



Quality in Otolaryngology: History, the Current State, and Possible Future Developments

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Abstract

Purpose of Review To help clinicians gain an understanding of quality improvement (QI) and value-based care (VBC) in healthcare, with a specific emphasis on otolaryngology. This review also attempts to examine the future landscape of QI and VBC, and emphasize the need for active physician participation.

Recent Findings Many efforts are underway to help define quality otolaryngologic care including otolaryngology-specific reporting measures, clinical practice guidelines, and a large, specialty-specific patient database (Reg-ent). Certain subspecialties (facial plastics and laryngology) and populations are underrepresented in the current literature.

Summary QI and VBC will become increasingly important as more alternative payment models (APMs) are investigated and implemented by governmental and commercial payors. Physician participation will be integral in ensuring appropriateness of these APMs, specifically with regard to defining quality care and optimizing value for patients.

Keywords Quality improvement · Patient safety · Value-based care · Otolaryngology

Introduction

The National Academy of Medicine defines quality in medicine as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes, and are consistent with current professional knowledge and best practices. The definition includes 6 aims that are necessary for quality healthcare delivery: patient-centered, safe, effective, timely, efficient, and equitable. Quality improvement (QI), therefore, is the outlined framework that can be utilized to systematically and methodically improve healthcare. By defining quality improvement, processes and structures can be standardized to create a common language around methodology, reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations.

Quality improvement, patient safety (PS), and value-based care (VBC) are often considered synonymous and

used interchangeably. However, it is important to consider each of these entities as separate definitions that are intimately related (Fig. 1). Patient safety specifically relates to the prevention of harm to patients, and emphasizes avoiding and learning from errors as well as building a safety culture. While this is an important facet of quality healthcare, patient safety does not incorporate all of the aspects related to providing the best care available in an equitable and efficient manner. Conversely, VBC is defined as the measured improvement in a patient's health outcome for a given cost needed to realize that result. The area where value-based care and quality improvement lack overlap not only includes the economic considerations that go into VBC, but also the development of new technology and therapeutics. QI research is generally not focused on treatment innovation, but rather the delivery of care that adheres to the 6 standards and healthcare that is steeped in current, evidence-based best practices.

VBC is becoming increasingly incorporated into the national conversation as US healthcare costs continue to rise exponentially and our national health outcomes further lag behind many other developed nations. VBC can help align the key stakeholders across the health system: patients, providers, health plans, employers, and government organizations. Primary care value-based reimbursement has

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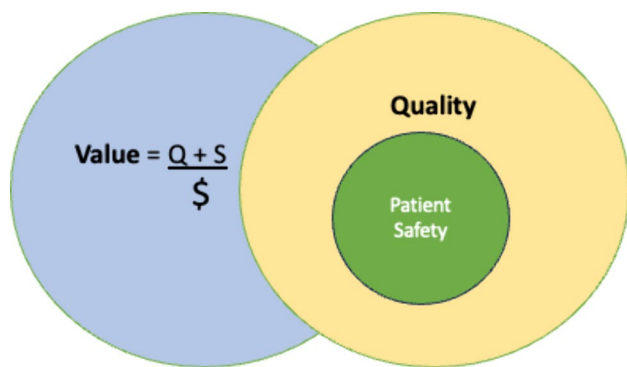


Fig. 1 Venn diagram depicting the relationship in healthcare of value (quality + service/cost), quality, and patient safety

increased from 30 to 40% of all payments across the United States healthcare system between 2016 and 2021, and 83% of payors report a likely increase in alternative payment models in the future [1]. Therefore, it behooves all healthcare providers, including otolaryngologists, to gain a basic understanding of both QI and VBC so we can join in the conversation and help guide the future of US healthcare.

History of Quality in Healthcare

Patient safety can trace its origins back to at least the 1850s when Florence Nightingale standardized methods for infection prevention, such as hand-hygiene techniques, surgical instrument sterilization, the use of clean water, and routine changing of linens for hospital beds [2]. Dr. Ernest Codman introduced the idea of tracking the outcomes of a procedure in order to measure the effectiveness and quality and started the first morbidity and mortality conferences during the 1910s and 1920s. His work served as the basis for what became the American College of Surgeons, as well as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [3]. In 1966, Avedis Donabedian published a lengthy paper with the title “Evaluating the Quality of Medical Care,” which served as the bedrock for the modern study of healthcare quality and medical outcomes research and contained the above-mentioned 6 core tenets of quality care. In 2000 and 2001, the Institute of Medicine published two reports, “To Err Is Human: Building a Safer Health System” and “Crossing the Quality Chasm: A New Health System for the 21st Century,” which became the seminal works that exposed the true magnitude of iatrogenic harm in the US healthcare system and brought it into the national consciousness. To Err is Human estimated that up to 98,000 Americans die in hospitals each year due to medical errors, which is equivalent to a 747 crashing every day, costing our country between \$17 and 29 billion annually. Based on more recent studies, this figure has been felt to be a gross

underestimation of the true measure of harm from medical errors, with some reporting numbers over 250,000 deaths per year [4], with 72,000 from hospital-acquired infections alone [5]. If we factor in outpatient care and misdiagnosis, estimates exceed 795,000 Americans becoming permanently disabled or dying annually [6•].

As the scope of this problem became more evident, several national and government regulatory bodies began instituting quality metrics and reporting to qualify for accreditation and reimbursement. The Joint Commission created the first national program in medicine for submitting quality measures in 1997. They continued to evolve these reporting requirements with multiple specific performance measures in areas such as venous thromboembolism, ortho/spine surgery, and ED performance for current hospital accreditation. The Centers for Medicare and Medicaid Services (CMS) also followed suit by reducing payments to healthcare facilities and physicians failing to report such data through the Hospital Inpatient Quality Reporting Program and the Physician Quality Reporting System (PQRS), respectively. The American College of Surgeons’ National Surgical Quality Improvement Program (NSQIP) and the Commission on Cancer’s National Cancer Database (NCDB) Program are examples where patient level data is standardized and aggregated into large datasets that can then be used to do research, establish and report quality metrics, and allow hospitals to benchmark themselves against peers; all of which are measures that can be utilized for quality improvement.

Current State of Quality in Otolaryngology

Concomitant with the rest of the medical establishment, otolaryngology as a specialty has continued to expand research efforts, and further refine the definition of “quality” otolaryngologic care. A recent systematic review search by Gettelfinger et al. [7•] resulted in a total of 738 otolaryngologic PS/QI research studies identified from 1981 to 2018, with an exponential rise in the number of manuscripts annually (sevenfold increase) when comparing 2010 to 2018. On further review of the manuscript themes and how they fit into the 6 aims for quality care, the majority of the otolaryngology PS/QI publications focused on providing effective care, with 232 of the publications (31.4%) having it as the primary area and 231 additional articles (31.3%) addressing effective care alongside one or more additional aims. Patient safety was the next most common focus, with 221 studies (29.9%) solely addressing PS. Overall, 640 (86.7%) of the studies in the systematic review explored effective care, safety, or both. The authors identified the most neglected research areas, accounting for less than 2% of all the otolaryngology PS/QI publications, were [1] the existence and impact of multidisciplinary care and [2] the investigation

of healthcare disparities. Additionally, facial plastics (3.4%) and laryngology (4.6%) were also identified as subspecialties with a paucity of literature and possible areas of opportunity for further exploration.

The Institute of Medicine also helped create and define the concept of clinical practice guidelines (CPGs), which are “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.” These guidelines synthesize the available evidence through a rigorous and standardized process, and present recommendations in a clear, concise, and unbiased manner. The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) created a process in 2012 built upon the standards for trustworthy guidelines outlined by the Institute of Medicine and the Guidelines International Network [8]. This process has been utilized since that time with the first guidelines on “Bell’s palsy” and “Improving Voice Outcomes After Thyroid Surgery” published in 2013. Since that time, 18 guidelines have been published on multiple different subspecialty topics, with several more in development over the next few years. These documents not only help outline what can be considered “best practice” based on the available evidence, but also highlight knowledge gaps and areas for research to further define “quality” in otolaryngologic care.

As mentioned above, CMS began requiring physicians to report certain standardized quality measures via the PQRS in 2006. These measures are subject to a rigorous process of development, assessment, and validation by the National Quality Forum. In addition to the many standard measures available for physicians to report, the AAO-HNS began developing more otolaryngology-specific measures in 2018 to add to the 7 that are already present in the general pool (2 on acute sinusitis, 2 on obstructive sleep apnea, 1 on appropriate testing for pharyngitis, 1 on referral of dizzy patients for otologic evaluation, and 1 for otitis externa). These were taken from the existing CPGs and, with great effort, put through the rigorous CMS process for approval. Currently, there are 11 more in use that were developed by the AAO with new topics including Bell’s palsy, dysphonia following thyroidectomy, BPPV management, tympanostomy tube management, and hearing tests in patients with chronic otitis media (Table 1). Physicians are not only able to report otolaryngology-specific data, but also gain feedback on their performance compared to their peers, an essential component to improving quality in care delivery. However, the effectiveness of this feedback can be muted by entrenched culture. For example, in a survey of pediatricians and otolaryngologists, only 30% of the pediatric practices adhered to the standard of utilizing pneumatic otoscopy when diagnosing otitis media [9]. Approximately 15% of otolaryngologists also did not use pneumatic otoscopy despite its

establishment as a “best practice” [10]. Various examples of this can be found throughout the literature, thereby highlighting the essential need for sustained, iterative feedback in any quality improvement effort.

With this feedback characteristic in mind, the AAO-HNS concurrently embarked on the creation of a national otolaryngology clinical data registry (Reg-ent), which began collecting data in 2015. Recently, the registry passed the benchmark of data on 10 million unique patients with over 48 million patient encounters from approximately 1600 otolaryngologists throughout the United States. The Reg-ent registry is a HIPAA-compliant (Health Insurance Portability and Accountability Act) platform that connects to the clinicians’ electronic health record (EHR) and extracts relevant data. Since Reg-ent is designated as qualified registry by CMS, these data can then automate PQRS reporting for clinicians through the Merit-based Incentive Payment System (MIPS), with estimates of over \$100 million in avoidance of CMS reimbursement penalties to those providers who have participated. In addition to streamlining this regulatory requirement, the Reg-ent team can also provide direct feedback to clinicians on their performance in their chosen measures, which generates the necessary iterative feedback for quality improvement. The fully unrealized potential, however, is that the registry is an incredibly rich and robust data source for otolaryngology clinical research, specifically in the areas of PS/QI and CPG adherence/impact. Researchers who belong to Reg-ent, and select AAO-HNSF committees, can now submit proposals to ask and answer clinical research questions using de-identified datasets on thousands, or potentially millions, of patients. The proposals undergo an outlined review process to assess for feasibility, prioritized based on relevance and avoid duplication of efforts. These data have the potential to not only conduct large-scale research efforts, but also to expand the external validity of the research findings by examining the quality of otolaryngologic care that is being practiced in both academic and private-practice settings.

Future Developments

As the world economy has demonstrated in the last two decades, access to “big data” is, and will continue to be, increasingly important and sought after by all sectors and stakeholders. In healthcare, these relevant parties include insurance companies, government and other regulatory bodies (i.e., CMS, state Medicaid offices, JCAHO, etc.), health systems, and specialty societies. As discussed above, VBC is increasingly being incorporated into payment structures nationally in primary care, but VBC payment models are being explored and are underway in many different specialties and will undoubtedly affect reimbursement for

Table 1 List of currently used PQRS otolaryngology-specific reporting measures

Measure name	Description	Details
QPP331	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis	% of adult patients with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms (inverse measure)
QPP332	Adult Sinusitis: Appropriate Choice of Antibiotic	% of adult patients with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis
QPP464	Otitis Media with Effusion: Systemic Antimicrobials	% of patients aged 2 months–12 years with a diagnosis of OME who were not prescribed systemic antimicrobials
QPP066	Appropriate Testing for Pharyngitis	% of episode for patients > 3 yo with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A strep test in the 7-day period from 3 days prior to the episode date through 3 days after the episode date
QPP277	Sleep Apnea: Severity Assessment at Initial Diagnosis	% of adult patients with a diagnosis of OSA who had an AHI, a RDI, or a REI documented or measured within 2 months of initial evaluation for suspected OSA
QPP279	Sleep Apnea: Assessment of Adherence to OSA Therapy	% of adult patients with a diagnosis of OSA that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually
QPP261	Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness	% of patients (peds and adult) referred to a physician for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness
AAO16	Age-related Hearing Loss: Audiometric Evaluation	% of patients aged 60 years and older who failed a hearing screening and/or who report suspected hearing loss who received, were ordered, or were referred for comprehensive audiometric evaluation within 4 weeks of the office visit
AAO23	Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines	% of patients aged 2 years and older with a diagnosis of allergic rhinitis who are prescribed or recommended intranasal corticosteroids or non-sedating oral antihistamines
AAO13	Bell's Palsy: Inappropriate Use of MRI or CT Scan	% of patients aged 16 years and older with a new onset diagnosis of Bell's palsy who had a MRI, or a CT scan of the internal auditory canal, head, neck, or brain ordered within 3 months after diagnosis
AAO37	Dysphonia: Laryngeal Examination	% of patients who were diagnosed with dysphonia who received or were referred for a laryngeal examination within 4 weeks of initial diagnosis
AAO21	Otitis Media with Effusion: Complete Audiometric Evaluation for Chronic OME	% of patients aged 6 months to 12 years of age with a diagnosis of OME including chronic serous, mucoid, or nonsuppurative OME of ≥ 3 months duration who had or received an order or referral for comprehensive audiometric evaluation
AAO12	Tympanostomy Tubes: Topical Ear Drop Monotherapy Acute Otorrhea	% of patients aged 6 months to 12 years of age at the time of the visit with a current diagnosis of an uncomplicated acute tympanostomy tube otorrhea (TTO) who were prescribed or recommended to use topical antibiotic eardrops and NOT prescribed systemic (IV or PO) antibiotics for acute TTO
AAO20	Tympanostomy Tubes: Comprehensive Audiometric Evaluation	% of patients aged 6 months through 12 years with a diagnosis of OME who received tympanostomy tube insertion and received a comprehensive audiometric evaluation within 6 months prior to tympanostomy tube insertion
AAO36	Tympanostomy Tubes: Resolution of OME in Adults and Children	% of patients aged 6 months and older with a diagnosis of OME who are seen 2 to 8 weeks after tympanostomy tube surgery and OME is resolved
AAO32	Standard BPPV Management	% of patients diagnosed with BPPV who received vestibular testing, imaging, and antihistamine or benzodiazepine medications
AAO38	Thyroidectomy and Parathyroidectomy Nerve Injury	% of patients that had a thyroidectomy and/or parathyroidectomy and experienced recurrent laryngeal nerve injury resulting in vocal cord paresis or palsy (inverse measure)

Table 1 (continued)

Measure name	Description	Details
AAO39	Neck Mass Evaluation	% of patients aged 18 years and older diagnosed with a neck mass and suspected/increased risk of malignancy who had a fine needle aspiration (FNA), or refer the patient to someone who can perform FNA with tumor human papillomavirus (HPV) test and receive a neck CT (or MRI) with contrast

specialists, including otolaryngology [11]. Integral to the equation of VBC care is the definition of “value” and “quality,” and who will be responsible for defining and benchmarking the relevant metrics.

Each of the relevant stakeholders will be trying to create and implement alternative payment models (APMs) by defining value and quality based on the data and evidence available to them. CMS has explored APMs in a few different iterations [accountable care organizations (ACOs), bundled payments for procedures/conditions, comprehensive primary care programs] with varying degrees of benefit to patients and healthcare costs [12–17]. CMS bundled payment programs have had some success at improving quality and generating value, with the greatest benefit seen in surgical procedures such as lower-extremity joint replacements [12], and less benefit seen in more chronic conditions (i.e., congestive heart failure and cancer) [18, 19]. These programs have been largely voluntary and single-sided risk models (reimbursement for high “value” care, but no penalty for poor performance). In contrast, double-sided risk models not only financially incentivize high-quality care that is cost efficient, but also penalizes the provider if certain metrics are not achieved. These models have shown greater success due to the appropriate aligning of incentives, and CMS will most likely pursue mandatory participation in double-sided bundled payment APMs for more procedures in the future [20]. Historically, commercial insurance and Medicaid often follow in the footsteps of CMS, which will lead them to adopt similar APMs. However, Medicare patient populations are quite different from those with commercial insurance and Medicaid, so it will be important to ensure these APMs are appropriately risk-adjusted to avoid penalizing those providers who care for historically disadvantaged populations, especially in double-sided risk APMs. Additionally, the stakeholder with some of the largest resources and datasets is the commercial insurance payor, whose interests may not always align with what is optimal for patient care. Due to the economic incentives, the insurance industry may choose to adopt its own APMs and be more inclined to define “value” in a way that maximizes profit.

When looking at the future APM landscape, it becomes increasingly evident that physicians must be involved in the conversation to ensure appropriate value and quality of care for our patients. For example, studies have shown

that physician-led ACOs generate greater savings and better quality than hospital ACOs likely due to appropriate incentivization that keeps patient benefit at the forefront [11, 21]. Central to the effort of advocating and participating in VBC development will be “big data” and evidence-based guidelines that can be used to investigate and define value. The AAO-HNS is actively working to expand the number of physicians and practices enrolled in the Reg-ent database. Additionally, more otolaryngology-specific measures and CPGs are in development, and can be proposed and receive feedback through public comment periods that are periodically open. These data can also be used to ensure appropriate risk stratification in the APMs adopted by CMS, Medicaid, and commercial payors to avoid potentially penalizing those providers who care for higher morbidity patients and/or increasing healthcare disparities in historically disadvantaged populations.

Conclusion

Value-based care, and thus quality and quality improvement, will become increasingly part of the United States healthcare system due to the current financial insolvency of the traditional fee-for-service model. APMs, including procedural-based bundled payments, are in development and will likely affect our specialty in the near future. As physicians, we must continue to advocate for our patients by participating in the development of VBC. This can be achieved by (1) continuing to investigate and improve the quality of otolaryngology care delivery, (2) contributing and researching “real-world” data on our patients to define value, and (3) engaging with commercial payors, CMS, and other governmental healthcare agencies to ensure appropriate APMs that provide the greatest benefit for our patients.

Author Contributions VM wrote the manuscript, prepared the figures and tables and reviewed the manuscript.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Conflict of Interest Vikas Mehta is the current Coordinator for Research and Quality for the American Academy of Otolaryngology-Head and Neck Surgery.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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