

Classification and Consequences of Errors in Otolaryngology

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Objective: To develop a preliminary classification system for errors in otolaryngology. **Methods:** A retrospective, anonymous survey was distributed to 2,500 members of the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS). Respondents were asked whether an error had occurred in their practice in the last 6 months, and if so, to describe the error, its consequences, and any corrective action taken. **Results:** There were 466 (18.6%) responses. Two hundred ten (45% of respondents) otolaryngologists reported 216 errors. A classification system for errors in otolaryngology was developed. Errors were classified as related to history and physical (1.4%), differential or final diagnosis (1.4%), testing (10.4%), surgical planning (9.9%), wrong-site surgery (6.1%), anesthesia-related (3.3%), wrong drug/dilution on the surgical field (3.8%), technical (19.3%), retained foreign body (0.9%), equipment-related (9.4%), postoperative care (8.5%), medical management (13.7%), nursing/ancillary (0.5%), administrative (6.6%), communication (3.8%), and miscellaneous (0.9%). There were 78 cases of major morbidity and 9 deaths. If these data are representative, there may be more than 2,600 episodes of major morbidity and more than 165 deaths related to medical error in otolaryngology patients annually. **Conclusions:** Human error in otolaryngology occurs in all practice components, including diagnostic, treatment, surgical, communication, and administrative. Types of errors reported by otolaryngologists differ from those reported by other specialists. Error classification systems may need to reflect each specialty's realm of practice. Errors in otolaryngology cause appreciable morbidity and mortality. Quantitative study of errors and the develop-

ment of targeted prevention and amelioration strategies should be a high priority. **Key Words:** Patient safety, complications, adverse events.

Laryngoscope, 114:1322–1335, 2004

INTRODUCTION

Many high-stakes human activities are critically dependent on human decision-making. Human error can be catastrophic in such fields as aviation, nuclear power, and chemical manufacturing. In these fields, the systematic study of human errors has led to targeted strategies for error prevention and amelioration and improved overall safety.^{1,2}

Medicine and surgery are likewise fields in which ordinary human fallibility can lead to catastrophic outcomes. In a landmark report, *To Err is Human*, the Institute of Medicine (IOM) summarized the best available data and suggested that from 44,000 to 98,000 patients die ever year from preventable medical errors in the United States.^{3–5} The morbidity and financial costs caused by medical error are harder to quantify than mortality but are certainly very large. The IOM report encouraged hospitals and physicians to develop error analysis identification programs and strategies for error prevention and amelioration.

Despite the utility of error analysis in other industries, medicine has been slow to treat human error as an important field for study.¹ The reasons may include the fact that most physicians are not trained in the systematic analysis of human error, the reluctance of physicians to appear to be critical of colleagues, their specialty, or medical practice in general,⁶ and fear of malpractice litigation.⁷

Large population-based studies have shown that up to two thirds of hospital adverse events may be surgery related, and most of these may be preventable.^{3,5,8,9} The Harvard Medical Practice Study conducted exhaustive reviews of over 30,000 charts and found that 47% of adverse events were associated with an operation, with wound infections and technical complications being the two most common surgery-related adverse events.^{3,9} Gawande et al.,⁸ using a similar methodology, reviewed over 15,000 charts and found that the adverse event rate for patients having surgery was 3%. Two thirds of these surgery-related adverse events were judged to be preventable.⁸

Presented at The Triological Society Annual Meeting, Scottsdale, AZ, April 30, 2004.

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Supported by the Joshua Shapiro Fund and The Childrens Hospital Otolaryngology Foundation Research Fund.

Editor's Note: This Manuscript was accepted for publication June 18, 2004.

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To analyze and plan to remediate a problem, it is first necessary to collect data about the problem and then to summarize that data. Collection strategies include traditional morbidity and mortality conferences, hospital-based incident reporting, exhaustive chart review,^{3,9} innovative and less labor-intensive methods for identifying patients most likely to be at risk for adverse events or errors,¹⁰ focused interviews,¹¹ and surveys.¹² Each strategy has unique strengths, and none is sufficient by itself.¹³ We chose an anonymous survey because it was a practical method to sample a nationwide group of otolaryngologists and to ensure anonymity.

To summarize data, a classification system is needed. Classification systems for medical errors are in their infancy. Because medical care is infinitely complex, so are medical errors and their potential classification systems. Errors may be classified according to the location of the event (e.g., in the operating room [OR]), the professional involved (e.g., a physician vs. a pharmacist), the agent involved (e.g., intravenous [IV] drugs vs. oral drugs), the cognitive error (e.g., an error in vigilance vs. an error of judgment), and also by contributing system factors (e.g., poor hand-offs, excessive workload, poor equipment).^{3,8,9,12,14–17} Some workers have examined human error very broadly and developed very comprehensive classification systems.^{14,15} These classification systems give important information but may be somewhat broad for the practical study of errors in a particular specialty.

The practical physician may be most interested in learning about the areas of patient care in which colleagues in his own specialty experience adverse events and errors. For this reason, some workers have developed classification systems unique to their specialty.^{12,18,19} The success of this approach has been best demonstrated in anesthesia, where focused attention to such issues as equipment design and care protocols have greatly reduced errors and adverse events.^{20,21} We also chose to work toward a classification system specific to otolaryngology. We did not attempt to develop a system in advance but rather planned to let the responses guide us in developing a system that would be most useful to the practicing otolaryngologist. The goals of the study were (1) to develop a preliminary classification system for errors in otolaryngology, (2) to identify the realms of practice in otolaryngology where errors occur, and (3) to collect pilot data about the severity and consequences of errors.

METHODS

Eligibility

An otolaryngologist was eligible to be included in this study if he or she was on the current American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) mailing list of members and resided in the United States.

Sampling

We purchased the AAO-HNS membership mailing list as preprinted sticky labels. This allowed us to ensure that no member was resurveyed, without recording any names. We used a pseudo-random sample by selecting one of the first seven names at random and then using every seventh name. At the end of the list, we cycled back to the beginning. We did not construct a true

random sample because it would have been labor intensive to number all the names on the list and because we did not believe that selecting every seventh name alphabetically would yield a systematic sample bias.

Survey Instrument

The survey instrument (Appendix I) asked the respondent whether an error had occurred in his/her realm of practice in the last 6 months. We purposely defined errors extremely broadly, using the following language from Dovey et al.:¹² “Anything that has happened anywhere in your practice (office, hospital, operating room, emergency room, etc.) that was not anticipated, should not have happened, and makes you say ‘I don’t want this to happen again.’” It can be small or large, administrative or clinical—anything that you feel could be avoided in the future.

Physicians were asked to describe the error, its consequences, any corrective action taken, and to provide limited demographic data about themselves and the affected patient. The anonymity of the process was stressed. If more than one error had occurred, we asked the respondent to describe the most recent error.

Mailings

An initial mailing was sent to 500 otolaryngologists. The response rate was 19.4%, and of the 97 respondents, 45% reported an error within the last 6 months. Because we hoped to collect a total of about 200 errors for classification purposes, a second survey of another 2,000 otolaryngologists was performed. The response rate was 18.3% for the second mailing, with 44% reporting an error. Data from both mailings were pooled for analysis.

Recruitment Period

We collected responses for 45 days after the mailing of each survey. The first mailing was sent out in July 2003 and the second mailing in November 2003. Responses received after the 45-day recruitment period were shredded.

Confidentiality

Surveys were mailed and responses received and opened by an administrative assistant who did not participate in any other aspect of the study and who followed a strict protocol designed to protect the anonymity of respondents. She opened each response and immediately shredded the envelope. She then read each response. If there was any identifying material (return address, reference to a specific hospital, or location), it was shredded. All responses were stored securely until the end of the 45-day recruitment period. The investigators were then given all responses simultaneously.

Development of a Classification System

We did not attempt to define a classification system in advance. Instead, we tried to let the reported events guide the development of the system. Two of the authors (R.K.S. and D.W.R.) read all responses several times. We considered several different ways of classifying events. We tried to develop a system that 1) maximized the interrater agreement, and 2) gave the most helpful information to practicing otolaryngologists. Ultimately, we developed a classification system based on “care flow” (Tables I and II). We conceptualized an idealized patient encounter beginning with history and physical examination, continuing through either medical or surgical therapy and postoperative care. We classified errors by where they occurred in the care flow. This system led to much greater agreement on classification than other methods we tried. We also feel it provides much more useful information to the practicing otolaryngologist.

TABLE I.
Idealized Care Flow and Potential Errors.

Care Flow Process	Potential Errors
Work-up and diagnosis	
Obtain history and perform examination	Errors in history or examination
Construct a differential diagnosis	Errors in differential diagnosis
Order testing to reduce differential	Testing errors
Reach definitive diagnosis	Errors in final diagnosis
Surgical management	
Choose a surgical therapy	Choose wrong procedure
Surgical planning (facility, personnel, preop tests)	Errors in surgical planning
Correct site surgery	Wrong site surgery
Anesthetic administered	Anesthesia errors
Drugs administered from field	Wrong drug/dilution from surgical field
Intraoperative patient management	Errors in management (e.g. failure to call consult intraoperatively)
Perform surgery correctly	Technical surgical errors
Remove all instruments and sponges	Retained foreign body
Surgical equipment available and functional	Equipment-related errors
Postoperative care	Errors in postoperative care
Medical management	
Choose correct therapy	Choose incorrect therapy
Administer medical therapy	Medication errors
Miscellaneous	
Nursing and ancillary care	Nursing/ancillary errors
Administrative	Administrative errors
Communication	Communication errors
Miscellaneous	All others

Classification of Events

We adopted the principle of accepting the respondent's version of events. For example, if the respondent attributed a problem to hospital administration, we accepted this assessment. We tried to scrupulously avoid "reading between the lines" or inferring information that was not specifically provided. All events were assigned at least one classification. In 17 cases, the reviewers could identify an additional "contributing" error; in two cases we identified two "contributing" errors, for a total of 21 "contributing errors."

Responsible Agents

We classified every error as having up to three responsible agents, which could be either persons (the attending physician) or other entities (hospital administration, equipment). We accepted the respondent's report in making these assignments. If the respondent did not specifically attribute responsibility for the agent, we assigned it on the basis of the function in question. For example, if a report of a technical error did not mention the presence of a resident, we classified the attending surgeon as the responsible agent.

Harm Index

We used a modified version of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index,¹⁷ developed to assess harm caused by medication errors (Table III). In this alphabetic system, harm is assigned a letter category from A (no harm, but circumstances predisposing to error) to I (death). Modifications were made to accommodate some nonmedication errors that do not fit well into this system. For example, some patients had delayed cancer diagnoses but were still in treatment with uncertain outcome. We

could not definitively state whether the delay harmed these patients. On the belief that such a delay would often but not always cause harm, we chose to assign a harm level of G.

Major Morbidity

Major morbidity was defined as categories F, G, and H: errors leading to additional hospitalization, surgery, anesthesia, permanent injury, or requiring treatment to sustain life.

Analysis/Statistics

These data were input on Microsoft Excel and then transferred to a Microsoft Access database (Microsoft, Redmond, WA). The responders' demographics were analyzed using Fisher's exact test, using Stata (College Station, TX). Binomial confidence intervals (CI) were calculated using the normal-theory method.²²

Additional Analysis

Our primary goal was to develop a classification system that would allow further, more quantitative study of errors in otolaryngology. However, as we read the responses, two additional aspects stood out that deserved independent analysis and discussion. One was the significant morbidity of many of the reported errors. Although this study was not designed to quantify the true incidence of errors or harm, certain areas were repeatedly associated with error-related injury. We highlight these areas as potentially deserving of targeted intervention.

The second striking feature of the responses was the emotional reaction of the respondents to errors, their willingness to take responsibility for errors, and their attempts (suc-

TABLE II.

Proposed Classification System for Errors in Otolaryngology, Number of Errors Reported in Each Category, Major Morbidities and Deaths Reported for Each Category.

Error Classification	Primary Errors	Major Morbidity	Deaths
Incomplete or incorrect H&P	3 (1.4%)	1 (33%)	
Patient withheld information	1	1 (100%)	
Physician error in history or exam	2	0 (0%)	
Incorrect differential or final diagnosis	3 (1.4%)	3 (100%)	
Errors in testing	22 (10.4%)	9 (41%)	
Wrong test ordered inadvertently	3	2 (67%)	
Test results incorrect			
Specimen lost/test not done	6	3 (50%)	
Results interpreted or labeled incorrectly	5	3 (60%)	
Results not received by MD	7	1 (14%)	
Results received by MD, but not acted on	1	0 (0%)	
Errors in surgical planning	21 (9.9%)	10 (48%)	
Wrong facility	2	0 (0%)	
Administrative scheduling	3	0 (0%)	
Tests/consults incomplete, personnel not available	10	4 (40%)	
Preoperative judgment	6	6 (100%)	
Wrong site surgery	13 (6.1%)	7 (54%)	
Wrong patient	3	1 (33%)	
Wrong organ	3	2 (67%)	
Wrong side	2	1 (50%)	
Incomplete surgery	3	3 (100%)	
No consent/identification band	2	0 (0%)	
Anesthesia errors	7 (3.3%)	6 (86%)	1 (14%)
Drugs	3	2 (67%)	
Technical	4	4 (80%)	1 (25%)
Wrong drug or dilution of drug on operative field	8 (3.8%)	2 (25%)	
Technical errors	41 (19.3%)	23 (56%)	
Endoscopic sinus surgery	7	7 (100%)*	
Cranial and other nerves	13	8 (62%)†	
All other technical errors	21	8 (38%)	
Retained foreign body	2 (0.9%)	0 (0%)	
Equipment-related errors	20 (9.4%)	6 (30%)	
Not available in the ED/hospital	3	0 (0%)	
In the operating room			
Equipment not available in operating room	6	2 (33%)	
Equipment not sterilized	1	0 (0%)	
Cautery injury	4	1 (25%)	
Miscellaneous equipment	6	3 (50%)	
Errors in postoperative care	18 (8.5%)	6 (33%)	6 (33%)
Postoperative death, unknown etiology	4		4 (100%)
Medication errors	4	2 (50%)	2 (50%)
Orders not carried out	5	2 (40%)	
Postoperative patient instructions incorrect	4	1 (25%)	
Miscellaneous postoperative	1	1 (100%)	
Medication errors (not in perioperative period)	29 (13.7%)	3 (10%)	
Involving allergy sera	8	1 (12%)	
Medication with known allergy/contraindication	11	0 (0%)	

TABLE II.
Continued

Error Classification	Primary Errors	Major Morbidity	Deaths
Adverse reaction (unpredictable)	5	1 (20%)	
Wrong medication/dose (other)	5	1 (20%)	
Nursing/ancillary error	1 (0.5%)	0 (0%)	1 (100%)
Administrative errors	14 (6.6%)	0 (0%)	
Charting/filing	4	0 (0%)	
HIPAA/insurance/billing	6	0 (0%)	
Miscellaneous	4	0 (0%)	
Communication errors	8 (3.8%)	2 (25%)	1 (12.5%)
Physician to patient	4	1 (25%)	
Physician to physician	3	1 (33%)	1 (33%)
Pager off	1	0 (0%)	
Miscellaneous errors	2 (0.9%)	0 (0%)	
Total reported errors	212 (100%)	78 (37%)	9 (4.2%)

Percentages are number of primary errors in a category relative to total number of primary errors (212). Contributing, or secondary, errors are not shown. Major morbidity is defined as modified NCC MERP categories F, G and H (See Table III): injuries requiring additional hospitalization, surgery or anesthetic, causing permanent injury, or requiring intervention to preserve life. Deaths are not included in the number of major morbidities.

* An eighth ESS-related error with major morbidity was classified as an error of preoperative judgment.

† If facial palsy of prolonged duration, but which ultimately resolves, were included, the major morbidity for nerve-related harm would be 12/13 (92%).

successful and unsuccessful) to implement changes that would prevent recurrence. These findings are being analyzed in a separate manuscript.

Human Subjects

This study was approved by the Children's Hospital Boston Human Investigations Review Committee.

RESULTS

Response Rate and Error Reporting Rate

The overall response rate was 466 from 2,500 (18.6%) mailed surveys. Two hundred fifty-six (55%) respondents reported no error in their practice in the last 6 months; 210 (45%) reported an error. Three physicians reported a

TABLE III.
Definition of Levels of Harm. NCC MERP Index for Categorizing of Medication Errors, With Added Definitions for the Current Study.

Category	NCC MERP Definition	Additional Definitions for the Current Study
No error	A	Circumstances or events that have the capacity to cause error
No harm	B	An error occurred but did not reach the patient ("an error of omission" does reach the patient)
	C	An error occurred that reached the patient but did not cause harm
	D	Error reached the patient, and required monitoring to confirm that no harm resulted and/or required intervention to preclude harm
	E	Error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
Harm	F	Error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
	G	Error occurred that may have contributed to or resulted in permanent patient harm
	H	Error occurred that required intervention necessary to sustain life
Death	I	Error occurred that may have contributed to or resulted in the patient's death

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total of six additional errors. Because our goal was to gather as many events as possible, we included these, giving a total of 216 events. Two physicians answered “yes” (that they had experienced an error) but left the rest of the form blank. Two more events were considered by both reviewers to have no identifiable error component, leaving a total of 212 analyzable error reports.

Demographics of Affected Patients

The mean age of affected patients was 40.5 (SD 23) years, with a range of 6 months to 82 years. The median age was 45 years old. Of responses that identified the patient’s sex, 95 were males and 94 females.

Demographics of Respondent Otolaryngologists

Table IV presents the respondents’ demographics. Otolaryngologists were more likely to report errors if they were under 50 years of age ($P = .002$) or had been in practice less than 20 years ($P < .001$). Practice structure (e.g., solo vs. group) and financial structure (e.g., salaried vs. fee-for-service) were not significant.

Classification System

A classification (taxonomy) of reported errors was developed on the basis of an idealized “care flow” of a patient (Tables I and II). Using this system, errors were categorized according to whether they occurred during evaluation and diagnosis, surgical management, or medical (nonsurgical) management. Major and subcategories were constructed within each of these realms.

Errors in History and Physical Examination

Errors in the history or performing the physical examination were 1.4% of all errors. An example of an incorrect physical examination was a respondent who did not appreciate that a patient had a prior canal wall down mastoid surgery in the office and discovered this at surgery.

Errors in Diagnosis

Errors of differential or final diagnosis accounted for 1.4% of all errors. All three cases led to major morbidity. A typical example was the clinical diagnosis of nasal polypsis (without biopsy) in a patient who ultimately proved to have an inverting papilloma.

Errors in Testing

Errors in testing were 10.4% of all errors. Half of these errors occurred in the otolaryngologist’s office, where incorrect tests were ordered inadvertently (3 cases) or reports not reviewed or acted on by physician (8 cases). The other half occurred in the laboratory, where specimens were lost and results interpreted incorrectly or labeled incorrectly (right/left).

The most common error was the filing of abnormal reports without physician review, which resulted in harm to four of the seven affected patients. Also common were loss of specimen or failure to complete the test (6 cases) and errors in labeling or interpretation of tests (5 cases). Nine testing errors led to major morbidity. In one case, an office staff member attempting to order a plain radiograph from a computerized menu inadvertently ordered a study

TABLE IV.
Demographics of 466 Respondents.

	No Error Reported	Error Reported	P value
Age of physician			
Less than 40 years	21 (42%)	29 (58%)	
40 to 50 years	46 (38%)	74 (62%)	
Older than 50 years	96 (59%)	67 (41%)	.002
Years in practice			
Less than 10 years	23 (40%)	34 (60%)	
10 to 20 years	31 (34%)	61 (66%)	
More than 20 years	85 (63%)	50 (37%)	<.001
Practice type (I)			
Solo	61 (56%)	47 (44%)	(All groups) .19 (NS)
Otolaryngology group	59 (45%)	73 (51%)	
Multispecialty group	24 (51%)	23 (49%)	
Other	0	0	
Practice type (II)			
Private fee for service	34 (61%)	22 (39%)	(All groups) .19 (NS)
Salaried HMO	4 (67%)	2 (33%)	
Academic	19 (45%)	23 (55%)	
Military	3 (60%)	2 (40%)	
Other	3 (75%)	1 (25%)	

NS = not significant.

Not all responders answered all questions.

requiring a general anesthetic in a young child. In another case, radiology failed to appreciate a small synchronous tumor in the contralateral sinus.

Errors in Surgical Planning

Errors in surgical planning (9.9%) included administrative errors (patients scheduled at the wrong time), failing to ensure that all studies were complete, and errors in surgical judgment in the preoperative period. One patient underwent major ablative surgery while a radiologic result was pending. The report, which showed untreatable metastatic disease, would have led to cancellation of the surgery. Another surgeon elected, for logistic reasons, to proceed with the second stage of a reconstructive procedure despite a minor local infection; the distal flap died, and the result was unsatisfactory. In the subcategory of errors in preoperative judgment, all six reported cases caused major morbidity.

Wrong-Site Surgery

There were 13 (6.1%) occurrences of actual or potential wrong site surgery. Two cases were recognized and corrected after the wrong patient was anesthetized but before the surgical start. One patient entered the OR without consent and one without an identification band. Three others had only part of the planned procedure (e.g., removal of only 1 of 2 oral cavity lesions). Six patients had incorrect procedures. One patient had the wrong skin lesion sprayed with liquid nitrogen. One patient had a tonsillectomy in addition to the planned tympanostomy tubes and adenoidectomy. One had a uvulectomy in addition to the planned tonsillectomy. Two cases involved laterality: one patient had the wrong vocal cord injected with gelfoam. One child had a cochlear implant placed in an ear that had he was still using for sound localization. Two respondents specifically mentioned time pressure in a busy surgical center as contributing to bringing the wrong patient into the OR.

Anesthesia-Related Errors

Errors occurred in the administration of anesthesia (3.3%), involving both medications (propofol given to a patient with a sulfa allergy) and anesthesia procedures (perforation of the esophagus during intubation with prolonged hospital stay).

Drugs Administered from the Surgical Field

There were eight (3.8%) errors in the use of an incorrect drug or dilution on the surgical field. Five of these involved the inadvertent injection or placement of 1:1,000 epinephrine. Four of these resulted in arrhythmias, including at least one episode of ventricular tachycardia.

Technical Errors

Technical errors were by far the largest single category (19.3%). Seven injuries related to endoscopic sinus surgery (ESS) were reported: blindness (2 cases), medial rectus injury (1 case), cerebrospinal fluid (CSF) leak/brain herniation (3 cases), and meningitis (1 case). Also reported were 13 injuries to cranial and other major nerves: VII (4 cases), X (1 case), XI (3 cases), XII (1 case), mental (1 case),

lingual (1 case), recurrent laryngeal (1 case), and sympathetic chain (1 case). There were two violations of the labyrinth and two unsatisfactory rhinoplasty outcomes. No other technical issue was reported more than once. Overall, 56% of technical errors led to major morbidity. However, 100% of ESS-related technical errors and 67% of nerve injuries caused major morbidity.

An eighth ESS-related injury occurred in a patient who had prior trauma to the face. The respondent specifically stated that his/her primary error was in preoperative judgment and preparation. As per our study design, we accepted this interpretation and classified this report within "preoperative judgment." One ESS-related injury (CSF leak) occurred in a patient with inflamed sinuses, polyposis, and excessive bleeding. The remaining six ESS-related injuries were not reported to have abnormal anatomy or excessive technical difficulty. Facial palsy of several months duration does not meet our criteria for "major morbidity" if it ultimately resolved, but if it were included 12 of the 13 nerve injuries would have been considered to have major morbidity.

Retained Foreign Bodies

Two cases of a foreign body (FB) left in the surgical field were reported. In both cases, the count was reported as correct. In one case, the FB extruded spontaneously; in one case it was noted and removed (from the throat) in recovery. Thus neither met our criteria for major morbidity.

Equipment-Related Errors

There were 25 reports of equipment-related errors. Three of these reports related to hospital wards and the emergency department (ED); a typical example was the lack of equipment to properly manage epistaxis in the ED. Twenty-two equipment-related errors occurred in the OR. There were three recurrent issues. The most common was equipment not being available (3 cases in the hospital, 6 in the OR). For example, the only tracheotomy tray in a surgicenter was being sterilized when a patient needed an emergency tracheotomy. The second was burns from poorly insulated or incorrectly assembled cautery units (4 cases). The third was the failure of complex equipment (4 cases), including an image guidance system for ESS, a coblation unit, a nerve integrity monitor, and a stapler. One respondent had an image guidance system fail and had to abort the planned ESS.

Errors in Postoperative Care

There were 18 reports of errors in postoperative care. There were four patients who died in the postoperative period without a clear etiology. Although it is possible that no error was involved in these cases, we included them because the physicians reported them to us and were obviously concerned that an error of some type might have occurred. Two postoperative deaths were attributed by the respondents to inappropriate narcotic administration, one as an inpatient and one at home. Other typical reports were of restarting Coumadin too soon after ESS, with subsequent bleeding, and leaving a nasal pack after ESS for several weeks, with no long-term morbidity. Four re-

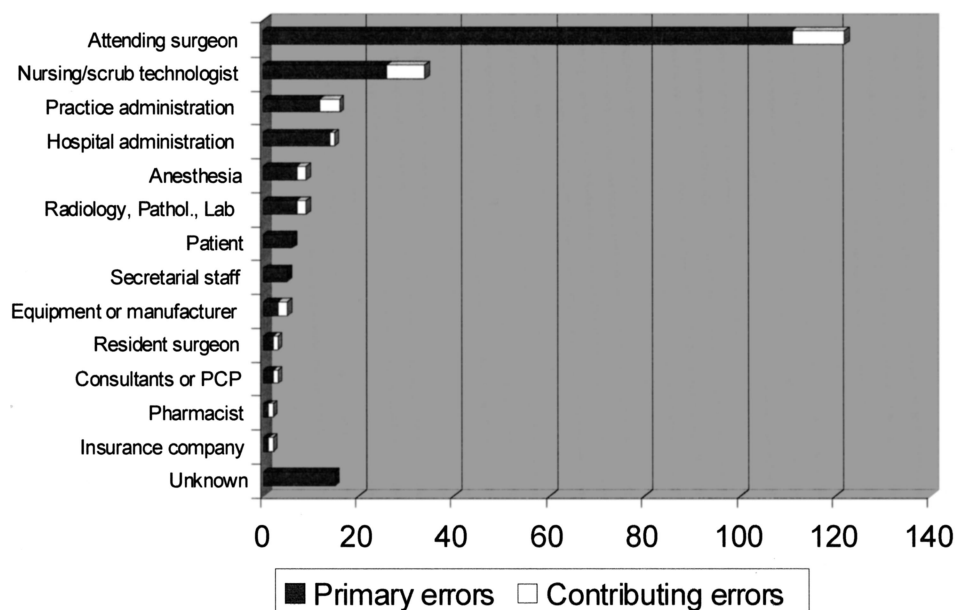


Fig. 1. Responsible agent in reported ORL errors. PCP = primary care physician.

spondents realized after complications occurred that their practice- or hospital-written patient postoperative instructions were incorrect.

Errors in Medical Management (Medication Errors)

We classified errors in purely medical management as a separate category. In theory, this category would include the choice of an incorrect therapy, although no respondent reported this. The 29 reports in this category were all related to medication administration. Only three caused major morbidity. Common themes in medication errors were the administration of incorrect allergy sera to patients (8 cases) and the administration of drugs to which the patient had a known allergy or contraindication (11 cases). Three patients had systemic reactions to the wrong allergy sera; one of these had anaphylaxis. None of the 11 patients who received known contraindicated drugs had major morbidity.

One of the more striking reports was of an elderly patient with limited English who was given a prescription for an ace wrap and received, from the pharmacist, a supply of OxyContin. Her understanding of the pharmacist's instructions was that she should take the OxyContin hourly. Fortunately she returned to the otolaryngologist's office to complain about the excessive cost of the medication, allowing the error to be identified and corrected. The three cases of major morbidity from medication administration were anaphylaxis after allergy serum, severe hypertension after inadvertent administration of IV neosynephrine, and several days of seizures following the injection of bupivacaine in the tonsillar fossae.

Nursing/Ancillary Errors

Only one error was reported that fit into this category. Forced flushing of a central line caused pulmonary embolus and death. However, nursing personnel were in-

involved in other categories of errors (e.g., failure to administer ordered postoperative medications) (Fig. 1).

Administrative Errors

Administrative errors (14 cases) included the crash of a computerized medical records system in a private practice and the loss of 1 month of billing revenues in another practice. There were inordinately lengthy delays in insurance for some cases, such as cochlear implantation. No major morbidity was identified because of administrative errors. However, administrative personnel were involved in other types of errors, for example, the filing of laboratory results before physician review (Fig. 1).

Communication Errors

Communication errors occurred between the physician and patient, nurses, and other physicians. For example, an ED was unable to reach an on-call otolaryngologist for a severe epistaxis because his pager was off and his child had taken their phone off the hook. One death resulted when ED physicians did not contact otolaryngology promptly about a patient with respiratory distress.

Consequences of Reported Errors

Fifty-eight percent of reported errors resulted in harm (Fig. 2). Seventeen percent resulted in minor harm (index E), 37% resulted major morbidity (index F–H), and 4.2% resulted in death (index I). Excluding the two unexplained deaths in the postoperative period and the two deaths cause by perioperative cerebrovascular accidents (CVAs), 2.4% of reported errors resulted in death.

Deaths

There were nine (4.2% of all reports) reports of patient deaths. Two were unexplained deaths in the postoperative period within a few days of discharge. Two were caused by CVAs that occurred during surgery or within 12

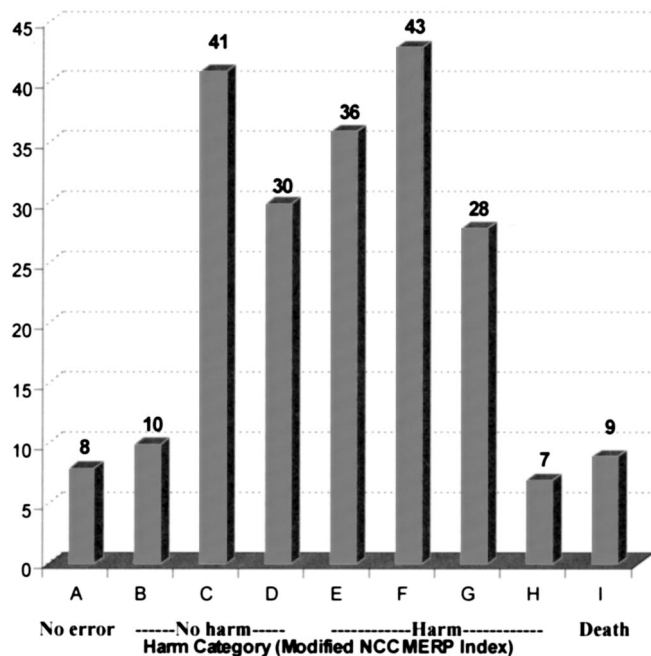


Fig. 2. Number of patients who experienced different levels of harm as a result of reported errors. NCC MERP = National Coordinating Council for Medication Error Reporting and Prevention.

hours after surgery without a clear etiology. Two deaths were attributed by the respondents to narcotic use in the postoperative period (1 in the hospital and 1 at home). One followed the forced flushing of a presumably clotted central venous catheter with pulmonary embolus. One involved failure of ED physicians to promptly consult otolaryngology. One was a failed intubation during induction resulting in an urgent tracheotomy, multiple complications, and ultimately death.

Three of the deaths occurred in patients with obstructive sleep apnea (OSA). One had an intraoperative CVA, one was felt to be caused by narcotic administration, and one was an unexplained death at home in the postoperative period. Two of the deaths occurred in adults with severe developmental delay: one was an unexplained death in the postoperative period, and one was a postoperative death attributed to narcotic use.

Delayed Diagnosis of Cancer

There were seven reports of delayed diagnosis of cancer. Two did not specify the length of the delay. The five reported delays were 2 months, 5 months, greater than 6 months, 8 to 12 months, and 12 months. Primary errors in these cases were considered to be failure to consider the diagnosis (2 cases), errors in testing (4 cases), and failure in communication with patient and primary physician (1 case). In all of these cases, the final outcome was unknown, and therefore all were considered to be harm index level G.

In two of these cases, the primary error was classified as diagnostic. One patient was treated for trigeminal neuralgia. Magnetic resonance imaging (MRI) of the brain

was negative, and nasopharyngoscopy was not performed. He was later found to have nasopharyngeal carcinoma.

In four of these cases, the primary error was related to testing. An example was a fine needle aspirate (FNA) report of suspicious cells filed without physician review.

In the final case, the primary error was classified as related to communication. A patient had a negative FNA of a neck mass and did not return for follow-up despite an enlarging mass.

Contributing Errors

The 21 contributing errors were distributed among history/physical (4 cases), diagnosis (2 cases), intraoperative judgment (3 cases), technical (1 case), equipment (4 cases), postoperative care (2 cases), medical management (2 cases), administrative (1 case), and communication (2 cases). Analysis of these errors added little to the results. One category, intraoperative judgment, is worth mention because there were no primary errors in this category, and it does not appear in Table II. An example of this classification is the otolaryngologist who, after a primary technical error, reported that he made a second error in not promptly calling an intraoperative consultation.

Responsible Agents for Errors

By a wide margin, respondents were most likely to accept personal responsibility for the errors they reported (Fig. 1). In some cases, this may reflect the fact that our survey instrument did not specifically ask who was involved, so respondents may not have told us about a resident's participation in a surgical case. If an error related to the surgeon's function (technical, ordering medication, etc.), and no agent was specified, we attributed it to the attending surgeon. Thus, Figure 1 may overstate the responsibility of the attending physicians. Nonetheless, only three errors were attributed to residents.

There were many different "responsible agents," and with the exception of the attending surgeon, none predominated. In modern otolaryngology, a very large number of individuals contribute to a patient's care and may make mistakes that put the patient at risk.²³

Legal Action

The survey did not specifically ask about legal action. Four respondents reported lawsuits (2 cases) or the threat of lawsuits (2 cases). The classified harm index of these four cases was E, F, G, and I.

DISCUSSION

Rationale for the Study of Medical Errors

It is the authors' belief that the vast majority of otolaryngologists are talented, well trained, and conscientious. The probability of an otolaryngologist erring on any individual decision is minuscule. However, because we all make millions of medical decisions, we will all make many errors during our careers. So will our physicians, nurses, pharmacists, and other health care colleagues. Most errors are made by good or outstanding providers. We applaud the integrity and professionalism of the 210 otolar-

ngologists who described honestly the errors that are the subject of this report.

Because a small error rate is inevitable, we believe, with many others, that error reduction will require understanding when and how errors occur and targeted intervention strategies.^{1,4,20,24–28} The goal of this report is to begin this process in otolaryngology.

Terminology: Errors versus adverse events

A distinction is often drawn between medical errors and adverse events. Calling an event a medical error implies a human failure of some sort. The failure may not be medically or legally culpable and may or may not cause patient harm.^{10,29}

An adverse event is defined as a negative consequence of treatment rather than the underlying disease. An adverse event may be caused by an error or may occur despite the best possible care. By definition, however, an adverse event involves patient harm and is caused by the treatment rather than the disease.^{10,29}

Many medical errors do not cause adverse events; many adverse events occur although no error has been made. However, our data and previous studies^{8,9,18,30} show that many errors do cause adverse events. Our goal was to gather as much information as possible about errors and their consequences. We chose to use the term “error,” but to define it very broadly as any unwanted outcome. We preferred, in this pilot study, to include all events rather than to limit our data with overly exacting definitions.

Limitations of these Data

Every data gathering technique has limitations. Our survey instrument was short and involved mostly free text responses. Almost certainly, the data are biased in several important ways.

First, 55% of the respondents reported no errors in their practice in the last 6 months. We doubt that many otolaryngologists go 6 months without encountering an error. The low reporting rate suggests that most respondent otolaryngologists are not trained to recognize errors. This is an important issue because safety-conscious professions derive much of their safety monitoring data from the analysis of “critical incidents,” in which errors are made, but no harm occurs. It is likely that surgeons need to be similarly educated to see small errors as learning opportunities, rather than wait for a patient injury to address a problem.^{2,31}

Second, 91% of respondents attributed the reported error to a single cause. Almost all errors have several underlying causes.^{15,32} Gawande et al.¹¹ used structured face-to-face interviews with surgeons and found that multiple causes were present for almost all errors. It is likely that a written survey instrument does not facilitate a complete understand of all contributing factors leading to an error.

Third, 37% of the reports involved major morbidity. This suggests that respondents were biased toward reporting incidents that caused harm. To acquire true incidence data and to accurately measure the true proportion

of errors that lead to morbidity will require different measurement techniques.

Fourth, many of our percentages are based on small numbers. For example, if nine deaths are reported in a sample of 466 respondents, the 95% CI for the true number of deaths experienced by a population of 466 otolaryngologists is 9 ± 6 (between 3 and 15). A similar CI for the total of 87 major morbidities and deaths (combined) is 87 ± 16 (between 71 and 103).

Finally, there may be a response bias in which otolaryngologists who experienced a major error were more (or less) likely to respond to the survey. Our response rate was 18.6%, roughly the same rate as the AAO-HNS obtains with other surveys involving other, less charged topics (Nielsen D, Executive Vice President, American Academy of Otolaryngology. Head and Neck Surgery, personal communication). This argues against such a selection bias.

Despite these limitations, we believe that the data offer an opportunity not only to construct a classification system but also to begin to identify high-risk areas within our specialty. Ultimately, error-reporting systems should be more robust and should be based at least in part on computerized extracts from an electronic medical record. Such systems would allow gathering of data with less bias and potentially in real time. This would allow not only global analyses of error patterns but real-time intervention for specific errors.³³

Choice of Classification System

There is no perfect classification system; any organization of data highlights some information at the expense of other information. For example, we received over 40 reports of medication errors. We considered a system in which these were all classified together as “medication errors.” This hid some of the critical information about where the errors occurred. The “care flow” classification, in contrast, allowed us to emphasize the dangers of medication errors at specific points in the patient’s care. For example, there were four medication errors in the postoperative period; 100% caused major morbidity or mortality. On the other hand, 29 occurred during the course of medical management; only 10% caused major morbidity.

The “care flow” classification we developed also led to a much higher agreement between the reviewers in classifying errors. Formal interrater reliability testing could not be performed because the system was developed concurrently with data review.

A potential disadvantage of this system is that the role of a particular service or provider may be hidden. In our data, for example, only one error was considered to be strictly a “nursing/ancillary” error. This may obscure the role of nursing in errors at multiple points in the care flow. We addressed this issue by assigning each error a “responsible agent” and analyzing that data separately.

Characteristics of Respondents

Otolaryngologists were more likely to report errors if they were under 50 years old and had been in practice less than 20 years. Practice structure and reimbursement structure did not affect reporting rates (Table IV). It is

possible that more senior otolaryngologists experience fewer mistakes in their practice; it is also possible that more junior otolaryngologists are more aware of the errors that they encounter or more willing to report them.

Errors are Ubiquitous

The most powerful result is that significant errors happen at all phases of a patient's care (Table II). There is no "magic bullet," no single area where change will eliminate error.¹⁶ Likewise, a multitude of individuals and services are involved in errors (Fig. 1). Although training physicians (or any other single profession) about errors should be beneficial, major strides in safety will likely require educating all those involved in patient care.

Types and Consequences of Errors

Significant errors occurred in every phase of patient care. However, some areas stood out as more commonly reported or more likely to result in major morbidity or mortality. In order of frequency these areas, and our recommendations, are as follows (Table V).

Technical errors: 19.3% of all errors, 56% major morbidity. As others have noted, there is less margin for error when performing surgery around high-risk structures than when prescribing medications.⁹ Half of all technical errors related to ESS or injuries to major nerves, and both these categories had very high morbidity. This is important information because potentially risk-reducing technology is available for both: image guidance during ESS and electrical monitoring of cranial nerves. Neither of these technologies has been proven to reduce injury, and we recommend that the practicing otolaryngologist decide whether to use them on the basis of clinical judgment. Research into the effectiveness of these two interventions should be a priority for our specialty. Cautery burns were frequent, although none caused major morbidity. We recommend checking the cautery meticulously for assembly and insulation and consideration of the use of a disposable cautery.

Medication errors (during medical management): 13.7% of all errors, 10% major morbidity. The most common event was prescribing a medication that a patient had a known allergy to; however, none of these events resulted in major morbidity. Two were recognized by the patients and two by the pharmacists. This speaks to the value of involving other health care professionals and the patient in detecting safety problems.^{34,35}

The second most common theme was eight injections of incorrect allergy sera. Three patients had reactions; one had anaphylaxis. Although not a cause of major morbidity in this study, this error is one that would be seen by the public as indefensible. We suggest a two-step process in which two staff members, or one staff member and the patient, confirm the correct sera before administration. After a possible misadministration, one respondent instituted a new policy requiring each patient to check his own vial before injection.

Errors related to testing: 10.4% of all errors, 41% major morbidity. Errors were distributed through all phases of testing. Incorrect tests were ordered inadvertently, specimens were lost, errors were made by radiology and pathology, and results were filed without physician review. Four cases of delayed cancer diagnosis were considered to be caused by testing issues. Because errors happen at multiple points, there is no simple solution. We recommend that every practice develop and maintain a system for ensuring that (1) ordered tests are completed and (2) results are reviewed by the physician.

Errors in surgical planning: 9.9% of all errors, 48% major morbidity. Some of these errors were administrative: telling the patient the wrong time for surgery or scheduling the patient in an inappropriate facility. None of these had major morbidity, although some required canceling surgery.

Sixteen of these errors related to going forward with surgery before having all consults, tests, and appropriate personnel in place or with errors in judgment about the procedure or medical management. Ten (63%) of these

TABLE V.
Top Ten Safety Recommendations.

1. ESS is a potentially high-risk surgery. The use of image-guidance has not been proven to reduce injury but may be considered.
2. Cranial and other major nerves are potential high-risk structures. Nerve monitoring has not been proven to reduce injury but may be considered.
3. Check cautery meticulously for intact insulation. Consider using a disposable cautery.
4. Ensure that allergy sera are clearly labeled and checked before administration. Have a second staff member or the patient confirm that the correct vial is used.
5. Develop and maintain a tracking system to ensure that the correct test is ordered, completed, and the results reviewed.
6. Have all consults, tests, and personnel in place prior to surgery. If there are relative contraindications to elective surgery, consider carefully before going forward.
7. When sophisticated equipment fails, it may be difficult to fix immediately. Have appropriate support for equipment and if possible test equipment prior to induction.
8. The perioperative and postoperative period is a high-risk interval. Risk factors for postoperative death may include narcotic use, developmental delay, and OSA.
9. Be aware of the potential for wrong site/wrong patient surgery, particularly in busy settings. Initial the surgical site and have a "time out" at the beginning of each procedure.
10. Eliminate concentrated epinephrine from the surgical field.

cases resulted in major morbidity. All six reports of error in preoperative judgment resulted in major morbidity. We recommend that the otolaryngologist be meticulous in surgical planning and ensure the completeness of all appropriate studies.

Equipment-related errors: 9.4% of all errors, 30% major morbidity. The common themes were unavailability of equipment (both in ED/hospital and in OR), cautery burns, and failure of complex equipment. Otolaryngology is an extremely equipment-dependent specialty. An otolaryngologist may use an array of complex devices on a typical day in the OR. We recommend ensuring that equipment is checked frequently, personnel are trained in maintenance, and verifying function of complex equipment function before patient induction.

Postoperative errors: 8.5% of all errors, 33% major morbidity and 33% mortality. Six of the nine reported deaths occurred in the perioperative or postoperative period. Four of these deaths did not clearly involve an error: two CVAs that occurred intraoperatively or within 12 hours postoperatively and two unexplained deaths at home shortly after hospital discharge. Two were felt by the respondent to be related to narcotic use. Of the six deaths in the postoperative period, two patients were adults with developmental delay and three had OSA. The deaths in these individuals did not have obvious common causes. Although these are very small numbers, we recommend that otolaryngologists be particularly vigilant when managing patients with developmental delay and OSA in the postoperative period.

Wrong-site surgery: 6.1% of all errors, 54% major morbidity. This is one of the areas of medical error that has received the greatest coverage in the lay press. Rightly or wrongly, it is perceived as indefensible by most of the public. The term wrong site is more accurate than wrong side because these errors can involve operating on the wrong patient, on the wrong organ, or on the wrong side. This was reflected in our data; only two reported cases involved laterality. We included in the “wrong-site surgery” category one case of a patient arriving in the OR without an identification band and one of a patient arriving without consent.

None of the reports of wrong-site surgery had catastrophic morbidity: there were four unnecessary anesthetics, an unnecessary incision, the unnecessary cautery of a benign skin lesion, the injection of the wrong vocal cord, an unplanned uvulectomy, an unplanned tonsillectomy, and the loss of a barely serviceable but hearing ear. Nonetheless, every instance of wrong-site surgery represents a potential catastrophe.

In a system where millions of operations are performed annually, and surgeons are pressured to produce high volumes, these events are real threats. The problem has been successfully addressed in some settings. Protocols that require the surgeon to initial the operative site, and to have a “time out” in which nursing, surgery, and anesthesia confirm the planned procedure before induction have been extremely successful in reducing wrong-site surgery in the Veterans Administration hospital system (Bagian J, Veterans Affairs National Center for

Patient Safety, personal communication). We recommend that all otolaryngologists follow such protocols.

Drugs on the surgical field: 3.8% of all errors, 25% major morbidity. Five of these eight reports involved concentrated epinephrine on the surgical field being inadvertently injected (3 cases), applied topically (1 case), or being caught just before injection (1 case). One case caused (successfully treated) ventricular tachycardia. Although it is rare, concentrated epinephrine has caused patient death.³⁶ We believe that expecting a single individual to dilute this drug on the surgical field without ever making an error is unrealistic. Similar problems have been reported with dilution of other agents.³⁷ At Childrens Hospital Boston, as a direct result of these data, we have eliminated concentrated epinephrine from the surgical field. Pharmacy predilutes epinephrine, which is stored for up to a week in our medication dispensing cabinets. Other potential solutions are the use of lidocaine with epinephrine for injection and oxymetazoline for topical application.

A Need for Specialty-Specific Error Classification

Our classification system is very different from those developed in family practice¹² or anesthesia.¹⁸ Generalized systems exist that attempt to categorize all human error as to underlying cause, cognitive error, contributing factors, etc.¹⁵ Such classifications should be familiar to all physicians. However, for immediate application within a particular specialty, we suggest that specialty-specific classifications are necessary. The experience in anesthesia in particular strongly suggests that specialty-specific research and targeted interventions can improve safety within a particular specialty.^{18,20,21}

Responsible Agents

The preponderance of attending surgeons as responsible agents argues that otolaryngologists, as most physicians, have what Bates and Gawande¹ call “a fierce ethic of personal responsibility.” We have suggested elsewhere²³ that personal responsibility is an extremely positive trait in physicians and surgeons but is not by itself sufficient to construct a safe system. The conglomeration of personally responsible physicians, nurses, pharmacists, and other providers must be combined in a way that produces a safe system.^{4,38,39}

Lawsuits

The number of lawsuits or threatened lawsuits reported is small relative to the number of errors and the morbidity of the errors. We did not specifically ask whether a lawsuit had been filed, although we suspect that most respondents would have reported a lawsuit when asked about consequences of the error. Other studies have shown that few errors or adverse events result in legal action.⁴⁰ The harm indices for these four cases were E, F, G, and I, which was above the average harm index for all reports (Fig. 2). However, the numbers are too small to draw conclusions.

The IOM Report: Fact or Fantasy?

The IOM report, *To Err is Human*, summarized the best available data and estimated that from 44,000 to 98,000 patients die from medical error in the United States annually.⁴ It would be inappropriate to extrapolate our data across all physicians, both because of the limitations of our data and because different specialties undoubtedly have different error and mortality rates. As an exercise, however, projecting our data to approximately 890,000 physicians in the United States suggests that at least $(5 \text{ deaths}) \times (890,000/466) \times 2 \approx 19,100$ patients die annually from medical errors. If the four unexplained deaths are included, the projection is approximately 34,400. This simple “back of the envelope” calculation clearly supports the approximate magnitude of the IOM estimates.

Errors in Otolaryngology: A Problem, and an Opportunity

Although these are not true incidence data, we believe it is reasonable to take the numbers we have gathered as the lower limit of the errors observed by our 466

respondents over a 6-month period. If this is true, because there are approximately 7,800 otolaryngologists in the United States (Nielsen D, personal communication), and this study covered a 6-month period, there are at least $78 \times 7,800/466 \times 2 \approx 2,600$ error-related major morbidities and at least $5 \times 7,800/466 \times 2 \approx 165$ error-related mortalities in otolaryngologic patients in the United States annually. Many of these could likely be prevented with modern error-reduction strategies. The opportunity for otolaryngology is very large.

CONCLUSIONS

Errors with serious consequences occur in every aspect of patient care in otolaryngology. Reducing errors will require a broad, multifaceted approach. We report a classification system for errors in otolaryngology. This classification system appears to have promise but needs further prospective study, including the assessment of interrater reliability.

Types of errors reported by otolaryngologists differed in important ways from those reported by other specialists. Error classification systems may need to be specialty-specific.

APPENDIX I

Survey Form Distributed to Otolaryngologists (Actual Form was Printed on Both Sides With More Room for Responses).

Dear Colleague:

We are conducting a voluntary survey study to determine the type of medical errors in Otolaryngology. This anonymous survey form is being distributed to a selection of American Otolaryngologists. We would like you, if possible, to describe one error that occurred in your practice in the last 6 months. If you choose to participate, please complete this survey and return in the enclosed envelope. DO NOT INCLUDE YOUR NAME, PATIENT'S NAME, OR ANY IDENTIFYING DETAILS. YOUR RESPONSE IS COMPLETELY ANONYMOUS. Your completion of this form serves as your consent for this data to be used in assessing the types of errors that occur in Otolaryngology.

For the purposes of this survey, “error” is defined broadly as:

Anything that has happened anywhere in your practice (office, hospital, operating room, emergency room, etc) that was not anticipated, should not have happened, and makes you say “I don't want this to happen again.” It can be small or large, administrative or clinical—anything that you feel could be avoided in the future.

Has any such event occurred in your practice in the last 6 months? YES NO

If applicable, please tell us about the most recent such event in your practice:

1. Was a specific patient involved? YES NO

AGE__ Gender: Male Female

2. Please describe the event in as much detail as possible:

3. Was there an adverse consequence to the event? (This may include a health, financial, and/or time consequence, but is not limited to these realms.) YES NO

Please describe the adverse consequence:

4. Was corrective action taken? Was corrective action appropriate? Please describe.

5. Physician demographics (please check):

Your age: <40 years

40–50 years

>50 years

Years in practice: <10 years

10–20 years

>20 years

Practice type (please check all that apply):

Solo

Otolaryngology group

Multispecialty group

Other

Private fee for service

Salaried H.M.O.

Academic

Military

Other

We sincerely thank you for your cooperation

Rahul Shah, MD

David Roberson, MD

Gerald Healy, MD

Children's Hospital Boston and Harvard Medical School

Although this study was not designed to obtain true incidence data, several high-risk areas stood out. We highlight our top 10 recommendations in Table V. Quantitative research on medical errors, and study of techniques to prevent and ameliorate errors, should be a high priority in otolaryngology.

Acknowledgments

The authors gratefully acknowledge the administrative assistance of Jodi Lanza, who was instrumental in preserving the confidentiality of the participants, Jean Connor and Lina Lander for discussions about data analysis, Katrina Chesnulovitch and Trevor McGill for critical comments on the manuscript, Vlad Gankin for database construction and Kimberlee Gauvreau for statistical assistance. This study was made possible by the respondent otolaryngologists' willingness to describe errors in their practice honestly. We thank the respondents for their time and integrity.

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