In 1999, the Institute of Medicine (IOM) released the landmark report, *To Err Is Human*. This publication described the human and economic costs of preventable errors in medicine and concluded that as many as 98,000 deaths occur annually as a result of preventable medical errors. Furthermore, the authors detail other losses caused by preventable medical errors including financial losses, a loss of trust in and satisfaction with the health care system, and a loss of morale by health care providers.1 A follow-up report, *Improving Diagnosis in Health Care*, focuses specifically on diagnostic errors, citing the need for increased data on the topic. The report concludes that “[i]mproving diagnosis will likely require a concerted effort . . . to better identify diagnostic errors and near misses, to learn from them, and, ultimately, to take steps to improve the diagnostic process.”2

The IOM reports increased awareness of the need for transparency in examining health care–related errors. The bulk of research was no longer centered on individuals but was focused on systems-level issues.3,4 This shift has resulted in the simplification and standardization of systems, which has in turn resulted in a reduction of systems-based errors.4

Patient safety is not the only motivation to avoid diagnostic delays and errors. The Doctors Company reviewed 7438 malpractice claims closed from 2007 to 2013 in varying medical specialties and discovered that 25% of these claims were diagnosis related. For surgical specialties, 14% were diagnosis related.5

Otolaryngology, as a specialty, is not immune to the aforementioned errors. During the past decade and a half, more attention has been focused on quality improvement and research into medical errors.6 In 2003, Shah et al disseminated surveys to members of the American Academy of Otolaryngology-Head and Neck Surgery asking respondents if an error had occurred in the previous 6 months; the reported errors were then classified along a newly devised classification schema. The 466 respondents reported 212 errors. The survey team categorized errors in both testing (10.4% of all errors) and diagnosis (1.4% of all errors).7 Although there are inherent weaknesses in self-reporting surveys, and the low response rate (approximately 4%) should lend caution, the survey helped initiate the conversation on errors within the specialty. This study

**Abstract**

A retrospective review of 100 sequential patients (2009-2012) with head and neck cancer was performed to determine the frequency of 5 types of diagnostic delays and errors outlined by the Institute of Medicine. There were a total of 105 diagnostic delays/errors. The most common was delay in being seen in the otolaryngology clinic after referral placement (28.6%), followed by diagnostic error by the referring physician (22%), delay in referral of a symptomatic patient to the otolaryngology clinic (16.2%), delay in employing an appropriate diagnostic test or procedure (15.2%), delay in action following reporting of pathology or imaging results for an incidental lesion (11.4%), diagnostic error by the otolaryngology clinic (2.8%), delay in action following reporting of pathology or imaging results for the symptomatic lesion (2.8%), and use of outmoded tests or therapy (1%). Increased awareness of these types of delays/errors will direct actions and processes to reduce or eliminate them.

**Keywords**
delayed diagnosis, diagnostic error, patient safety, quality improvement, head and neck neoplasms

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aimed to expand on these initial findings, especially given the paucity of prospective and retrospective studies that examine diagnostic delays and errors, likely related to a lack of willingness to report what may be viewed as a negative reflection on an organization or individual. The IOM also explicitly identified several types of diagnostic delays and errors, including an error or delay in the initial diagnosis, failure to employ an indicated test, use of an outmoded test or therapy, and failure to act on the results of monitoring or testing. Therefore, it is imperative that the errors, delays, and adverse events that affect patient care be better characterized. The ultimate goal of this study is to identify factors that contribute to diagnostic delays and errors at the study institution and subsequently implement actions to mitigate those factors. The readily available and consolidated data on patients with head and neck cancer at the study institution facilitated a retrospective chart review. The study hypothesis is that clinical reviews of the presentation and management of these patients will reveal if diagnostic errors or delays (as outlined by the IOM) occur in their care. This type of retrospective review is similar to clinical case reviews that occur monthly in traditional morbidity and mortality quality conferences at many departments and institutions. However, in this study, instead of examining a single occurrence or event, 100 sequential cases were reviewed in detail to identify recurrent trends and to quantify the greatest opportunities for improvement.

Methods

The institutional review board of the Richard L. Roudebush Veterans Affairs Medical Center (VAMC) granted approval for the study. A retrospective chart review of 100 sequential head and neck cancer (HNC) patients who were evaluated and had their malignancies worked up/staged and/or treated at the VAMC between 2009 and 2012 was completed exclusively using the Computerized Patient Record System. The Computerized Patient Record System provides a consolidated, easily navigable record and time line of referrals, consultations, imaging results, operative reports, pathology reports, and multidisciplinary tumor board conferences. Two reviewers coordinated data extraction evenly among the 100 patients using a standardized data abstraction form that was developed a priori. A separate investigator conducted an audit of 15 patients randomly selected from within the initial cohort, split approximately evenly among patients reviewed by each of the 2 reviewers. The auditor agreed with the extracted data and found no discrepancies between the 2 reviewers, thereby confirming accurate data extraction and interreviewer concordance.

Incidence of diagnostic delays and errors was assessed as defined in the IOM report. The outlined delays and errors were then further subcategorized. An error in diagnosis was categorized to either the referring health care provider (type 1a) or the otolaryngology clinic (type 1b). A delay in diagnosis was defined as greater than 2 weeks for referral placement in a symptomatic patient (type 2a), or a greater than 2-week delay for the patient to be seen in the otolaryngology clinic following the initial referral (type 2b). Two weeks is the standard expected time for completion of a clinic consult request in the Veterans Affairs system. Failure to employ a diagnostic test and/or surgery was defined as 2 months from identification of a lesion to the diagnostic test and/or therapy (type 3). The use of an outmoded test and/or therapy was defined as deviation from the National Comprehensive Cancer Network clinical practice guidelines in oncology (type 4). Last, failure to act on results was defined as 2 months inaction following pathology and/or imaging results for a symptomatic lesion (type 5a), and 2 months of inaction following the reporting of pathology and/or imaging results for an incidental lesion (type 5b). The American College of Radiology (ACR) guidelines for managing incidental findings were used to determine if a type 5b error occurred. Documentation of an incidental finding in the radiology report prompted reference to ACR guidelines to determine if appropriate action was pursued. Inaction was defined by a lack of documentation, following an extensive medical record review, in the otolaryngology service note referencing the findings and/or lack of appointment, referral to, or consultation with the appropriate specialty for management of the incidental finding.

Results

There were a total of 105 distinct diagnostic delays/errors identified by 2 reviewers analyzing 50 cases each (Table 1). The number of delays/errors noted by each independent reviewer was nearly identical (53 by reviewer A and 52 by reviewer B). The frequency of a diagnostic delay and/or error per patient was zero (34 patients, 34%), one (41 patients, 41%), 2 (15 patients, 15%), 3 (6 patients, 6%), and 4 (4 patients, 4%). As shown in Table 1, the frequency of types of diagnostic delays and/or errors in descending order was the following: delay for patient to be seen in the otolaryngology clinic, error in diagnosis by the referring health care provider, delay in referral placement for a symptomatic patient, failure to employ a test or therapy, delay following report of an incidental lesion, error in diagnosis by otolaryngology clinic, delay following report of a cancerous lesion, and use of an outmoded test or therapy.

Type 2b delays (28.6% of delays/errors identified) were defined as a 2-week delay for the patient to be seen in the otolaryngology clinic following initial referral. Seven of the 30 type 2b delays were caused by the patient...
missing or cancelling his or her appointment. The remaining type 2b delays were caused by delay in scheduling of the appointment (ie, the first available appointment, or the first appointment that worked well for the patient was >2 weeks from date of referral).

Type 1a errors (22% of delays/errors identified) were defined as an error in diagnosis by the referring health care provider. The majority of these errors occurred because the referring health care provider treated the presenting symptom/lesion as an infection. In one instance, the referring provider prescribed several courses of antibiotics, delaying the referral to otolaryngology by 20 to 30 days. In another example of a type 1a error, lymphadenopathy was treated as reactive lymphadenopathy for 6 months before a referral was made to the otolaryngology service.

Type 2a delays (16.2% of delays/errors identified) were defined as >2 weeks for a referral placement in a symptomatic patient. In every type 2a delay, the health care provider who initially saw the patient treated the patient as having an infection. Type 3 delays (15.2% of delays/errors identified) were defined as a failure to employ a diagnostic test or procedure, meaning there was ≥30 days from the identification of a lesion to a diagnostic test or procedure. Ten of the 15 type 3 delays coincided with a type 2a or 2b error. This meant a delay in referral by the health care provider, or delay in being seen by the otolaryngologist following referral caused the type 3 error. One patient left his appointment before a biopsy could be taken, and one patient presented with an outside biopsy result, which was taken >30 days from his initial presentation.

Type 5b delays (11.4% of delays/errors identified) were defined as >2 months of inaction following the reporting of pathology and/or imaging results for an incidental lesion. The ACR guidelines for defining and managing incidental findings were utilized across all patients to ensure consistency. Some significant type 5b errors included inactivity following the description of lung nodules and other pulmonary lesions, adrenal nodules, and hepatic or renal cysts/lesions.

Type 4 errors (1% of delays/errors identified) were defined as deviation from the gold standard in testing and workup of the specific lesion. In one instance, a plain radiograph of the neck was ordered when a patient presented with a neck mass. This patient had a final diagnosis of poorly differentiated squamous cell carcinoma of the tonsil. This patient did ultimately undergo positron emission tomography/computed tomography in accordance with National Comprehensive Cancer Network guidelines.

**Discussion**

Evaluation of medical delays and errors continues to be of benefit to any health care organization. This study identified varied examples of diagnostic delays and errors. There are very few published studies that review diagnostic delays and errors within institutions or practices. A possible reason for this is that most practitioners and institutions are hesitant to report findings that may be interpreted as a negative reflection of their practice or organization. The V AMC is ideally suited to lead such health care improvement efforts, as one of its core values is to strive for the highest quality and continuous improvement. Its award-winning electronic medical record system is well suited for such introspective studies. Time and time again the V AMC has proven to be a bellwether for clinical practices, affecting both community and academic medical centers. Therefore, it would be reasonable to postulate that these findings are not exclusive to the V AMC.

Recently, Lucian Leape, a renowned health care quality authority, penned an editorial titled “Hospital Readmissions Following Surgery: Turning Complications into Opportunities.”

### Table 1. Number and Frequency of Delays and Errors Identified in Patients Presenting With Head and Neck Cancer.

<table>
<thead>
<tr>
<th>Type of Delay/Error</th>
<th>N</th>
<th>Percentage of Total Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Error in diagnosis</td>
<td>26</td>
<td>24.8%</td>
</tr>
<tr>
<td>1a: by referring physician (eg, PCP, ED)</td>
<td>23</td>
<td>22.0%</td>
</tr>
<tr>
<td>1b: by Otolaryngology—Head and Neck Surgery</td>
<td>3</td>
<td>2.8%</td>
</tr>
<tr>
<td>2: Delay in diagnosis</td>
<td>47</td>
<td>44.8%</td>
</tr>
<tr>
<td>2a: &gt;2 weeks for referral placement</td>
<td>17</td>
<td>16.2%</td>
</tr>
<tr>
<td>2b: &gt;2 weeks to be seen after referral placement</td>
<td>30</td>
<td>28.6%</td>
</tr>
<tr>
<td>3: Failure to employ a test or therapy</td>
<td>16</td>
<td>15.2%</td>
</tr>
<tr>
<td>4: Use of outdated test or therapy</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>5: Failure to act on results</td>
<td>15</td>
<td>14.2%</td>
</tr>
<tr>
<td>5a: ≥2 months inaction for HNC</td>
<td>3</td>
<td>2.8%</td>
</tr>
<tr>
<td>5b: ≥2 months inaction for incidental finding(s)</td>
<td>12</td>
<td>11.4%</td>
</tr>
</tbody>
</table>

Abbreviations: ED, emergency department; HNC, head and neck cancer; PCP, primary care physician.
into ‘Treasures,’” in response to an article reporting readmission rates following surgical cases from the American College of Surgeons National Surgical Quality Improvement Program. Dr Leape promotes the labeling of complications as “treasures,” as is done by Japanese quality experts, because the analysis of such episodes provides many opportunities for improvement. It is with this philosophy that these data and results on diagnostic delays and errors should be viewed to advance our understanding surrounding episodes of care and, ultimately, to improve care for patients everywhere.

Although 105 diagnostic delays or errors in a population of 100 patients may appear to be quite numerous, the denominator or potential number of delays or errors may be infinite. Therefore, the results of this study should be approached with the mind-set of quality improvement. These data and results provide a quantitative reference for delays and errors in HNC patients that heretofore have not been available. The data from this study provide valuable information that highlights various improvement opportunities for the care of patients with HNC. The majority of errors discovered in this study were misdiagnoses and/or delays in referral to a specialist. These are precious opportunities for improvement as they affect all subsequent steps in patient care. For example, the majority of delays in diagnostic procedures/testing seen in the present study resulted from either a delay in referral placement or a delay in being seen after referral placement. Misdiagnosis by a primary provider and resultant ineffective treatment may delay referral placement. Similarly, patients for whom the primary provider correctly placed the referral but, because of scheduling issues, are unable to be seen in a timely fashion will experience subsequent delays in care (ie, biopsy, imaging/staging, definitive therapy). Targeting the errors that occur early in the course of a patient’s presentation may provide cascading downstream benefits, given the potential to prevent subsequent associated delays and errors from taking place. For example, one potential solution to prolonged time to be seen by a specialist is reservation of a commensurate number of open appointment slots for referrals in which a malignancy is suspected. This intervention may reduce the number of delays to be seen by a specialty clinic following referral placement. The specific number of appointment slots to be made available could be determined based on the number of referrals for a suspected malignancy a particular clinic has received over the previous year. Another opportunity for improvement may be increasing awareness among primary care providers of risk factors and presenting symptoms and signs of HNC. This would enable earlier recognition of patients with a potentially malignant lesion and more prompt subsequent referral to a specialty clinic.

An additional improvement opportunity is found in the management of incidental findings. The ACR has outlined clear parameters for many incidental findings and implementation of institutional processes may ensure appropriate management of these lesions, thereby increasing the value of the imaging study. Furthermore, the IOM has detailed the importance of enhanced cohesion across the health care team, including collaboration with radiologists to “improve diagnostic testing processes.” In addition, increasing patient education may beneficially affect patients’ preference for a delayed date, patient no-shows, or cancellations—all of which can lead to delays in care. Patients are potentially more likely to honor timely appointments if they are made aware of the possible implications of a suspected diagnosis. Engagement of patients and their family members may engender valuable information toward a correct and prompt diagnosis. Also, in the event of a diagnostic error or delay, fostering patient collaboration may provide feedback that benefits the diagnostic process or leads to improvements within the health care system.

In every type 2a delay/error, in which >2 weeks lapsed before a referral was placed for a symptomatic patient, the health care provider who initially saw the patient treated the patient as having an infection. Although the initial clinical presentation may be similar in patients with infections and HNC, provider education regarding duration of symptoms (ie, >2 weeks of sore throat or hoarseness), risk factors (ie, tobacco and/or alcohol use), failure of symptomatic improvement on a prior course of antibiotic and other associated symptoms (ie, otalgia, dysphagia, unilateral pain, hemoptysis, weight loss) would expand and prioritize the differential diagnosis to include earlier referral to the otolaryngologist. In addition, in most cases the appearance and physical examination of the oropharynx can differentiate an infection from a malignancy. Within a system such as the VAMC, enhanced collaboration and cooperation (eg, regularly scheduled, multidisciplinary educational initiatives) among primary care providers and specialists may promote enhanced recognition of, and agreed-upon management plans for, at-risk patients. Another potential application of this study is development of an automated tracking system for referrals to improve consistency, timing, and follow-up care. One possible manifestation of this system would be immediate automatic notifications to involved providers once a specific diagnosis has been confirmed.

Errors made in a health care/institutional setting often are the result of multiple causes. Zirkle and Roberson describe how “Normal Accident Theory” focuses on the complexity of a system and the coupling of components within that system, and how such systems are the setting in which errors occur. This theory fits well when describing...
the modern-day hospital or health care system,\textsuperscript{18} systems that fit the previously described example and yet have a low rate of errors and failures do so because they are flexible and adapt to changes. They recognize delays and errors and respond by making appropriate changes.\textsuperscript{19} It is the authors’ goal to now determine the cause(s) of the errors that were identified and implement changes that will not only rectify the delays and errors but also allow the service to remain flexible in adapting to future delays and errors that undoubtedly will be encountered.

One limitation of chart reviews is that there are potential events or actions that are not recorded in the electronic medical record. Furthermore, even if the events are identified, the interpretation of an event’s significance may be incorrect secondary to incomplete or improper documentation.\textsuperscript{5} For example, if a provider or service failed to document that he/she discussed a significant incidental finding with the patient, a type 5b delay/error was recorded. Of note, this study did not examine clinical outcomes or the impact of diagnostic delays and errors on tumor staging and survival.

There are no well-defined standards for certain parameters assessed in the present study. For example, the 2-month time period specified for inaction following lesion identification is arguably excessively generous. The rationale behind this time interval was to ensure subsequent follow-up actions related to the findings were captured and to mitigate the argument or concern that perhaps a large proportion of actions occurred immediately after a more restrictive time period (eg, one month). Future analysis of the effects of different time intervals (eg, one month instead of 2 months) may provide more nuanced information regarding delays and errors along with better-defined standards to be met. A shortened time interval, being a more restrictive criterion, likely would increase the inaction rate identified. The fact that the very generous 2-month follow-up period still yielded a 14.2% failure to act on results (Table 1) is concerning and is exactly why this type of study is important for increasing awareness among clinicians and health care organizations to design processes and implement solutions to enhance continuity of care and prevent communication lapses.

The diagnostic delays and errors identified in this study may or may not be directly associated with changes to overall clinical outcomes, though the literature is replete with evidence that patient survival diminishes with advancing cancer stage (ie, size, tissue involvement). A subsequent prospective study would be useful to validate the findings described above and to measure their potential relation to various outcomes (eg, patient satisfaction, disease-free survival and overall survival times, health care costs). Additionally, further studies are needed in various types of institutions for enhanced generalizability of these findings.

**Conclusion**

Clinicians must remain attentive to potential delays and errors on both individual and system-based levels. In addition, practitioner and organizational leaders should encourage transparent examination of processes and a comprehensive review of the entire spectrum of care to identify delays and errors so actions can be specifically directed to achieve resultant improvements. The role of the otolaryngologist in providing diagnostic education to primary care and emergency medicine physicians should not be undervalued. It is likely that through education and increased awareness by health care providers and the public, and leveraging technology, reduction or elimination of diagnostic delays and errors can be realized. This study’s findings not only prove that there is potential for improvement in the care of patients with HNC, they also demonstrate specific improvement opportunities and potential avenues for better quality patient care. It is the authors’ hope that continued efforts will lead to increased awareness of diagnostic delays/errors and efforts to eliminate them.

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