Patient Safety/Quality Improvement Primer, Part I: What PS/QI Means to Your Otolaryngology Practice

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Abstract
Patient safety/quality improvement (PS/QI) is the cornerstone of 21st-century health care. Otolaryngology—Head and Neck Surgery is excited to provide a dedicated PS/QI primer. The overarching goal for this PS/QI series is to provide a comprehensive and practical resource that assists readers, authors, and peer reviewers in understanding PS/QI research, its unique methodology, and the associated reporting standards for trustworthy performance measures. The target audience includes resident and fellows, faculty from the private sector and academia, and allied health professionals. This inaugural primer reviews PS/QI background as it relates to otolaryngology practice. It explores the history, goals, and development of performance measurement. In addition, it highlights opportunities for integrating PS/QI into otolaryngology practice. Payers will drive patients to quality care based on outcomes. Otolaryngologists have a responsibility to embrace a culture of PS/QI. In doing so, we will define optimal, quality otolaryngology care through objective data and metrics.

Keywords
patient safety, quality improvement, national registry, MIPS reporting

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The vision of the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) is “empowering otolaryngologist—head and neck surgeons to deliver the best patient care.” This fiduciary role to the patient and public prompted the establishment of a dedicated patient safety/quality improvement (PS/QI) platform in Otolaryngology—Head and Neck Surgery. The journal now publishes a biannual PS/QI section, has a slate of editors and peer reviewers with PS/QI expertise, and has established a PS/QI-specific manuscript format reflecting the unique methodology in which PS/QI research differs from conventional investigations.

Recognizing the impact of PS/QI on otolaryngology care and the need for continuing PS/QI education in an era where value increasingly replaces volume as a key health care driver, the deputy editor partnered with members of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) PS/QI Committee and respective PS/QI leaders in the field to establish a dedicated primer. Through a series of conference calls and in-person meetings, the vision, mission, and audience were defined with an outline of topics.

The overarching goal for this PS/QI primer is to provide a comprehensive and practical resource that assists readers, authors, and peer reviewers in understanding PS/QI research, its unique methodology, and the associated reporting standards for trustworthy performance measures. The target audience for the series includes resident and fellows in training, otolaryngology faculty from the private sector and academia, and allied health professionals, including nurses, speech language pathologists, and other advanced practice providers. Topics covered in the ensuing dedicated Otolaryngology—Head and Neck Surgery PS/QI sections will include a broad range—from best practices for conducting clinician-level PS/QI projects to implementing departmental/institutional PS/QI change and managing disruptive behavior. The inaugural issue of this PS/QI primer series opens with a review of the PS/QI background as it relates to

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Table 1. Otolaryngology Patient Safety/Quality Improvement Primary Pearls.

- Patient safety and quality improvement are the cornerstone of 21st-century health care.
- The Institute of Medicine defines high-quality, state-of-the-art health care as safe, effective, patient centered, timely, efficient, and equitable. The goal is to improve patient care and outcomes.
- Patient safety aims to protect patients from harm by preventing errors and promoting a culture of safety.
- Quality improvement is a collaborative effort to enhance health care outcomes.
- Value is defined as health care outcome per dollar spent and is quickly replacing clinical volume as a key health care driver.
- Performance measures are evidence-based numeric quantifiers of health care quality intended to promote safety and quality.
- Understanding performance measures is imperative for otolaryngologists because these measures improve patient care and are now used by policy makers and payers for reimbursement.
- The AAO-HNSF Project Jumpstart utilizes evidence-based clinical practice guidelines to develop otolaryngology-specific performance measures by adapting the key action statements to measurable clinician activity.
- The AAO-HNSF national registry Reg-ent is designated by the Centers for Medicare and Medicaid Services as both a Qualified Clinical Data Registry and a Qualified Registry, thereby supporting Merit-Based Incentive Payment System reporting.

Abbreviation: AAO-HNSF, American Academy of Otolaryngology—Head and Neck Surgery Foundation.

Otolaryngology practice (Table 1). This primer explores the history, goals, and development of performance measurement within otolaryngology—head and neck surgery.

History of PS/QI

PS/QI is far from a modern-day concept. Hospital-based improvements have been documented as far back as the 1850s, when Florence Nightingale initiated hand-washing standards, surgical instrument sterilization, routine changing of bed linens, and utilization of clean water. In 1966, Avedis Donabedian classified health care performance measurement as structural, process, or outcome measures, and this scheme was later applied to surgery.

The Institute of Medicine (IOM) is a nonprofit organization established in 1970 under the umbrella of the US National Academy of Science. As such, it functions outside the framework of the government to provide public health and science recommendations that are evidence based. Nearly 20 years ago, the IOM published To Err Is Human: Building a Safer Health System, thrusting the shortfalls of US health care delivery onto the public consciousness. Within days of the IOM report, the Clinton administration dedicated multiple hearings on Capitol Hill to medical errors, and the US Congress earmarked $50 million to the Agency for Healthcare Research and Quality (AHRQ) for PS research. The 2001 follow-up, Crossing the Quality Chasm: A New Health System for the 21st Century, took an even broader focus on the restructuring of the health care system in an effort to foster innovation and improve the delivery of healthcare. The IOM outlined 6 aims necessary for the delivery of consistent, high-quality, state-of-the-art care in the United States: safe, effective, patient centered, timely, efficient, and equitable.

In response to growing pressures to contain health care costs and improve quality, the Joint Commission instituted in 1997 the first national program in medicine (ORYX Initiative) for reporting quality measures. Initial data were not publicly available, and performance measures were not explicit. Seven years later, the Joint Commission made data available to the public, and the Centers for Medicare and Medicaid Services (CMS) instituted reduced payments to health care facilities failing to report such data. In 2009, President Obama signed the HITECH Act into law (Health Information Technology for Economic and Clinical Health Act), mandating meaningful use of the electronic health record (EHR) to improve quality and safety in the delivery of health care.

These practices set the stage for current quality reporting of value-based reimbursement paradigms. Today, the Joint Commission continues to require reporting of performance measures for hospital accreditation, and the CMS mandates Physician Quality Reporting System (PQRS) use to avoid a 2% payment penalty. The American College of Surgeons’ National Surgical Quality Improvement Program helped advance PS/QI efforts, as has the Accreditation Council for Graduate Medical Education mandate of PS/QI training for graduates.

Differentiating “Safety” and “Quality”

The terms patient safety and quality improvement are often used interchangeably despite carrying distinct meanings (Figure 1). The IOM defines PS as “prevention of harm to patients.” PS efforts emphasize health care systems of delivery that prevent errors, enable learning from errors, and build a culture of safety. Conversely, QI is defined as the result of combined efforts of all parties involved in health care delivery to make changes leading to better patient outcomes. Therefore, QI research is not about developing new treatments but rather ensuring that patients receive the best care available at the time, free from error and iatrogenic harm.

Whereas the modern PS movement focuses on identifying and preventing adverse events that directly affect patients, QI focuses on optimizing all outcomes relating to diagnosis, treatment, and prevention of harm. PS and QI endeavors often work in concert, as illustrated in the operating room QI preoperative checklist, which led to the prevention of patient harm through an associated decrease in

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wrong-site surgery. Last, QI efforts often require large cultural change within a system, whereas PS improvements are often observed on an individual level.

**National Quality Metrics and Performance Measures**

The IOM defines performance measures as “numeric quantification of healthcare quality.” Performance measures promote PS and QI by identifying best practices and by assessing the extent to which clinicians adhere to them for relevant patients. Performance measures are intended for public reporting, quantitative comparisons among health care providers, and pay-for-performance programs. They undergo rigorous validation to ensure that incentives for maximizing scores on quality measures are evidence based and do not compromise patient-centered care. These measures must accurately and efficiently capture the event (structure, process, or outcome) being measured and minimize interventions between the measured parameter and desired “improved” performance, all with little to no chance of unintended adverse consequences.

Understanding performance measures is imperative for otolaryngologists because the measures not only improve patient care but are also now used by policy makers and payers for reimbursement. National quality metrics are utilized by external agencies, such as the CMS and AHRQ, to identify performance variation. Data are compared at multiple strata, ranging from national and regional to facility- and individual-provider levels. If poor measure adherence by clinicians is identified or if variations in care are identified beyond what might occur by chance, incentive programs can be established to target improvement. The goal is to promote best practices by aligning clinical performance with evidence-based best practice utilizing sources such as clinical practice guidelines (CPGs) and systematic reviews.

Public and private payers are increasingly incorporating performance data into incentive programs to promote value-based care. The Merit-Based Incentive Payment System (MIPS) is a component of the Medicare Access and CHIP Reauthorization Act of 2015, which falls under the CMS (Figure 2). MIPS is one example of this push for stronger association between quality measurement and QI. In this program, participants earn performance-based payment adjustments based on evidence-based and practice-specific data relating to quality, improvement activities, advancing care information, and cost.

**Otolaryngology-Specific Performance Measures and Reg-ent**

Performance measures are optimally developed in partnership with national organizations, such as the AHRQ and the American Medical Association Physician Consortium for Performance Improvement, and professional medical societies. Each measure is ideally subjected to rigorous testing and open comment by the developers and may be submitted to the National Quality Forum (NQF) for additional assessment and validation. Quality measures for otolaryngology—head and neck surgery, including those in the PQRS, encompass specialty-specific measures as well as those overlapping with general medicine.

While still in the early stages of performance measure development, the AAO-HNSF has made tremendous advances in developing specialty-specific measures, especially when one considers that only 6 of the original 38 PQRS quality measures were related to otolaryngology (3, acute sinusitis; 1, chronic sinusitis; 2, otitis externa). These advances have been facilitated by dedicated support staff at the AAO-HNSF and an engaged group of clinician volunteers, by integration of measure development with the Academy’s qualified clinical data registry (Reg-ent), and by having an existing collection of evidence-based multidisciplinary CPGs developed with trustworthy methodology that facilities clinician action and performance measurement.

The 2018 MIPS otolaryngology specialty measures currently under development (spring 2018) include 9 otolaryngology-specific measures with associated rationale: age-related hearing loss, allergic rhinitis, Bell’s palsy, benign paroxysmal positional vertigo, dysphonia following thyroideectomy, rhinoplasty, tympanotomy tube otorrhea, vestibular disorders, and cerumen impaction. The Reg-ent Executive Committee and Clinical Advisory Committee prioritized these topics on the basis of their importance, feasibility (eg, availability of codes for data extraction: International Classification of Diseases, Tenth Revision and Current Procedural Terminology), and linkage to existing CPGs. The most updated and detailed description of these quality measures is available from the CMS and on the AAO-HNSF website (Table 2).

Through the AAO-HNSF Project Jumpstart, CPGs are utilized to develop otolaryngology-specific performance measure by adapting the key action statements to
measurable clinician activity. QI has always been the driving force behind recommendations in AAO-HNSF guidelines,17 thereby creating an opportunity for efficient and direct linkage to a corresponding performance measure (or measures) to implement the guideline recommendation. The AAO-HNSF is also pursuing a de novo measure development process that does not require a preexisting guideline, which was the basis for the age-related hearing loss measurement set. All measure development is conducted with external methodology consultants and professional information specialists to maximize validity.

Performance measures are used to quantify how often an evidence-based desired practice is performed15—for example, using tympanometry or pneumatic otoscopy to diagnose otitis media with effusion in children.18 Despite a multidisciplinary evidence-based approach, only one-third of pediatric practices documented adherence to this performance measure,19 and 14% of otolaryngologists surveyed do not adhere to this standard.20 Experience has shown that CPGs may be slow to translate into desired outcomes when practices are entrenched. A 2017 study demonstrated a 3- to 4-fold increased likelihood (odds ratio) of antihistamine, antibiotic, and intranasal steroid administration when otitis media with effusion is diagnosed, despite guidelines to the contrary.21 Such findings underscore the importance of culture change.

National clinical data registries provide an important tool for aggregating robust specialty-specific data and serve as an additional mechanism benchmarking quality assessment and performance measure development. The AAO-HNSF is investing tremendous time and resources into developing the national otolaryngology clinic data registry Reg-ent.22 The registry provides a HIPAA-compliant (Health Insurance Portability and Accountability Act) electronic platform to collect patient outcome data from the private and academic sectors, with the ultimate goal to define and guide best otolaryngology practice. A primary goal of Reg-ent is to minimize the administrative burden of quality reporting for clinicians by mapping relevant fields from the patient’s EHR to the registry fields (eg, numerator and denominator) for the performance measure and then enabling a software interface that either “pushes” relevant data from the registry to the EHR or permits the registry to “pull” the data as needed.

Reg-ent is designated by the CMS as both a Qualified Clinical Data Registry and a Qualified Registry, allowing the registry to support MIPS reporting (Figure 2). The utility of a specialty-specific registry such as Reg-ent is that it reaches beyond performance measure development by providing a platform for dedicated otolaryngology PS/QI research and an opportunity for Maintenance of Certification. The registry can also prioritize the needs for new measures by identifying existing gaps in clinical care and can function as an ideal testing ground for new measures before submission to the CMS or the NQF. The NQF is a nonprofit organization established in 1999 by the president’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The mission of the NQF is the promotion of PS and quality health care through measurement and public reporting. Ultimately, the Reg-ent focus on QI and patient outcomes provides an essential tool poised to advance outcomes in our field. With robust participation, our specialty will be at the forefront of defining quality in otolaryngology, thereby ensuring that measures are appropriate and truly improve patient care.

Additional opportunities for de novo measure development include partnership with otolaryngology subspecialty societies. Examples include global safety measures to reduce mortality and morbidity secondary to surgical site infection, pneumonia or organ system insult, hemorrhage requiring transfusion, reintubation, reoperation, or readmission.23 Otolaryngology procedure-specific outcomes can assess effectiveness, such as improvement in hearing following tympanoplasty, relief of nasal obstruction after
Table 2. 2018 Quality Clinical Data Registry Specialty-Specific Measures Available to Reg-ent Members.16

<table>
<thead>
<tr>
<th>Measure Description</th>
<th>AAO Measure Number</th>
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<tbody>
<tr>
<td>Otitis media with effusion</td>
<td>AAO 8</td>
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<tr>
<td>Avoidance of inappropriate antihistamine/decongestant use</td>
<td></td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 11</td>
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<tr>
<td>Avoidance of topical intranasal corticosteroids</td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 20</td>
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<tr>
<td>Hearing test</td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 21</td>
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<tr>
<td>Audiometry of chronic OME in children</td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 26</td>
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<tr>
<td>Diagnostic evaluation—assessment of TM mobility</td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 27</td>
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<tr>
<td>Resolution of OME in children (outcome measure)</td>
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<tr>
<td>Otitis media with effusion</td>
<td>AAO 28</td>
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<tr>
<td>Resolution of OME in adults (outcome measure)</td>
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<tr>
<td>Cerumen impaction</td>
<td>AAO 15</td>
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<tr>
<td>Percentage of patients with CI and suggestive history of nonintact TM who receive just manual removal</td>
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<tr>
<td>Cerumen impaction</td>
<td>AAO 18</td>
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<tr>
<td>Percentage of patient visits with hearing aids where otoscopy is routinely performed</td>
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<tr>
<td>Allergic rhinitis</td>
<td>AAO 22</td>
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<tr>
<td>Percentage of patients with AR who do not receive sinonasal imaging for allergic rhinitis</td>
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<tr>
<td>Allergic rhinitis</td>
<td>AAO 23</td>
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<tr>
<td>Percentage of patients with AR who are offered intranasal corticosteroids or oral antihistamines</td>
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<tr>
<td>Allergic rhinitis</td>
<td>AAO 24</td>
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<tr>
<td>Percentage of patients with AR who do not receive leukotriene inhibitors</td>
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<tr>
<td>Allergic rhinitis</td>
<td>AAO 25</td>
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<tr>
<td>Percentage of patients with AR who do not receive IgG-based immunoglobin testing</td>
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<tr>
<td>Age-related hearing loss</td>
<td>AAO 16</td>
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<tr>
<td>Audiometric evaluation for older adults with HL</td>
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<tr>
<td>Age-related hearing loss</td>
<td>AAO 17</td>
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<tr>
<td>Avoidance of advanced diagnostic imaging of bilateral presbycusis or symmetric SNHL</td>
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<tr>
<td>Age-related hearing loss</td>
<td>AAO 19</td>
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<tr>
<td>Shared decision making for treatment options for bilateral presbycusis or symmetric SNHL</td>
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<tr>
<td>Bell's palsy</td>
<td>AAO 13</td>
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<tr>
<td>Inappropriate use of MRI or CT (inverse measure)</td>
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<tr>
<td>Bell's palsy</td>
<td>AAO 14</td>
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<tr>
<td>Inappropriate use of antiviral monotherapy (inverse measure)</td>
<td></td>
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<tr>
<td>Tympanostomy tubes</td>
<td>AAO 12</td>
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<tr>
<td>Topical ear drop monotherapy for children with acute tympanostomy tube otorrhea</td>
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Abbreviations: AR, allergic rhinitis; CI, cerumen impaction; CT, computed tomography; HL, hearing loss; MRI, magnetic resonance imaging; OME, otitis media with effusion; SNHL, sensory neural hearing loss; TM, tympanic membrane.

Incorporating PS/QI into Everyday Otolaryngology Practice

Engagement in the PS/QI process is driven by the collective desire to deliver quality care. The pursuit of practice-based learning and improvement remains core to a physician’s being—the continual assessment and evaluation of patient care practices based on one’s experience and the assimilation of scientific evidence. While this characteristic is an innate part of all physician identity, incorporating PS/QI into daily practice requires conscious, dedicated effort and resource allocation. Opportunities need to be created to periodically collect and reflect on PS/QI metrics, ultimately driving change and health care improvement.

Change management in health care, whether aimed toward PS or QI, requires a unique skill set beyond the traditional medical knowledge and patient care emphasized during medical school and residency training. Advanced development of the other core competencies may prove more important to leading PS/QI change.28 For example, systems-based practice can focus on understanding systems theory and analysis as well as providing cost-conscious and effective care. Medical economics and health care policy education enable one to switch from task execution to big picture thinking. Interpersonal/communication skills can include training that emphasizes empathy and understanding of cultural and economic diversity. Conflict management skills, training on effective performance feedback, improving emotional intelligence and self-awareness, and professionalism are equally important.

At the most basic individual physician level, PS begins with the application of up-to-date knowledge in medical and surgical patient care. Historically, most PS improvements have been triggered by an adverse patient event. The M&M conference utilized by most academic otolaryngology departments is a practice that initially arose in the field of general surgery during the early 20th century as a means to learn from errors. Participation in M&M and similar PS reviews are a required component of residency training as mandated by the Accreditation Council for Graduate Medical Education.29 While M&M has been extensively utilized as a practice-based learning tool in academia,
adoption outside of graduate medical education is growing. Large medical hospitals and medical groups may hold similar M&M conferences. Smaller otolaryngology physician groups may formally or informally review issues as a regular part of their business meeting. Ultimately, the cases addressed in M&M can become the nidus for change.30

Historically, M&M fostered a mind-set centered on discovering and correcting individual physician error, and the analysis often led to physicians perceiving errors as a failure of their personal responsibility, resulting in solutions that emphasize change in personal practice.

However, errors and adverse events arise primarily from complex, poorly functioning systems of health care delivery. As noted in the aforementioned IOM reports and illustrated by British psychologist James Reason’s “Swiss cheese” model,31 PS/QI efforts must shift away from individual blame to the recognition of system failures facilitating medical errors. Many medical errors never reach the patient, and errors that do reach the patient may not cause discernible harm (Figure 3). Not all adverse events are the result of error, and only a small subset of these adverse events is attributable to a single provider’s negligence or unacceptable performance. Ultimately, systems-based approaches apply the greatest opportunities for improving safety and quality.

Meaningful PS/QI improvement necessitates infrastructure and process modification to prevent adverse events. Hospital enterprises are accustomed to developing and implementing such strategies, utilizing formal QI teams well versed in the design and coordination of QI initiatives. Engagement in change requires coordination among stakeholders, time investment, alignment with management, and cultivation of a culture for safety and quality. For this reason, many departments and clinics specifically identify a PS/QI officer.

While PS/QI concepts are sometimes elusive and burdensome, many practical ways exist to incorporate quality and process improvement initiatives into individual and group practice. The AAO-HNSF provides an anonymous online PS event reporting tool aimed at identifying and prioritizing otolaryngology PS/QI opportunities.32 As outlined here, Reg-ent provides an electronic platform for reporting quality metrics through the EHR. This national registry provides the unique opportunity to assess one’s practice performance with respect to national standards and to develop meaningful, personalized QI initiatives. In both examples, the strength and utility of the platform are directly linked to member participation. Given the increasing emphasis of pay for performance, otolaryngologists must work in concert to define and ultimately own what is meaningful “quality” for patients and the specialty.

The role of surgeons in driving overuse has received increased scrutiny in recent years.33 Embracing tangible transparent measures to monitor quality of care over time is critical for otolaryngologists. Practice efficiency includes evaluation of procedural and resource utilization (number of surgical cases vs outpatient visits), wait time from registration to provider in room, or length of surgical times for commonly repeated procedures. Common measures of access and equity include time to next available appointment and feasibility/time to obtain diagnostic testing.34,35 Risk mitigation and safety measures may be addressed in the perioperative environment by utilizing presurgical time-outs, performing postoperative debriefs with the surgical team, and providing detailed standardized informed consent.

While PS/QI originated in the hospitalized setting, the ambulatory setting is gaining appropriate increased awareness. Noting that the majority of health care is rendered in this setting, the AHRQ recently requested a technical brief

to elucidate the scope of ambulatory safety issues and interventions.\textsuperscript{36} Ambulatory safety concerns include medication safety, safety culture, transitions among providers, timely and accurate diagnosis (to include issues arising from referrals from one provider to another), and management of test results. Patient engagement and timely, accurate diagnosis were identified as safety research gaps specific to the ambulatory setting, which warrant future attention.

**Conclusion**

PS/QI is the cornerstone of 21st-century health care and the future for otolaryngology–head and neck surgery. Otolaryngology–Head and Neck Surgery is excited to lead in promoting PS/QI for our field with a dedicated educational PS/QI primer on research and performance reporting. Part 1 of this series provides the historical context for PS/QI and is a resource for information on national quality metrics and otolaryngology-specific performance measures. In addition, it highlights opportunities for integrating PS/QI into one’s otolaryngology practice. Ultimately, payers will drive patients to quality care based on outcomes. Otolaryngologists have a responsibility to embrace a culture of PS/QI. In leading this discussion, we will define optimal quality otolaryngology care through objective data and metrics.

**Author Contributions**

Ceccelia E. Schmalbach, design, substantial contribution, revisions, final approval, accountable for all work; Michael J. Brenner, design, substantial contribution, revisions, final approval, accountable for all work; C. W. David Chang, design, substantial contribution, revisions, final approval, accountable for all work; Emily F. Boss, design, substantial contribution, revisions, final approval, accountable for all work; Julie L. Goldman, design, substantial contribution, revisions, final approval, accountable for all work; Richard M. Rosenfeld, substantial contribution, revisions, final approval, accountable for all work.

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