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ORIGINAL ARTICLE

Development of Tool for Case Submission and Review as Foundation for Department Patient Safety/Quality Improvement Program

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Abstract

Objective: Describe creation and implementation of secure case collection tool for the foundation of otolaryngology department Patient Safety/Quality Improvement (PSQI) program. Describe how tool decreased burden while fulfilling stakeholders' reporting requirements.**Methods:** Incorporation of elements of required reports into online tool, facilitating improved case submission for Morbidity and Mortality conference (M&M) review. Reviewer commentary and conference discussion notes are recorded within the project. Regular reports tailored to each stakeholder were designed. **Results:** During first 8 months of implementation, 83 cases were submitted 5250 surgical procedures were performed by our department in that period compared to 75 cases submitted via prior system in a same time period the year before (6930 surgical procedures performed). Elements of routine reports for interdepartmental use and external stakeholder requirements determined and reported. **Discussion:** Preliminary description of secure online tool with a single platform serving multiple stakeholders with unique reporting elements. This presents an opportunity to reduce the burden of essential administrative tasks while providing a reliable PSQI repository. Future metrics for ongoing evaluation will be identified and incorporated. Case submissions were maintained through a period of altered clinical activity (SARS-CoV-2 pandemic). **Implications for Practice:** This tool will allow our department to review cases for our required M&M with improved efficiency and efficacy, while supporting our PSQI program and generate necessary reports to stakeholders. Reduction of electronic task burden may reduce risk of physician burnout. Facilitating implementation of essential and required PSQI efforts will strengthen our curriculum and clinical work.

Keywords: ● Patient safety/quality improvement, ● Resident education ● Physician burnout, ● Outcomes

1 | INTRODUCTION

Recent years have brought fresh attention and dedication to our department's Patient Safety/Quality Improvement (PSQI) program, as has been the case with many academic departments throughout the country. Initiatives have increased since 1999, when the Institute of Medicine reported that 44,000-98,000 patients die in hospitals annually from medical errors the more conservative end of that estimate would make these errors the 8^{th} leading cause of death in the country at the time of the report. (1)Such dramatic risks have inspired efforts to make meaningful reductions in risk and adverse events. The Institute of Medicine's report, To Err is Human, encouraged the development of structured error identification and analysis programs that would inform strategies to prevent errors and reduce patient harm. The mechanisms by which we achieve these reductions in medicine have been informed by other industries, regulations, and our own shared experiences. Across medicine, the traditional tactic for identification and discussion of errors has been a regularly scheduled Morbidity and Mortality (M&M) conference. However, many physicians can recall instances in which assignment of blame superseded development of constructive plans to prevent future harm. Thankfully, recent development of structured PSQI curricula now help physicians understand how to make meaningful improvements for their patients and healthcare environments. (2) Less appealing are the cumbersome ways in which well intentioned reporting systems create increased electronic reporting burdens for physicians. Electronic administrative tasks have been identified as some of the greatest risks for physician burnout. (3), (4), (5) By tailoring our selected cases for discussion at M&M, our faculty direct the case reviews to cover the pertinent clinical details and link them to specific PSQI concepts. Specifically, we highlight patient safety, quality improvement, value, and performance as has been encouraged and detailed through the American Academy of Otolaryngology Head and Neck Surgery's PSQI Primer. (6) By anchoring these concepts to immediate clinical scenarios, we hope to teach systematic approaches to clinicians to address issues of patient safety. They then possess skills to enact changes in clinical practice to advance quality. (7) The reporting system that feeds into these PSQI events relies on voluntary reporting as an adjunct to mandatory case reporting (e.g. mortality, re operation) per departmental policy. To some degree, this is a self-fulfilling phenomenon in which we aim to promote a culture of safety by insisting that all complications are submitted for review with relevant discussions both in conference and in real time via the same mechanism that collects "near misses," in which no harm reaches the patient. We use a deeper development of concepts of PSQI to produce lasting changes in behavior and decision processes. Creating a single portal for all cases that can be submitted by our entire department faculty, staff, and residents there by fosters a culture of safety: all reports may generate discussion and ideas for improvement.

2 | METHODS

Our case submission tool is a secure, web-based platform using the Research Electronic Database Capture (REDCap) for reporting a broad range of cases within our department. Cases can be submitted for the primary purpose of consideration for M&M. Other submissions illustrate PSQI project ideas and suggestions for didactic conferences. All members of our Otolaryngology department have the ability to submit items to the system. Development of the tool involved ongoing communications within our department and with the patient safety team of our children's hospital and the surgical arm of the Process Improvement and Patient Safety (PIPS) at our children's hospital. The strong contributions from the pediatric stakeholders was influenced by

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the rigorous processes involved in application for the Children's Surgery Verification (CSV) program from the American College of Surgeons (ACS). This process involved departmental review of all patients returning to the emergency room, hospital, and operating room within specified time frames from their initial date of surgery.

The previous iteration of our M&M relied on a standard paper form to submit complications. As we merged our PSQI curriculum with M&M, our department intentionally shifted from reporting complications to finding and discussing opportunities to improve overall care. Simultaneously, our pediatric hospital began its application for CSV through the ACS. Identified priorities included: reducing the administrative burden of reviewing a case through multiple avenues and improving the security of our communications for the benefit of our patients. We began incorporating the required elements of the ACS reporting into a single project in REDCap that would let us have a unified, secure tool with online access. (Table 1)

Table 1. Elements required by respective national reporting initiatives

Report	Elements
Post-tonsillectomy hemorrhage	Postoperative day (with automated calculation for primary versus secondary hemorrhage), attendings involved (initial surgery and hemorrhage management, if different), residents involved (initial surgery and hemorrhage management, if different), management techniques used
American College of Surgeons – Children's Surgery Verification (CSV) Reporting	Required patient identifiers, attendings involved, residents involved, summary of events, timing of event (per ACS categories), categorization of event (per ACS categories), Clavien Dindo Classification, patient related factors (if any), provider related factors (if any), system related factors (if any), date of review by department, departmental discussion details and action items (as relevant, from M&M or other conversations)
American Academy of Otolaryngology – Head and Neck Surgery – Patient Safety Event Reporting Tool	Type of event (NCC MERP classifications), evidence of harm to patient at time of report, summary of event, location of event, patient age (per AAOHNS categories), extent of harm (per AAOHNS categories), timing of event discovery (per AAOHNS categories), interventions to "rescue" patient, impact of event on length of stay, notification of patient/family, details of review and discussion (including action plan, as indicated)

Abbreviations:

ACS = American College of Surgeons

CSV = Children's Surgery Verification, from the American College of Surgeons

AAOHNS = American Academy of Otolaryngology Head and Neck Surgery

NCC MERP = National Coordinating Council /for Medication Error Reporting and Prevention

A secondary reporting goal was incorporation of elements that would allow us to regularly examine our post-tonsillectomy hemorrhage rates for all attending s and residents, as recommended in the Clinical Practice Guideline: Tonsillectomy in Children, with a standardized report. (8) As we worked to build our tool, the AAOHNS Patient Safety Event Reporting Tool (PSERT) was announced. We immediately adapted our plans to include the elements of the PSERT, whose development has been described in prior publications. (9) Of note, development details of the CSV include elements not readily available in publication. The standard review for the CSV report included clinical categorizations and patient impact categorizations, which we incorporated directly. (Figure 1)

It also makes use of the Clavien Dindo Classification System for Surgical Complications. (10) (Table 2)

Table 2. Clavien Dindo Classification of Surgical Complications from Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240(2):205-213.

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical endoscopic, and radiological interventions Allowed therapeutic regimens are drugs as antiemetics, antipyrectics, analgesics, diuretic, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusion and total parenteral nutrition are also included
Grade III -IIIa -IIIb	Requiring surgical, endoscopic, or radiological intervention -Intervention not under general anesthesia -Intervention under general anesthesia
Grade IV -IVa -IVb	Life-threatening complication (including central nervous system complications) requiring intermediate care or intensive care unit -Single organ dysfunction (including dialysis) -Multiorgan dysfunction
Grade V	Death of a patient
Suffix "d"	If the patient suffers from a complication at the time of discharge, the suffix "d" for "disability" is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

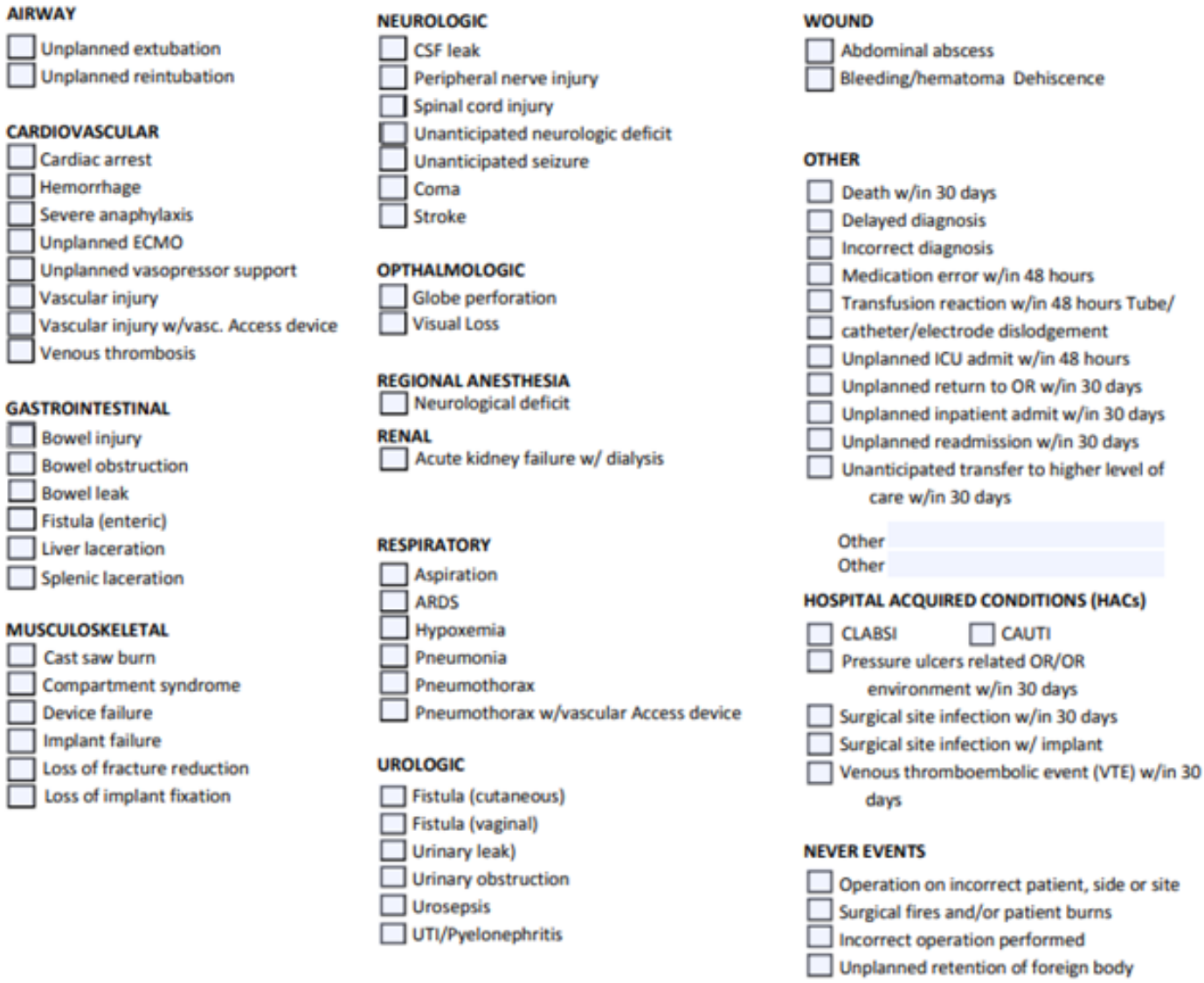

FIGURE 1: ***Clinical Categorizations from standard review for American College of Surgeons Children's Surgery Verification.***

We divided the tool into two sections one set of components for submissions and one set for review. Within the submission section, all relevant clinical data could be collected, and the categories from the ACS were selected. Submissions without an associated event that were strictly PSQI opportunities could be submitted without patient information or as an additional component of a case submission. The reviewer section included identification of patient, provider, and systems based elements relevant to the case. Most elements were multiple choice, though free text components to provide further explanation and details are essential elements. Recommendation for selection for M&M discussion was placed in the reviewer section of the tool. For cases selected, the presenting resident, faculty advisor, and details of the presentation were entered. The tool allowed for real time collection of presentation components at our regular conference. Any action items were recorded in another section. These components of the case review are highly valued elements for both the CSV and PSERT. (Figure 2)

Reports were designed to allow for a secure patient safety work product (PSWP) that could be provided regularly to the Surgical PIPS team. The elements of the PSERT were compiled into its own report that can be easily transferred to the online tool. Similar

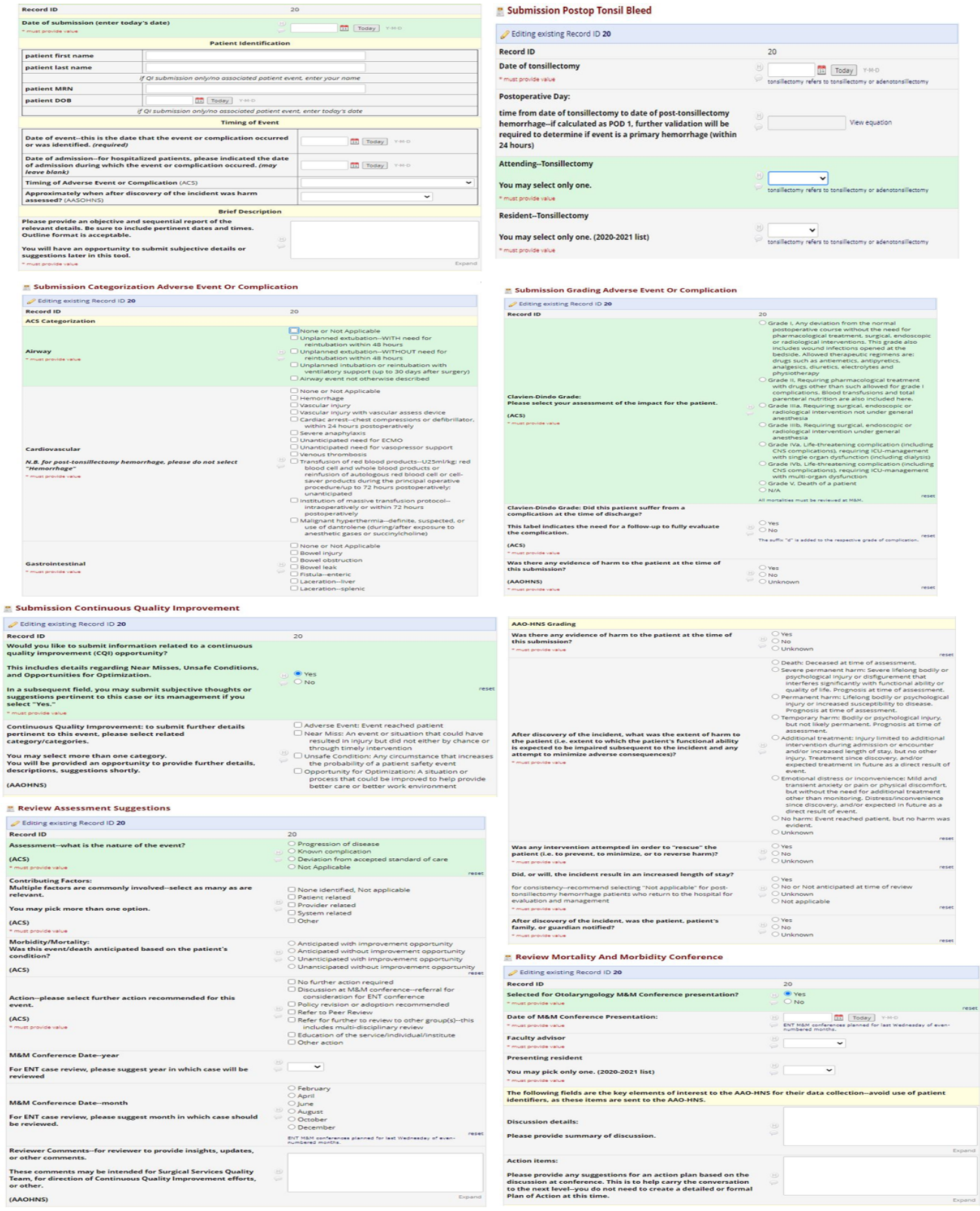

FIGURE 2: ***Images from oursecure collection tool in Research Electronic Database Capture (REDCap) illustrating submission and review elements.***

items in the submission tool for example, descriptors for timing of events are labeled to designate to the user which stakeholder requires that element.

The Saint Louis University (SLU) Institutional Review Board (IRB) reviewed the project and exempted it from direct oversight, as it fell under the category of PSQI projects. However, we felt that some oversight of the tool and the surrounding efforts was likely warranted. Therefore, we sought guidance from the general counsel of the SLU School of Medicine (SOM). These conversations enlightened both parties. General counsel noted that M&M as an entity involved components of privileged conversations and protected information. "Privilege" refers to conversations between an attorney and his client here, that refers to the SOM general counsel and the physicians in the practice supported by the SOM. These conversations are considered confidential. (11) The clinical and educational elements of the case review were determined to be part of a privileged conversation, albeit sometimes in electronic form. The protected component pertains to the identifying patient information, as detailed in the Health Information Portability and Accountability Act of 1996. (12) As physicians, we never operate outside of the constraints put in place for the privacy of our patients unless direct permission is provided, and M&M and PSQI abide by this protection. By consensus, we determined that a secure system for collection and management of these cases was possible. Provisions put in place to ensure responsible management of the data included drafting an agreement that access would be restricted and determined jointly by the faculty responsible for case reviews and general counsel and that detailed how access would occur. Each conference is preceded by a statement reminding all attendees of our responsibility to the privacy of our patients. Our intent is to maintain an ongoing conversation between our department and general counsel as needed.

All faculty and residents in the otolaryngology department may submit cases. Additionally, one member of the Surgical PIPS team, who maintains their database and reports to the ACS for CSV, also submits cases for review. Beginning January 1, 2019, we debuted our REDCap tool for case submission. The descriptive statistics of the initial case submissions and reviews were collected and compared with the number of surgeries performed by our service during the initial 8 months of implementation and during the analogous period in the year prior, in order to account for seasonal variation in some surgical scheduling.

3 | RESULTS

Our initial implementation period, January through August 2020, collected 83 cases. During this period, which was dominated by the ongoing COVID pandemic during which elective surgical cases were temporarily suspended, 5250 inpatient procedures were billed by our service a 1.6% submission rate. During those same months in 2019, 75 cases were submitted through our previous system, and 6930 cases were billed a 1.1% submission rate. (Table 3) Of the 83 submitted cases, 13 were selected for presentation (16% submitted cases were presented) at our bimonthly conference during the initial implementation period. The number of cases selected for presentation in the pre implementation period was not recorded.

Table 3. Initial metrics following implementation of secure case submission tool

	Pre-Implementation January – August 2019	Initial Implementation January – August 2020
Total inpatient cases performed (at primary adult and pediatric hospitals covered)	6930	5250
Paper/RED Cap submissions	75	83
Rate of submissions/inpatient cases performed	1.1%	1.6%
Number of cases selected for M&M presentation	Data unavailable	13
Rate of cases selected for M&M presentation/submitted cases	--	16%
Number of PSQI projects developed from submissions	3	8

We provided monthly reports to our Pediatric Surgical PIPS team. Reports for information to submit to the AAOHNS PSERT have been generated following conferences. The faculty and residents performing tonsillectomies have just received their

initial reports regarding post-tonsillectomy hemorrhages. This includes a calculated rate for attendings (denominator comes from billing data) and a numerator for residents (who can calculate their post-tonsillectomy hemorrhage rate by identifying the denominator from their case logs). Departmental rates for post-tonsillectomy hemorrhage (adult and pediatric cases combined) were primary hemorrhage 0.2% and secondary hemorrhage 4% in 2019, and primary hemorrhage 0.3% and secondary hemorrhage 5% in 2020. (Table 4)

Table 4. Post-tonsillectomy hemorrhage details from preimplementation and initial implementation phases

	Pre-Implementation January – August 2019	Initial Implementation January – August 2020
Tonsillectomies performed (CPT 42820, 42821, 42825, 42826)	875	611
Hemorrhage		
Primary—within 24 hours of surgery	2 (0.2%)	2 (0.3%)
Secondary—more than 24 hours after surgery	38 (4%)	31 (5%)

Hemorrhage was defined, based on the method of case identification by our Pediatric Surgical PIPS team, to be any adenotonsillectomy or tonsillectomy patient who presented to any emergency department or physician's office in our hospital system within 30 days of surgery and reported any amount of bleeding. To improve case capture rates, we chose to include patients with: active bleeding; blood clots identified on physical examination; patient descriptions of blood in oral or nasal secretions.

Metrics for future analysis of our clinical care as well as for evaluation of the case submission system have been collected through the reporting tool as well as via M&M and other conversations. These include tracking number of submissions each year, by user, for conference, for didactic s, expansion of the tool to other services, PSQI projects details, and time from event to submission. Ongoing improvements will be incorporated at regular intervalsthus far, improved reports assisting with ongoing case review and PSQI tracking have been implemented. (Table 5)

Table 5. Improvements identified during initial implementation to incorporate for future evaluation

Improvement opportunities to tool suggested by users
Ability to denote case to be saved for didactic conferences
Report to monitor cases still requiring review, planning case assignments for conference
Report for identified PSQI projects and corresponding creation of new departmental communication tool for projects
Metrics for future measurements
Number of submissions by academic year (or other defined interval)
Number of submissions by user
Time from event identification to submission
Number of cases selected for conference
Number of cases identified for didactics
Number of services using this tool
Number of PSQI projects
Number of cases submitted to AAOHNS' PSERT

We plan to examine each of the elements within the tool after initial improvements have been incorporated for one year.

4 | DISCUSSION

This preliminary description of a secure, online tool for case submissions for our regular M&M and PSQI efforts demonstrates that we have been able to: a) capture the elements of external reporting requirements, b) improve our department's internal patient safety initiatives, and c) reduce the collective administrative task burden for our department. The development of this tool ensured that we adhered to principles of privileged conversations and protected our patients' information while working to improve our clinical care and the processes by which we deliver that care. Considering known drivers of burnout such as excessive workload and work inefficiency, this tool to improve efficiency for required case review work aligns with interventions recognized to offer relief. Efforts to reduce burnout are more efficacious when they address individual physician needs paired with institutional support. (5) This project has benefited from the collaboration of all stakeholders and, in fact, is only successful in reducing administrative burden because we created outgoing reports acceptable to our stakeholders.

We believe that this reporting tool fits into the mandated national quality reporting Joint Commission's performance measures required for hospital accreditation and Centers for Medicare and Medicaid Services (CMS) requirements to maintain reimbursement rates. It also meets our institution's obligations to hospital and health system event reporting, as well as CSV program case review. In addition, we may find a constructive way to incorporate some aspect of the otolaryngology specific Merit Based Incentive Payment System (MIPS), a CMS program, into the metrics we track through our tool. One may imagine the challenges for how to consider MIPS measures such as cerumen impaction and allergic rhinitis in the same venue as surgical complications. (13) In an ideal world, perhaps one system could allow event reporting, case review, and collection of performance metrics. The tool presented in this journal:

a) reduces the number of times that we have to review specific cases, b) while responsibly handling patient information, and c) generates reports for internal and external use.

Shortly after this online tool was deployed, we, along with the rest of the country, halted elective surgeries due to the COVID pandemic. Despite a decrease in surgical case volume 5250 cases during 8 month period in 2020 versus 6930 cases during the corresponding months in 2019 our department submitted more cases, 83 versus 75, through our new system than we did through our previous paper based system. While the surgical case volume does not serve as a true denominator we encourage broader submissions from encounters such as those in clinic and nonsurgical consultations, as well as from non clinical events that represent PSQI opportunities the case volume still provides perspective for the level of clinical activity. We are encouraged by increased submissions in the face of decreased clinical activity. The PSERT from the AAOHNS collected 53 cases in 22 months in its initial report, and we will have started to monitor how many cases we contribute each year to the PSERT. (9) Some programs have used incentives to increase resident submission of events. (14) However, a study of 26 hospitals found that nurses submitted the plurality of event reports with less than 2% provided by physicians. (15) We intend to incorporate education in our PSQI curriculum regarding how event reporting is usedacross institutions with our own cases and PSQI projects as examples we hope this will increase submissions as well as improve individual engagement with the tool throughout the department.

We sought to merge the work required by our institution with those of the AAOHNS. Our department has immediately subscribed to the potential benefits of a large anonymous database reliant on voluntary reporting that the Academy has advocated. Critically, we believe that that investment in a culture of safety within the AAOHNS mirrors our own departmental commitment to patient safety. In addition to constructing a secure database for M&M, the same database allows us to glean the relevant details to ensure that we can communicate within the multidisciplinary review bodies of our hospitals and preserve key didactic points. Meanwhile, our report of information for upload to the AAOHNS PSERT site was easily created to exclude any identifiers. Initially, the Surgical PIPS team had provisionally adopted the CSV format, but our pediatric hospital has achieved CSV status, thus those requirements are now formalized.

Our plan is to expand the work to all the pediatric surgical specialties REDCap projects are easily modifiable, so the names of attending s and residents are easily adapted or removed entirely, as a service deems necessary. Additionally, the ability to secure and monitor access to the data, rather than relying on distribution and collection of paper forms in a manner that reliably protects patient information, is a decreased burden for our PIPS stakeholders. As more institutions achieve CSV status, the potential audience for a tool to streamline collection and storage of data required by the ACS grows. Projects within REDCap are easily shared across institutions via the REDCap site or a downloaded data dictionary (excel file). A standardized report could be designed for use by all participating or interested pediatric hospitals in the country, even if they each had their own institution based versions of the secure collection tool.

A limitation of this study is that this is only a preliminary report of its inception and deployment. However, by reporting this tool's creation and details

early, we hope to garner interest that would generate collaboration more otolaryngology programs working on this together could be an opportunity to improve the tool while still in its infancy. Faculty reviewers have found categorization, and inter-rater reliability of categorization, challenging however, we address this by consulting each other as we review cases and rely on the ability to adjust selections in the tool as needed. Subjective elements are part of medicine, and we will continue to improve reliability by consensus as we work with the tool, the faculty reviewers do find that we are improving in our reviewing skills. All reporting tools risk some degree of reporting bias; however, our PIPS team works consistently to alert our department of any possible adverse events, and each case they submit is reviewed. Our M&M faculty reviewers include updates during conferences on the REDCap tool and point out important submissions that might not be selected for review to educate and encourage our department about all categories of cases we hope to have submitted. This will likely always be an ongoing effort, though we believe that the corresponding strength of the project is that it is providing an efficient mechanism to ensure that opportunities for improvement are captured and communicated. Administrative burden is a significant component of physician burnout, but ensuring that we can share and then capitalize on our good ideas is motivatingplus, it is simply nice for all stakeholders to know there is an audience for their suggestions.

We are excited to improve our metrics to evaluate the tool on an ongoing basis. Broader utilization within our institution and within Otolaryngology would certainly be a means to improve the way the tool collects information and how it can be used. At this time, there are 37 Verified Children's Surgery Centers in the United States, with expanding certification,there are at least 36 other pediatric centers who could immediately make use of this system and contribute to its refinement. [16]

5 | IMPLICATIONS FOR PRACTICE

The creation of this online, secure tool that allows for efficient collection, review, and distribution of necessary information to stakeholders has been a satisfying mechanism to match cases for review at M&M with PSQI concepts in Otolaryngology. Engagement of faculty, residents, staff in collective effort in patient safety will only increase as pay for performance becomes more widespread. (17) To reduce burnout in this new environment, efficient tools may improve the administrative burden on our faculty and residents by ensuring that we can have a centralized, uniform way to handle these cases. This would also enhance our clinical and didactic objectives within the department while also preparing the required information for outside reports. The format of the tool can be tailored to individual departmental and institutional needs while maintaining the essential elements required by national bodies, such as the ACS and AAOHNS. This then would help standardize reporting. This would allow for ongoing refinement of the tool through expanded use and incorporation of suggested improvements as more programs capture similar data. Ultimately, these data provide our specialty an opportunity to further its commitment to a culture of safety and specific PSQI endeavors.

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- JB: Design/concept, conduct, analysis, manuscript, presentation
- GW: conduct, analysis, manuscript

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