute of Medicine (IOM) titled *Crossing the Quality Chasm: A New Health System for the 21st Century* highlighted the gap that exists between what we know to be effective, beneficial care and the care that is often delivered to an individual patient.¹ In the report, the IOM stated, “Between the health care we have and the care we could have lies not just a gap, but a chasm.”^{1(p1)} The report, signifying a national initiative to improve the quality of care in the United States, articulated the following 6 aims for a new health care system: (1) to increase the safety of health care by avoiding injuries to patients through care intended to help them; (2) to provide effective services based on scientific knowledge and to avoid services of no proven benefit; (3) to deliver individualized treatment respectful of and responsive to the patient’s preferences, needs, and values; (4) to deliver timely care by reducing wait times and harmful delays; (5) to increase efficiency by not wasting equipment, supplies, ideas, and energy; and (6) to deliver care that is equitable and does not vary by personal characteristics, patient sex, ethnicity, geography, and social economic status. The IOM also recognized a need to optimize quality cancer care in the United States.

Two cases bring to view this national initiative’s pertinence to cancer care and, specifically, to head and neck cancer care. In these 2 cases, the patients’ subsequent treatment was complicated by an initial error in diagnosis (patient 1) and deviation from accepted treatment guidelines (patient 2). Patient 1 was an adolescent who presented with a nodule in the parotid gland. The initial diagnosis was a cyst or a lymph node. An excision was performed and the pathologic diagnosis was benign salivary gland tissue. Over the ensuing 4 months, the mass returned and progressively enlarged; the patient underwent a parotidectomy, with a new pathologic diagnosis of acinic cell carcinoma. The patient then underwent definitive treatment of a parotidectomy with selective neck dissection and sparing of the facial nerve. Pathologic analysis revealed an acinic cell carcinoma, with 38 nodes nega-

tive for tumor. Because of the prior incomplete surgery and the recurrent nature of the tumor, postoperative radiotherapy was recommended. This case highlights the effect of the initial error in the pathologic diagnosis and surgery that failed to remove the tumor, requiring 2 additional anesthetics (with associated costs) and postoperative radiotherapy.

Patient 2 presented with a T2N2c squamous cell carcinoma of the supraglottic larynx and was treated with 6 cycles of weekly carboplatin and docetaxel. The patient had a complete response to induction chemotherapy but no radiotherapy was administered. Seven months later, the patient presented with a large supraglottic recurrence and adenopathy in the upper neck. Concurrent chemotherapy and radiotherapy were administered and, 2 years after treatment, the patient remains free of disease.

The first case illustrates the difficulties with the correct interpretation of salivary gland carcinoma, a group of rare neoplasms that can pose diagnostic chal-

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lenges for a pathologist who lacks experience with these tumors. The second case highlights the failure to follow evidenced-based guidelines. The National Comprehensive Cancer Network (NCCN) treatment guidelines for supraglottic cancer outline 2 therapeutic options: (1) total laryngectomy, lymphadenectomy, and postoperative radiotherapy (if indicated), and (2) concurrent chemotherapy and radiotherapy.² The second patient's treatment deviated from accepted guidelines; although the patient's cancer remained controlled with definitive therapy, the cost of treatment was significantly increased and the outcome could have been very different.

Suboptimal cancer care is often portrayed as catastrophic events exemplified by wrong-site surgery, fatal chemotherapy overdoses, or excessive doses of radiation inadvertently administered through incorrect dosimetry. Optimizing cancer care requires more than avoidance of such events. The correction of much less momentous events can decrease costs and, more importantly, may increase the chances for disease control and patient survival. "Quality care," according to the Agency for Healthcare Research and Quality, is "doing the right thing, at the right time, in the right way, for the right person—and having the best possible results."³

The quality of the initial therapy and the success of that therapy in obtaining disease control greatly influence outcome. When initial treatment for head and neck cancer fails, treatment options are often limited. Jarrard Goodwin Jr, MD,⁴ in his thesis submitted to the Triological Society, focused on the negative impact that the need for salvage therapy has on survival. He noted that, for patients with cancers of the oral cavity and pharynx whose initial treatment is unsuccessful, the long-term survival rate is far less than 50%. Goodwin's thesis underscores the following tenet of cancer care: "We have to get it right the first time." Not only is outcome negatively affected but also an estimated one-third of health care expenditures are squandered on either inappropriate care or "do-overs" in cases in which subsequent intervention is necessary owing to inadequate initial therapy.

Certainly, many patients do receive appropriate, quality care. The National Initiative for Cancer Care Quality (NICCCQ), initiated by the American Society of Clinical Oncology, reviewed the care delivered to patients with breast cancer and colorectal cancer based on 36 quality measures.⁵ The NICCCQ uses a carefully designed sampling protocol to ensure that sampled patients are representative of the population of patients with the same cancer diagnosis, puts in place procedures for protecting the privacy and confidentiality of patients, includes rigorously developed measures of the quality of cancer care that are validated and up-to-date, and uses an ongoing data collection protocol that relies on at least 3 sources of available data. The NICCCQ study demonstrated that 82% to 87% of patients with breast cancer received appropriate care and that 78% of patients with stage II or III rectal cancer received radiotherapy as recommended by current evidenced-based guidelines.⁵ These results were encouraging in that many patients with breast and colorectal cancer receive evidence-based care, but the investigators noted significant variation in care and that opportunities for improvement existed.

The IOM, in collaboration with the National Cancer Policy Board, analyzed the quality of cancer care delivered in the United States and noted wide variability by region.⁶ The study, titled "Ensuring Quality Cancer Care," concluded that, based on the best available evidence, some individuals with cancer do not receive care known to be effective for their condition.⁶

A host of other organizations and institutions are evaluating the quality of cancer care in the United States and are attempting to develop guidelines and measure adherence to them. These include governmental entities, nongovernmental agencies, and professional societies. A sampling of the list speaks to the breadth of this effort: the Centers for Medicare and Medicaid Services (CMS); the Agency for Healthcare Research and Quality; the National Quality Forum, working to identify and evaluate quality measures for cancer care; the American Society of Clinical Oncology, through the Quality Oncology Practice Initiative and the NICCCQ; and the American College of Surgeons, through sponsorship of the National Surgical Quality Improvement Project.

Driving these initiatives for improved quality in cancer care are a multitude of groups with a substantial stake in the outcome: (1) patients or consumers of health care; (2) the payers, both health maintenance organizations and the CMS; (3) businesses that purchase health care benefits for their employees; (4) professional organizations such as the American Board of Medical Specialties; and (5) specialty societies such as the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, and the American Head and Neck Society.

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) has organized a parent committee, designated Translating Research Into Cross-Specialty Measures, that will serve as an interface between representatives of the CMS, major health plans, and employer sponsors of pay-for-performance programs. Representation from the American Board of Otolaryngology, the American Head and Neck Society, sister societies, and other stakeholders in the quality measurement process will work together to develop specialty-specific quality guidelines. The AAO-HNS is a member of a national consortium and is actively identifying performance measures for the specialty, with easily accomplished collection of data from both paper-based and electronic medical records (EMRs). The American Head and Neck Society has organized a Quality Committee to develop quality care guidelines for head and neck cancer. The committee will interface with initiatives under way by the AAO-HNS.

Several interrelated factors led to some of the challenges posed by head and neck cancer. The first is the rarity and heterogeneity of the disease. Head and neck cancer accounts for fewer than 3% of solid tumors diagnosed in the United States annually, and differences in biological behavior that are site- and histology-specific create a dilutional effect, limiting the experience of practitioners in treating patients with these tumors. Level I evidence from randomized prospective phase 3 clinical trials is limited; in fact, fewer than 2% of patients with head and neck cancer are enrolled in clinical trials. There-

fore, treatment decisions are often based on personal or treatment-center philosophies, dogma, or data from case series. Next, optimal pathologic analysis and imaging data used to formulate the treatment plan are not readily available in all treatment centers. Last, the level of practitioner experience, training, technical skill, and knowledge of contemporary literature is not always optimal. These factors may extend to the treatment center, where a multidisciplinary team, adequate infrastructure, and high patient volume are often absent.

STRATEGIES FOR IMPROVING QUALITY OF CARE

Many strategies to improve the quality of head and neck cancer care exist. First, in response to the explosion of knowledge in the cancer field, we must adapt our residency and fellowship programs in otolaryngology–head and neck surgery to provide the cancer specialist with the tools and skill set needed to manage a challenging disease.

Second, we must create multidisciplinary head and neck cancer teams with the education and experience to deliver high-quality care based on the overarching principles of maximizing survival and functional preservation.

Third, strategic priorities for our discipline include participation in national initiatives to improve the quality of cancer care through the development of quality measures that are disease specific and based on the best evidence available. Fundamental to this endeavor will be the implementation of the EMR, which will serve as a data repository for individual patients. Quality data can be captured in the EMR and placed in the public domain, thus providing patients and payers with practitioner- and institution-specific quality data to assist them in making informed decisions regarding health care.

Fourth, directing patients with head and neck cancer to regional and tertiary care facilities with the specialty expertise and infrastructure to care for them will ultimately reduce costs and improve the quality of care. John Loré Jr, MD,⁷ wrote more than 20 years ago that head and neck cancer care should be performed by well-trained, experienced experts and not on an occasional basis by what he termed *the dabbler*, ie, “one who manages a few patients . . . , does not have the necessary support personnel, lacks appropriate rehabilitation facilities, and fails to keep abreast of the continuing education in head and neck oncology.”^{7(p1165)} For technically complex procedures, volume-based quality has been demonstrated to improve outcomes. Lamont et al⁸ demonstrated improved survival among patients with head and neck cancer who traveled more than 15 miles to receive care, suggesting that these patients had a better outcome by seeking specialized care.

Fifth, disseminating and implementing the NCCN treatment guidelines for head and neck cancer and supporting the enrollment of patients in prospective clinical trials will promote evidence-based treatment and lead to new therapeutic paradigms.

The implementation of each of these strategies is attainable. The first strategy is to adapt residency and fellowship programs. The field of head and neck medicine is broad and comprises several subspecialties that treat

disorders of the head and neck ranging from routine to complex. With this subspecialization has come a tremendous advancement in knowledge, which in turn presents significant challenges for mastering the knowledge base necessary for the general otolaryngologist–head and neck surgeon to meet the complexities of practice today. The opportunity for residents to perform technically complex procedures has diminished because the treatment approach has shifted away from surgery as the principal treatment modality for cancers of the laryngopharynx to nonsurgical therapy. This has significantly affected surgical training: residents completing programs today do not have the surgical experience afforded their predecessors. A dilutional effect has occurred, and residents may now graduate with only minor experience in maxillectomy, laryngopharyngectomy, partial laryngectomy, and skull base surgery.

The consequences range from patient care to credentialing. When surgical privileges are requested in hospitals, credentialing committees carefully review the applicant’s case experience obtained during residency training. If the applicant’s experience is not commensurate with the procedures requested, the credentialing body may require the surgeon to demonstrate adequate skill by having a senior surgeon participate for a predetermined number of cases before independent privileges are granted.

Leaders in our specialty have begun a dialogue to reassess specialty training for residents and to reexamine the residency curriculum. One modification would be to scale the training from the more general to a more specialized curriculum, providing a basic surgical experience for 6 to 12 months, followed by training in general otolaryngology for 18 to 24 months with an option to pursue focused training in head and neck surgery or other areas of subspecialization for the next 24 months. The curriculum would include rotations in diagnostic radiology, pathology, radiation oncology, medical oncology, and research. Residents choosing a career path in head and neck surgery would be afforded the opportunity to perform procedures that are relatively uncommon today, providing them with more technical surgical experience. Those who complete training in head and neck surgery would provide care for patients in regional centers as part of a multidisciplinary team; others would seek additional training in head and neck surgical oncology or microvascular surgery that would include a 12- to 18-month laboratory experience or a master’s degree in public health. These “superspecialists” will be well positioned to become leaders of multidisciplinary teams in tertiary care centers.

The second strategy is implementation of multidisciplinary teams. The multidisciplinary programmatic approach is the contemporary management paradigm for the treatment of patients with cancer of the head and neck. Ideally, the surgeon, medical oncologist, and radiation oncologist have a principal focus on caring for these patients, with expertise gained through fellowship training or experience. The paradigm also includes reconstructive surgeons, pathologists, radiologists, maxillofacial prosthodontists, endocrinologists, speech and swallowing therapists, and representatives from other disci-

plines who provide the patient with state-of-the-art, individualized cancer treatment and optimum rehabilitation. Quality and performance measures that gauge the effectiveness of the team involve pretreatment consultations by experts in surgery, medical oncology, and radiation oncology, and by other team members as appropriate, including a referral for smoking cessation. Practitioner- and discipline-specific performance and quality measures are used to assess the effectiveness of the surgeon, medical oncologist, and radiation oncologist. Surgery-specific indicators are numerous and may include length of stay, unexpected return to the operating room, 30-day mortality, perioperative wound infections, and patient satisfaction. Team-specific quality and performance indicators likewise are numerous and include the expectation that patients are prospectively presented at a multidisciplinary treatment-planning conference before treatment is initiated. Other measures are disease specific and stage specific and may encompass locoregional control, disease-specific survival, overall survival, patient satisfaction, treatment package time, treatment breaks, unscheduled hospitalizations during the acute phase of treatment, and treatment-related deaths. Analogous to practitioner-specific data, outcomes reporting for multidisciplinary teams would be available for review by patients and payers.

The third strategy is participation in national initiatives to improve health care. The EMR is the future repository for patient data. Within the next decade, it should be universally implemented and will facilitate coordination of care among the multidisciplinary team members for their patients with head and neck cancer. Pathology templates will be an integral part of the EMR and, if implemented, will provide consistency in the reporting of pathologic data and the inclusion of vital information important for therapeutic decisions. Collaboration among leaders in head and neck surgery and the College of American Pathologists will be mandatory for template-driven pathology reporting to become a reality. Advantages of such templates will include the standard reporting of critical data elements, such as histology and tumor differentiation, margin status, biomarker data (as these data become available), and the presence or absence of perineural invasion and extracapsular lymph node spread. Thus, for example, with template-driven reporting, vital omissions in the report will be avoided and will increase the likelihood of patients receiving adjuvant therapy when indicated.

The fourth strategy is to appropriately direct patients to regional or tertiary care centers with specialty expertise. Many patients with head and neck cancer are eligible for participation in clinical trials. Phase III prospective clinical trials provide the highest level of data supporting new and more effective treatment approaches. In the table of contents of the head and neck cancer treatment guidelines, the NCCN states that "the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged."²

In a secondary analysis of the Radiation Therapy Oncology Group 3-arm study 91-11 for laryngeal preservation, patients treated at regional centers vs National Cancer Institute-designated comprehensive cancer centers

had similar outcomes in time to laryngectomy and overall survival.⁹ The findings from this analysis underscore the NCCN recommendation that enrollment in clinical trials should be encouraged. Although the secondary analysis of 91-11 data is still under way, it supports the supposition that well-designed trials with stringent quality control at each participating center can produce similar outcomes for patients regardless of the institution or patient volume.

The fifth strategy is the development of evidence-based medicine. Perioperative care pathways have been demonstrated to reduce variability of care, decrease length of stay, lower costs, and diminish morbidity.¹⁰ A care pathway is an evidence-based collaborative process among surgeons, nurses, physical therapists, and speech pathologists. The goal of the perioperative pathway is to reduce the variability of interventions and diminish the need for memory in prescribing interventions necessary on the continuum from surgery to discharge. Key pathway elements are prophylactic antibiotic administration, early ambulation, tracheostomy care education for the patient and family, speech and swallowing rehabilitation, and early discharge planning. For complex head and neck cancer procedures, care pathways have significantly diminished the length of stay, unscheduled readmission rates, total charges, and the incidence of nosocomial pneumonias.

Other performance-driven initiatives will play a significant role in optimizing head and neck cancer care. The reporting of quality and performance indicators may affect the future of head and neck cancer care in many ways, but the desired effects will be to reduce costs and improve the quality of care. On the horizon, pay for performance, evidence-based hospital referrals, and directing patients to practitioners and facilities that have been credentialed to provide care may become realities. Pay-for-performance programs link pay to a measure of individual, group, or organizational performance. They all share the idea that, in cases in which a worker's effort can vary output, the prospect of increased pay will lead to greater performance. The CMS is evaluating a process to improve the quality of health care by expanding the information available about quality of care and by providing direct incentives to reward superior care.¹¹ Through the Premier Hospital Quality Incentive Demonstration, the CMS anticipates a significant enhancement in the quality of inpatient care by awarding incentive payments to hospitals that achieve predetermined quality benchmarks and by reporting extensive quality data on the CMS Web site. The demonstration involves a CMS partnership with Premier, Inc, a nationwide organization of not-for-profit hospitals. High-performance hospitals will see an increase in their payment for Medicare patients. Pay-for-performance programs that pay hospitals an incentive for achieving greater than 90% adherence to evidenced-based quality guidelines have been implemented by the CMS. Examples include the administration of aspirin and β -blocker therapy for patients with acute myocardial infarction.¹² Institutions not meeting at least 80% of the guidelines are at risk of decrements in reimbursement for certain diagnosis related groups.

A coalition of public and private organizations has come together under the moniker of The Leapfrog

Group.¹³ Member organizations that buy health care combine their purchasing power to support improvements in America's health industry. Through the evidence-based hospital referrals, The Leapfrog Group directs patients with high-risk conditions to hospitals with characteristics shown to be associated with better outcomes. This method uses volume-based outcomes for complex surgical procedures typified by pancreaticoduodenectomy and esophagectomy. Mortality rates for these procedures are roughly 50% lower for high-volume hospitals than for low-volume hospitals.¹⁴

THREE-TIER MODEL FOR OPTIMIZING CARE

One could envision a 3-tier model for optimizing the care of patients with head and neck cancer. The role of the community hospital will be to diagnose and refer patients with head and neck cancer to regional or tertiary cancer centers with the multidisciplinary team and facilities available to provide optimum care. Regional institutions will have the capability to provide high-quality care for many patients with head and neck cancer but may need to refer patients for complex reconstruction, craniofacial resection, or therapy unique to a particular experimental protocol. In this model, tertiary and quaternary cancer care centers will provide research-driven patient care. Examples of these institutions are National Cancer Institute–designated comprehensive cancer centers, academic medical centers, and major metropolitan tertiary care centers. Patients referred to these centers would benefit from the breadth and depth of expertise available, and it is expected that a large percentage of patients would enter clinical trials. Shaping the 3-tier model for head and neck cancer care will be patients who make informed choices based on quality and performance data available in the public domain and payers who direct patients to institutions most able to deliver high-quality cost-effective cancer care.

As John Loré Jr^{7(p1168)} so presciently wrote 20 years ago:

Physicians, medical organizations, and associations must work to solve these problems. Failure to take the lead in assuring good training and treatment centers while avoiding the proliferation of inadequate patient management efforts will lead to the external imposition of standards. Optimal care for head and neck cancer patients depends upon the skill of the care providers and the quality of the care facilities.

I believe we have a unique opportunity and a societal obligation to reengineer head and neck cancer care for the betterment of our patients. The road ahead will not

be easy, but the rewards are great. To quote Johann Wolfgang von Goethe, "Knowing is not enough; we must apply. Willing is not enough; we must do."

Submitted for Publication: July 17, 2007; accepted July 29, 2007.

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Financial Disclosure: None reported.

Previous Presentation: This address was presented at The American Head & Neck Society 2007 Annual Meeting; April 29, 2007; San Diego, California.

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