Soundings
PUBLISHED IN THE INTEREST OF OUR MEMBERS AND THEIR PATIENTS

The Pennsylvania Academy of Otolaryngology—Head and Neck Surgery

President's Message

Ahmed M.S. Soliman, MD

It is hard to believe that my term as president of the Pennsylvania Academy of Otolaryngology—Head & Neck Surgery has come to an end. It has been a whirlwind two years indeed with advocacy for our membership and their patients as the focus of my tenure. There have been, and there continue to be, attacks from multiple sources. We are all aware of IBC's ill-advised 25 modifier policy which we fight on many fronts. More recently, Highmark has tried to bundle several codes including CPT code 69210 into the E&M, and CMS has proposed similar changes for Medicare and Medicaid. The fight is far from over as we continue to work with PAMED, the American Academy of Otolaryngology—Head & Neck Surgery as well as other state societies to stave off the assault on physicians and patients.

On the legislative front, the PAO-HNS continues to actively engage the Pennsylvania Academy of Audiology in drafting the new Hearing Aid Dispenser bill. We have drawn on the AAO-HNS's experience nationally on this issue to guide us, and talks are ongoing. A more worrisome issue facing otolaryngologists in the state is the proposed venue rule change which would allow plaintiffs to "venue shop" in other counties for a more sympathetic jury. This would likely increase the number of settlements, increase premiums and decrease access to physicians by again making Pennsylvania an inhospitable state to practice medicine. We have again partnered with PAMED and are strongly encouraging all members to voice their opposition to this proposal by writing to Karla M. Shultz, Counsel, Civil Procedural Rules Committee, Supreme Court of Pennsylvania.

It has been a whirlwind two years indeed with advocacy for our membership and their patients as the focus

Finally, a new version of the Ambulatory Surgical Center tax has been proposed by Governor Wolf for this year with additional details to come. New compounding regulations are also to come out shortly but through our work with the Pennsylvania Pharmacists Association, in-office immunotherapy is not to be included. The PAO-HNS has also sent a letter to IBC in support of hypoglossal nerve stimulation as a standard therapy for obstructive sleep apnea based upon the current literature to which we received a very favorable response. Similarly, after much effort from the PAO-HNS, Highmark has updated their medical policy to allow standalone balloon sinus dilation as a treatment option on appropriate patients. We continue to receive invaluable input from our government relations firm, Milliron & Goodman, in these matters.

I am pleased to announce that our new website (www.otopa.org) is up and running. Its content is robust and continues to grow. We have also expanded our use of social media and would encourage all members to follow the PAO on Twitter (@PAOHNS) as a way of rapid communication which will be invaluable going forward. I would like to thank Mike Ondik, chair of the website committee, Barbara Husic, our

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President's Message

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executive director, and all committee members who have worked to provide updated material for our members and patients. The website is always a work in progress and will continue to expand and be updated going forward.

I am very pleased to announce the formation of the Women in Otolaryngology Committee this year. As a father of three daughters, one of whom is to start medical school in the Fall, I am particularly proud of this achievement. I am also indebted to Karen Rizzo for her relentless dedication to this cause. We had our inaugural session during last year's meeting and another planned for this year in Hershey. In fact, this year's meeting promises to be one of our best ever with a session dedicated to challenging airway cases, and others to focus on the multidisciplinary management of cutaneous malignancies, general otolaryngology "chalk talks" and a session on physician wellness. I would like to thank the entire planning committee and in particular our program co-chairs Jessyka Lighthall & Colin Huntley, and Events Manager Jessica Winger for all their efforts to make our meeting a success.

I would also like to recognize the efforts of Ellen Deutsch who has spearheaded our initiative on patient safety and quality. As we are all aware, this is a very timely subject. Her "Patient Safety" column has been a welcome addition to Soundings and one that we will continue going forward.

Finally, I would like to thank the membership for entrusting me with its leadership for the past two years. It has been one of the highlights of my career and an experience that I will cherish forever. I am extremely grateful to the superb team that has made my presidency successful including Barbara Husic, Jennifer Keeler, Kim Whetsell, Melissa Harper, Jessica Winger and the entire council. I am confident that I am leaving the organization in good hands with Johnathan McGinn as its new president.

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AAO-HNS Board of Governors Update

Karen A. Rizzo, MD Governor

The BOG is working hard on numerous fronts to help all Otolaryngologists improve their practices via advancements in communication, networking, practice management, toolkits, and involvement opportunities.

In an effort to harness the best state tracking technology, the AAO-HNS started in 2019 a new tracking system, State Scape. Legislative alerts customized by ENT topics are sent to volunteer state trackers who screen the numerous proposed bills for issues that may require advocacy action. For more information on this check the State Advocacy website: Legislative Tracking by State.

Multiple states are considering legislation that would remove otolaryngology in hearing assessments and the dispensing of hearing aids. Missouri has proposed a statewide hearing aid program with all assessments performed by audiologists/hearing instrument specialists. Legislation in Nebraska excludes otolaryngologists from the Children of Nebraska Hearing Aid Act. The bill only covers hearing impairments diagnosed by an audiologist. In South Carolina, HB 3284, inappropriately assigns the diagnosis of hearing loss to only audiologists. The AAO will work diligently to protect the role of Otolaryngology in hearing assessment and treatment.

HB 2026 in Virginia proposes to amend the Board of Health regulations to screen for congenital CMV in newborns who fail the newborn hearing screening. The AAO-HNS has concerns over the LEAD-K legislation introduced in Virginia, South Carolina, Oklahoma, New York, Indiana, and New Hampshire that would prevent parents of deaf/hard of hearing children from being fully informed of all their choices

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PAO-HNS
OTOLARYNGOLOGY
The Pennsylvania Academy of
HEAD AND NECK SURGERY

2019

ANNUAL SCIENTIFIC MEETING

JUNE 14-15

The Hotel Hershey · Hershey, PA

Educational Topics

- General Otolaryngology Chalk Talks
- Therapeutic Updates for Cutaneous Malignancy
- Physician Wellness Seminar
- Scary Clinical Scenarios Case Discussion
- Resident Research Presentations & Resident Conchal Bowl

Women in Otolaryngology Happy Hour: Leadership and Mentorship in Otolaryngology *(non-CME)*

Registration Fees

	by May 31	after May 31
PAO-HNS Physician	$130	$180
Nurse/Affiliate	$80	$80
Resident/Student	$40	$40
Non-member Physician	$305	$355
New Member Physician	Join for $95 and register for the meeting at the member rate!	

Online registration available at: www.otopa.org

Approved for 8.75 AMA PRA Category 1 Credit™

Accreditation: This activity has been planned and implemented in accordance with the accreditation requirements and polices of the Accreditation Council for Continuing Medical Education through the joint providership of the Pennsylvania Medical Society and the Pennsylvania Academy of Otolaryngology - Head and Neck Surgery. The Pennsylvania Medical Society is accredited by the ACCME to provide continuing medical education for physicians. The Pennsylvania Medical Society designates this live activity for a maximum of *8.75 AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Legislative Update

Milliron & Goodman, LLC

On January 1, 2019, a new legislative session began and so far it has been off to an interesting start. About three weeks after the swearing in day ceremony, two high-ranking Republican Senators announced their departures would take place at the end of February. One of those Senators was of particular importance to PAO-HNS legislative priorities, Senator Don White. As you may know, Senator White was the majority chairman of the Senate Banking and Insurance Committees. Any changes to insurance law are referred to this committee. At the time of this writing, no replacement has been named as the chair. As always, we'll be sure to keep you informed when a new chairman is named.

In addition to these political changes, Milliron Goodman has been monitoring the discussion around revisions to the hospital regulations. The Dept. of Health is currently working on a complete re-write of the 30-year-old hospital regulations. The proposed regulations must be approved by the Governor and then reviewed by the Attorney General for compliance with existing statutes. Once the regulations are through that process, they will be posted for public comment by the Independent Regulatory Review Commission (IRRC).

Another legislative idea to watch: The Governor's office and Dept. of Health announced the Pennsylvania Rural Health Model. In this program, the Commonwealth has partnered with five hospitals and five insurance providers to change the payment structure in those five hospitals. The structure will change from a fee-based system to a global budget payment. The global budget allows for hospitals to receive predictable payment amounts every month rather than the unreliable payments that are associated with a fee-based system. The program is expected to expand to 18 rural hospitals by 2020 and to 35 rural hospitals by 2021.

Last, but certainly not least, over 50 new members have been elected to the General Assembly. If you have a new legislator representing where you live, or where you practice, be sure to reach out and introduce yourself as a constituent. A strong grassroots network is critical to achieving success. If you aren't sure who your lawmakers are, please reach out to us at Milliron Goodman and we'll make sure we get you connected to the right people.

Below is a list of the remaining session days for the spring/summer legislative session:

2019 SENATE SESSION SCHEDULE

May 6, 7, 8
June 3, 4, 5, 10, 11, 12, 17, 18, 19, 24, 25, 26, 27, 28

2019 HOUSE SESSION SCHEDULE

May 6, 7, 8, 13, 14, 15, 22-23 (NV)
June 3, 4, 5, 10, 11, 12, 17, 18, 19, 20, 24, 25, 26, 27, 28

AAO-HNS Board of Governors

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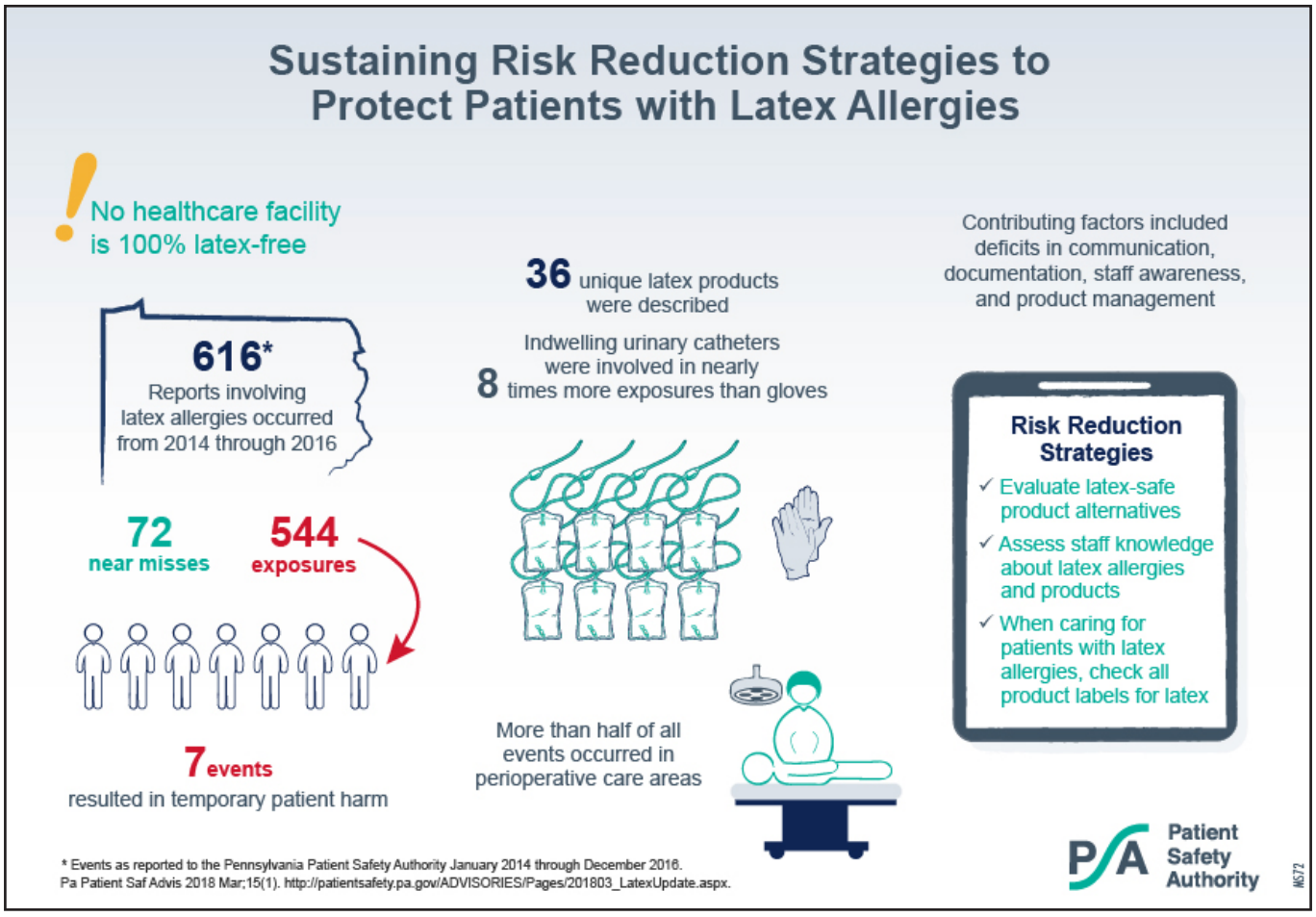
on auditory/medical interventions and communication modes, not just American Sign Language.

The BOG Spring Meeting and Leadership Forum will take place this year in Alexandria, Virginia, April 26-28. Panels of experts will discuss optimizing advanced practice provider relationships, mentorship, engagement of younger and senior physicians, networking and social events. Discussion on sleep hygiene, effects of micro aggressions, legislative updates, and the Opioid crisis will occur. A State Otolaryngology Roundtable will take place, providing an opportunity for state Oto societies to discuss common issues and share best practice ideas to further Otolaryngology awareness, relevance, grass root engagement, and enhance communication between State and National Oto societies. An Executive Director and Society Administrators Meeting will occur as well. Each BOG Society is now represented by a Governor and 1-2 Alternate Governors with elimination of the titles SEGR and Leg Affairs Reps which created confusion. Ten Regional Reps will help to update contact lists for each state/local Oto Society. Information on the Women in Otolaryngology 10 Year Anniversary Fundraising Campaign will be discussed as well. All otolaryngologists are encouraged to attend.

What can we learn from analysis of Pennsylvania Patient Safety Reporting System (PA-PSRS) data?

Ellen Deutsch, MD, MS, FACS, FAAPT

Latex: A Lingering and Lurking Safety Risk



Abstract:

After the topic of latex allergies surfaced in the 1980s, awareness grew and risk reduction strategies were created; however, a review of events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) questions the persistence of latex exposure protections. Pennsylvania healthcare facilities reported 616 latex-related events through PA-PSRS that occurred from 2014 through 2016, including 72 near miss events. Analysis revealed that latex indwelling urinary catheters were the most common source of inadvertent exposure in patients with documented latex allergies (75.0%, n = 408 of 544). The perioperative care area accounted for the highest number of both exposures and near misses (57.1%, n = 352 of 616). Event narratives highlight contributing factors such as deficits in communication, documentation, supply management, and staff awareness. Strategies to address these contributing factors may include screening, thoughtful handoffs, evaluation of product alternatives, assessment of staff awareness, and observation of practice patterns.

The full article can be found in the Pennsylvania Patient Safety Advisory:

http://patientsafety.pa.gov/ADVISORIES/Pages/201803_LatexUpdate.aspx

Pa Patient Saf Advis 2018 Mar;15(1)

MRI Screening: What's in Your Pocket?

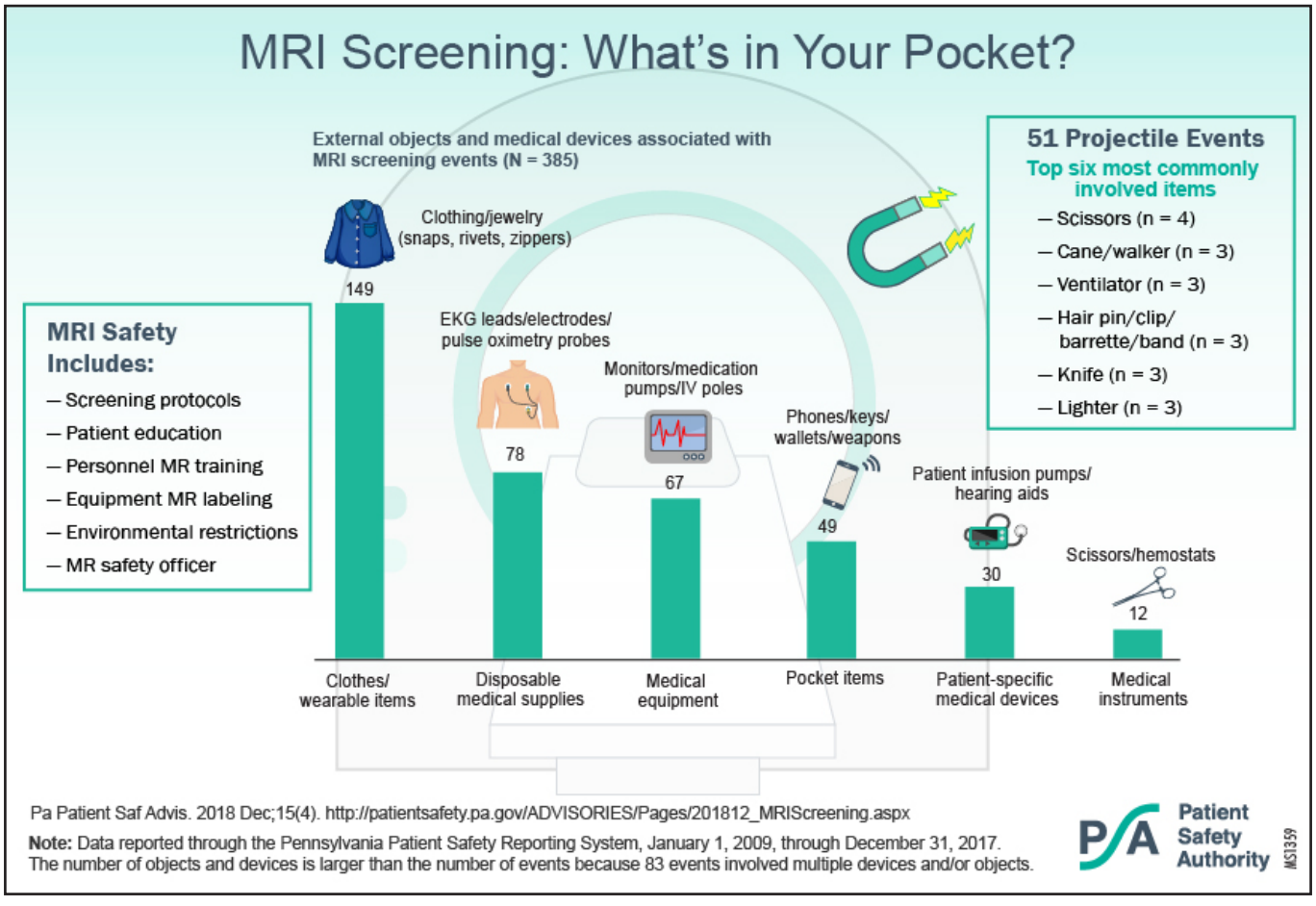
Abstract:

Magnetic resonance imaging (MRI) is a frequently used diagnostic imaging modality that may be an alternative to other types of radiologic imaging (e.g., computerized tomography, nuclear medicine imaging). It can detect soft tissue characteristics (e.g., inflammation), and because magnetic resonance (MR) uses a magnetic field and radio waves to produce images, it does not expose patients to ionizing radiation. Strict attention to MRI screening to prevent ferromagnetic objects and devices from reaching the MR scanner's magnetic field is important for safe MRI. Significant injury can occur to individuals in the MR scanner suite if a ferromagnetic object or a device with ferromagnetic components is exposed to the magnetic field and radiofrequency energy of the MR scanner. To prevent injuries, MRI screening is done to identify ferromagnetic objects before patients, staff, or equipment enters the MR scanner room. The Pennsylvania Patient Safety Authority was asked to review reports of MRI screening events submitted to the Authority. A query and analysis were completed of MRI screening events submitted from 2009 through 2017 through the Pennsylvania Patient Safety Reporting System (PA-PSRS), which identified 1,108 screening events. More than one-quarter of the events involved a device or object brought into the MR scanner room that was not considered safe for MRI. The most common objects or devices involved in MRI screening events were pacemakers (32.3%, n = 353 of 1,093 objects).As medical technology advances, so do the risks for MRI screening events. It is essential to maintain high standards of MRI safety: research all medical devices for MR compatibility, educate patients and healthcare personnel regarding MR safety, and provide comprehensive MRI screening of all individuals entering the MRI suite.

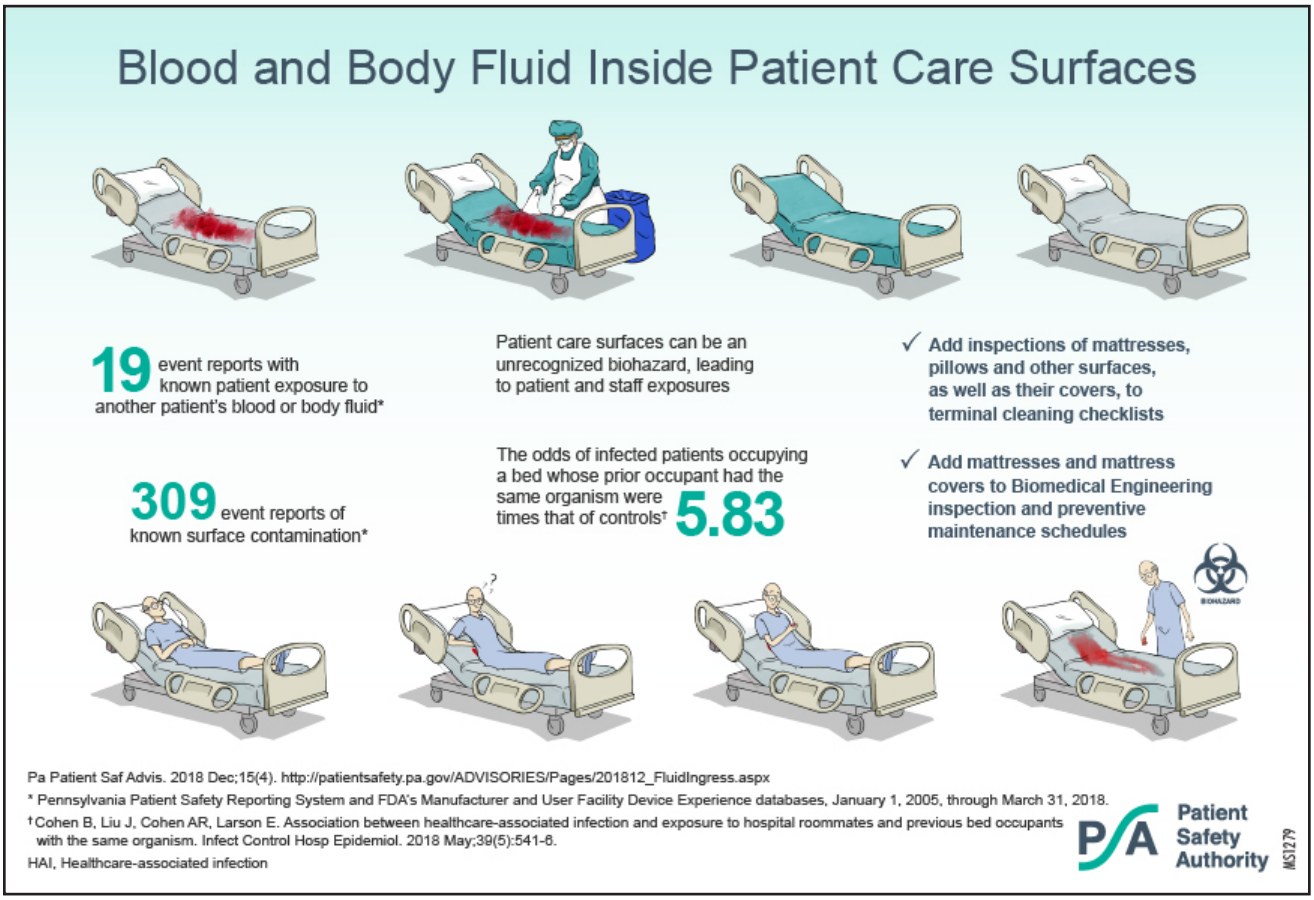
The full article can be found in the Pennsylvania Patient Safety Advisory:

http://patientsafety.pa.gov/ADVISORIES/Pages/201812_MRIScreening.aspx

Pa Patient Saf Advis 2018 Dec;15(4)



How Wet Is Your Patient's Bed?
Blood, Urine, and Microbiological Contamination of Mattresses and Mattress Covers



Abstract:

Body fluid and microbiological contamination can remain on, or within, bed and stretcher mattresses and mattress covers after cleaning. This puts subsequent patients and even staff at risk of exposure to infectious materials. Mattress and mattress cover contamination may go unrecognized and unreported, unless a patient experiences body fluid oozing from the mattress surface. To increase knowledge about the prevalence of patient safety events related to mattress and mattress cover contamination, Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) and the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) databases for reports of body fluid and microbiological contamination of bed and stretcher mattresses and covers submitted between January 1, 2005, and March 31, 2018 (PA-PSRS), and between January 1, 2008, and March 31, 2018 (MAUDE). Analysts identified 14 events reported through PA-PSRS of patient exposure to a previous patient's blood or urine when it oozed out of their support surface. In addition, analysts identified five reports in the MAUDE database of patient bloodborne pathogen exposure to a previous patient's blood when it seeped out of the support surface. Review of PA-PSRS and MAUDE event reports provides insight about how these events occur and adds depth to FDA's 2017 guidance and 2013 Safety Communication regarding the problem of body fluid ingress in hospital mattresses and covers. To reduce the risk of such contamination, a joint initiative with the infection prevention and control, environmental services, and clinical/biomedical engineering departments to address inadequate mattress cover reprocessing and deficient inspection of mattresses and mattress covers may be needed.

The full article can be found in the Pennsylvania Patient Safety Advisory:

http://patientsafety.pa.gov/ADVISORIES/Pages/201812_FluidIngress.aspx

Pa Patient Saf Advis 2018 Dec;15(4)

Are You Ready to Respond?
Reports of High Harm Complications after Surgery and Invasive Procedures

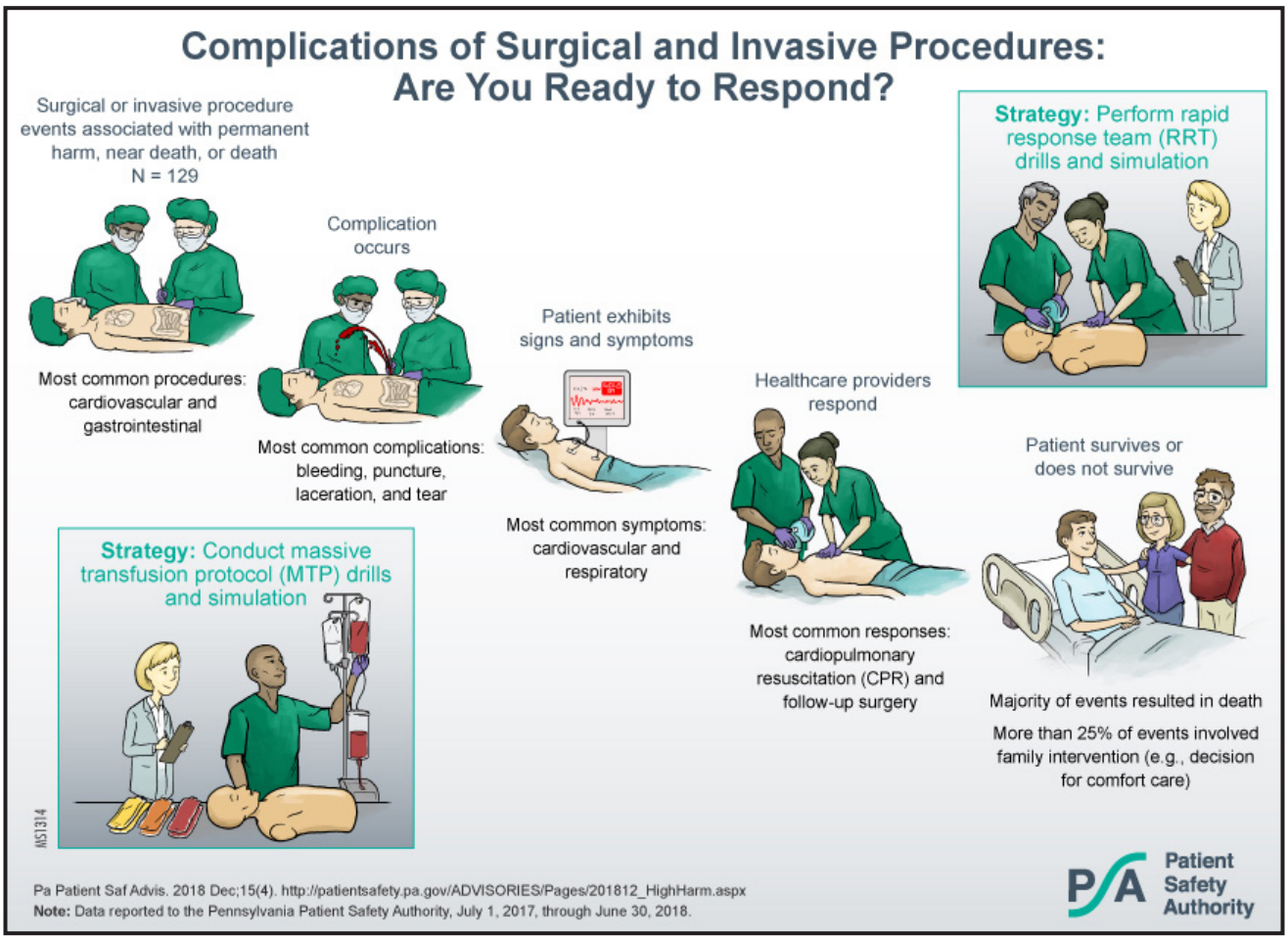
Abstract:

Surgery and other invasive procedures carry risk of complication and mortality. Recognizing and responding rapidly to such complications can improve patient outcomes. The Pennsylvania Patient Safety Authority sought to explore surgical complications and healthcare providers' responses by analyzing events reported as complications after surgery that resulted in permanent harm, near death, or death outcomes (high harm events). Analysts queried the Pennsylvania Patient Safety Reporting System for these high harm events submitted under the "complication following surgery or invasive procedure" event subtype for the 2018 academic year (i.e., 12 months ended June 2018). The query yielded 129 events of which cardiovascular and gastrointestinal procedures predominated (59.7%, n = 77 of 129). In these categories, bleeding and puncture, laceration, or tear were the most common complications (73.6%, n = 95 of 129). The majority of these high harm events (85.3%, n = 110 of 129) described some type of patient symptomatology to which healthcare providers responded 90.7% (n = 117 of 129) of the time. The majority of events resulted in death (65.1%, n = 84 of 129). Healthcare facilities can act now by using a similar analysis on their own cases and evaluate complication-response mechanisms to identify priorities for surgical-care learning and improvement.

The full article can be found in the Pennsylvania Patient Safety Advisory:

http://patientsafety.pa.gov/ADVISORIES/Pages/201812_HighHarm.aspx

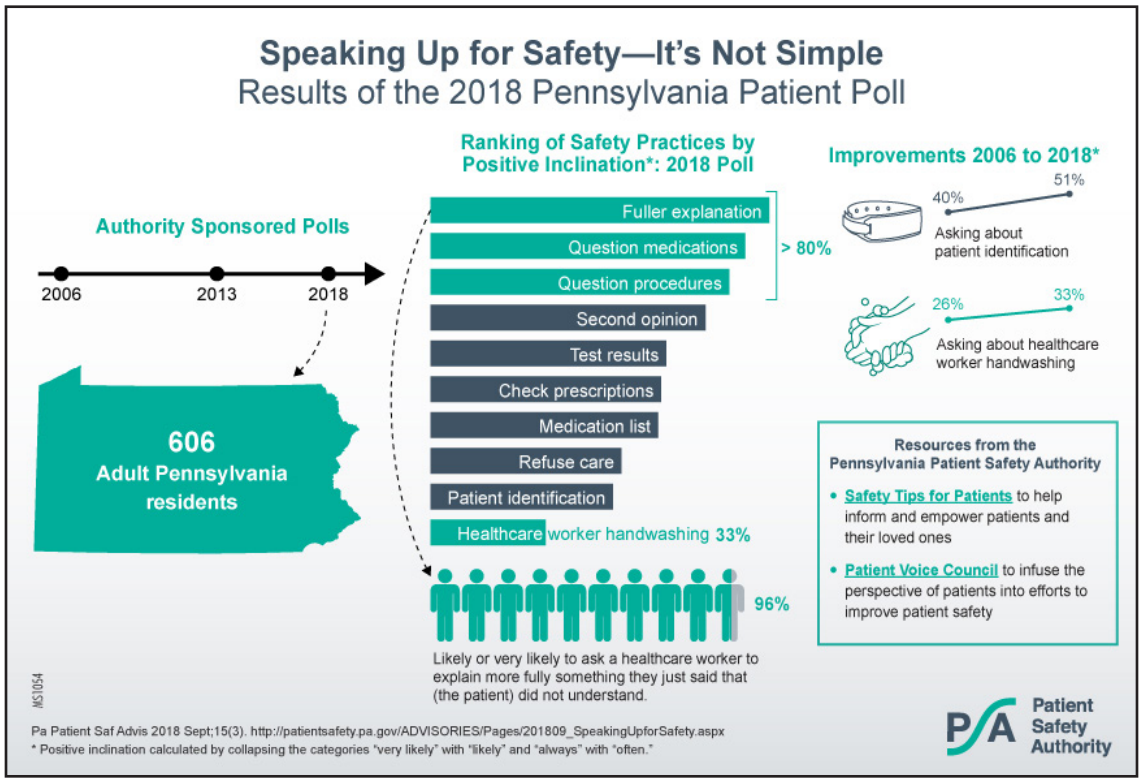
Pa Patient Saf Advis 2018 Dec;15(4)



Speaking Up for Safety—It's Not Simple

Abstract:

Patient education, engagement, and empowerment have been at the core of many organizations' efforts to make healthcare safer. To measure and focus such efforts, the Pennsylvania Patient Safety Authority developed a patient poll about basic safety practices, such as asking about healthcare worker handwashing. The poll was administered in 2006, 2013, and, most recently, February through April 2018. Results from 2018 remain consistent with the previous two iterations: high reported likelihood to ask questions to gain understanding and low reported likelihood to question potential safety breaches. In 2018, 96% of patients reported positive inclination towards asking for a fuller explanation, and just 33% reported positive inclination towards asking a healthcare worker if they washed their hands. This gap represents an opportunity for future safety work in Pennsylvania and beyond.



The full article can be found in the Pennsylvania Patient Safety Advisory:

http://patientsafety.pa.gov/ADVISORIES/Pages/201809_SpeakingUpforSafety.aspx

Pa Patient Saf Advis 2018 Sep;15(3)

Additional articles in the Pennsylvania Patient Safety Advisory that may be of interest:

- From the Database: Deaths after Ambulatory Surgery
  http://patientsafety.pa.gov/ADVISORIES/Pages/201812_ASFDeaths.aspx
- Perioperative Medication Errors: Uncovering Risk from Behind the Drapes
  http://patientsafety.pa.gov/ADVISORIES/Pages/201812_Perioperative.aspx
- Identifying and Learning from Events Involving Diagnostic Error: It's a Process
  http://patientsafety.pa.gov/ADVISORIES/Pages/201810_IdentifyingandLearning.aspx
- Acquiring Diagnostic Skill: Understanding the Decision Making Processes Used by Experts
  http://patientsafety.pa.gov/ADVISORIES/Pages/201810_acquiringskill.aspx
- The Breakup: Errors when Altering Oral Solid Dosage Forms
  http://patientsafety.pa.gov/ADVISORIES/Pages/201809_AlteringDosage.aspx
- Why are Safety Stories Important?
  http://patientsafety.pa.gov/ADVISORIES/Pages/201812_Commentary.aspx#

The Opioid Epidemic and the Role of Otolaryngologists

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Background information on opioids and opioids in ENT:

Since 2006, the national opioid prescribing rate had been steadily rising, climbing to its peak in 2012 with a prescribing rate of 81.3 prescriptions per 100 people.[1] Over the last two decades, opioids have become the preferred first-line modality in treating postoperative pain among many surgical specialties.[2] Within the field of Otolaryngology, this is not an insignificant amount.[3,4] Opioids are often prescribed to ensure adequate pain control after surgery. However, as amounts of prescribed opioids increased, the number of overdoses and deaths involving prescription opioids increased with it, though the amount of pain reported by Americans has not changed.[5] Most chronic opioid abusers started with a prescription opioid and the most common sources were from friends, family, and personal prescriptions.[7,8] 8-10% of opioid users continue using opioids even 1 year after, regardless of the extent of surgery. 33.3% of head and neck cancer patients who underwent primary surgical resection were found to continue using opioids 90-180 days postoperatively.[6]

A number of studies have recently emerged within the field of otolaryngology describing opioid prescription habits and usage patterns among patients.[7] These studies have only begun to shed light on the degree of overprescription within our field and provides the necessary feedback to reflect and change our clinical practice. It is well known that the U.S. consumes a large percentage of the world's opioids; however, the true nature of this pattern is better revealed in a study conducted by Li et al. who compared postoperative opioid use internationally between two academic otolaryngology departments, one in Hong Kong (H.K.) and one in the U.S. They found significantly less postoperative opioid use in patients in H.K. compared to patients in the U.S. (0.4% vs. 87% opioid use on postoperative day 6) after major head and neck procedures. They suggested these major disparities were due to cultural differences in pain perception, differences in patient expectations for pain management, industrial influence from pharmaceutical companies, historical recognition of pain as a vital sign, and the economic influence patient satisfaction has on hospital reimbursement.[8] In the face of Medicare reimbursements being determined by patient satisfaction, healthcare providers may be more likely to order unnecessary tests and over-prescribe medications.[9]

Current prescribing practice and overprescription patterns:

Multiple studies within the past few years within General Surgery and Otolaryngology show up to 75% of prescription opioids are unused by patients.[2,10,11] Opioid prescription size is strongly associated with increased opioid use, with patients consuming 5 additional pills for every 10 pills prescribed.[12] Within our institution as well as in recent literature, we have found wide variations in the number of opioids prescribed between providers for common otolaryngologic procedures (eg, thyroidectomies, parathyroidectomies, parotidectomies, tonsillectomies, etc).[13,14] Preoperative pain counseling was found to be significantly associated with a decreased likelihood of prescribing postoperative opioids and higher utilization of non-opioid pain management.[14] Within our own institution, since we have started investigating our own prescribing practices and having frequent, open discussions among the faculty, we have also observed a decreasing trend of opioid prescriptions. Our findings and current literature highlight the need for an open dialogue among the faculty within each institution to evaluate opioid prescribing practices, the need for an evidence-based guideline to manage postoperative pain while reducing opioid overprescription, and the need for us to actively counsel patients preoperatively on postoperative pain.

Our initiative:

Within our institution, our department has initiated a longitudinal quality improvement project to address these needs. Our goals are to evaluate the pain experience, opioid prescribing practices, and patient satisfaction in common head and neck procedures and to establish prescribing guidelines for our department as well as establish a standardized preoperative pain counseling. Since our study has begun, we have found a decreasing trend in the opioids prescribed among our

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otolaryngologists, faculty and resident physicians alike, highlighting the need for these discussions among other institutions.

While our study is still in progress, we recommend all otolaryngologists to begin discussing and reflecting on opioid prescribing habits among faculty, resident physicians, and other staff members. Acknowledging and evaluating the degree of potential opioid overprescription is the first step. Determining the right modality to treat pain is the next. Evaluating one's own patient population and identifying risk factors for increased need for pain control help to titrate prescriptions appropriately. A prerequisite to successfully implementing non-narcotic multimodal modalities is to understand the postoperative pain experience of individual patients and procedures. Finally, proper education and expectation setting with patients prior to surgery are essential in reducing the overprescription of opioids.

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Balloon Dilation of the Eustachian Tube, a Direct Procedure for Eustachian Tube Dysfunction

Michael Jonathan Clark, MD
The Guthrie Clinic

Until 2016, myringotomy with placement of a tympanostomy tube remained the only FDA approved surgical treatment for eustachian tube dysfunction (ETD). However, in 2010 Ockermann et al introduced a new approach to eustachian tube dysfunction by publishing a pilot study of eight patients who underwent trans nasal endoscopic balloon dilation of the cartilaginous eustachian tube for severe dilatory dysfunction. (1) Since the introduction of this procedure, multiple clinical trials have provided evidence of safety and effectiveness of eustachian tube balloon dilation. Patients not only reported improvement in subjective symptoms as evaluated by the Eustachian Tube Dysfunction Questionaire-7 Symptom scores (ETDQ-7), but also objective findings including tympanometry, otoscopic appearance and ability to perform valvsalva. Minor complications have been reported including eustachian tube puncture, worsening eustachian tube dysfunction and minor bleeding. Contraindications for the procedure include injury of a dehiscent carotid artery and patulous eustachian tube dysfunction.

Several cadaver studies have been performed to evaluate the safety of inserting a balloon catheter in the eustachian tube and all determined that the procedure involved a straight forward technique with a minimal learning curve.(2-4) Analysis of the tissue after the procedure revealed only minor mucosal injury without causing injury to the cartilage or to the carotid canal. Additional clinical studies provided evidence of the safety and effectiveness of the procedure for treatment of ETD.(6-9, 11, 14, 15) Histopathology research has demonstrated the procedure reduces inflammatory burden of the eustachian tube by crushing portions of the epithelium while sparing the basal layer and crushing lymphocytes.(10) It is theorized that the impact on the epithelium and the underlying lymphocytes and lymphoid follicles explain why the procedure has produced lasting results.

The procedure for dilation of the cartilaginous eustachian tube involves inserting the balloon device in a minimally invasive, trans nasal technique along he inferior meatus under direct visualization. Once the device enters the nasopharynx, the eustachian tube orifice is identified and the balloon is guided into the cartilaginous eustachian tube. In 2016 two specific devices obtained FDA approval to treat ETD directly with balloon dilation. Both devices are designed to follow current recommendations to insert a balloon into the cartilaginous eustachian tube and perform the dilation to 12 ATM for 2 minutes. The Aera Eustachian Tube Balloon Dilation System (Acclarent) uses an angled lumen to guide a 6mm x 16 mm balloon into the cartilaginous eustachian tube and is designed with a bulb tip in order to avoid advancing the devices beyond the eustachian tube isthmus.(13) The balloon has a yellow marker at a measurement of 31 mm from the tip in order to gauge the total insertion length into the eustachian tube. The Xpress ENT Dilation system (Entellus) uses a malleable tip, bent at a 45 degree angle at the 2cm marking.(14) The company provides a selection of devices with different balloon lengths and diameters in order to place a 5-7mm diameter balloon a total of 2 cm into the eustachian tube as measured by the markings on the probe. Currently, these devices are only approved for use on adults; pediatric eustachian tube balloon dilation is considered off label.

Two recent randomized control trials have been published providing strong evidence of objective and subjective improvement over medical therapy. The first study reported significant improvement in normalization of tympanograms with dilation and medical therapy (51.8%) vs medical therapy alone (13.9%, P<0.0001). At 24 weeks the treatment group showed an additional normalization of tympanograms up to 62.2%.(15) The EDTQ-7 scores were used to evaluate symptoms improvement and at 6 weeks normalization was 56.2% of investigational patients versus 8.5% controls (P<.001). A second randomized control trial included one year follow up and reported technical success in 100% of the procedures attempted (91/91) with 72% of the procedures completed in the office under local anesthesia.(14) Other studies have also supported the ability to easily perform this procedure under local anesthesia.(11-12) The ETDQ-7 scores showed an overall change of -2.9 in the procedure group vs 0.6 in the controls (P<0.0001) along with improvement

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in abnormal tympanograms.(14) One year follow up showed continued improvement in the ETDQ-7 scores and tympanograms. Both studies also showed improvement of the appearance of the tympanic membrane on examination and improvement in the patient attempting Valsalva maneuvers.(14-15)

Over the past decade research in balloon dilation for ETD support that this is a safe and affective procedure with improvement of symptoms and exam findings. Although the EDTQ-7 questionnaire, tympanograms and exam findings are all helpful in supporting the diagnosis of ETD, further research is indicated to determine how to determine which patients will benefit the most from this procedure instead of other therapeutic options. Current research has shown lasting results over the first year, but additional follow up is required to determine if patients need to continue medical treatment or will eventually require another dilation procedure. Also, there is no current indication for ET balloon dilation in the pediatric population clinical trials are underway.

In summary, insurance coverage for the procedure remains an issue in many areas of the country. However, considering the ability to perform the procedure in the office as well as combine it with sinus procedures, a growing number of patients will likely benefit from this therapeutic option. With additional research, clinical guidelines may be developed to help support obtaining insurance coverage.

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Update on Pediatric Tracheotomy Quality and Safety Improvement

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Tracheotomy is one of the most common procedures that the otolaryngologist performs. The term "trach" is often synonymous with tracheotomy as well as tracheostomy. For clarity, this article will define "tracheotomy" as the surgical procedure of creating an opening between the airway and the skin and "tracheostomy" as the opening or stoma created during the procedure (1). Over 100,000 tracheotomies are performed every year in the United States (2). Only 5,000 are performed in children and of these, 50% are performed in children under one year old (3-4). There are a multitude of reasons to account for the relatively small number of pediatric tracheotomies, including a lack of consensus on optimal tracheotomy timing, varying parental preference, and increased complication rates and mortality in children undergoing the procedure compared to adults. Even with these challenges, the incidence of pediatric tracheotomies has increased over the past few decades, especially in tertiary care centers (5).

Forty years ago, pediatric tracheotomies were primarily used to relieve airway obstruction from infections such as epiglottitis and diphtheria (6). Advances in neonatology, vaccinations, and ventilators have changed these indications. Today, the most common indications for pediatric tracheotomy include neurologic anomalies, cardiopulmonary disease, upper airway obstruction, and craniofacial anomalies (3,6-7). The majority of these patients have complex and chronic medical conditions and often have prolonged intubations prior to undergoing a tracheotomy (8). At one tertiary care facility, the average time to tracheotomy after admission was 42.2 days (9).

Even though they account for only a small proportion of all tracheotomies, children with tracheostomies on average have inpatient stays which cost around $200,000 per child (5). Beyond this financial burden, taking care of children with tracheostomies also requires a significant investment in time for caregivers at home and can lead to negative effects on the caregiver's quality of life, sleep, and ability to work (10).

Pediatric tracheostomies have higher complication rates than their adult counterparts; as many as 15-19% of children will experience a tracheostomy-related complication (4, 11-12). The majority of these complications are relatively minor, such as peristomal wound breakdown, granulomas, and stoma bleeding (12). The major complications like accidental decannulation, pneumothorax, pneumomediastinum, mucus plugging, and trachea-innominate fistulas are more rare, but can be life threatening. Nearly 8% of children with tracheostomies do not survive their hospitalization (4) and the mortality rate at 10 years post-tracheostomy ranges from 9-15% (13-14). It is important to note that the majority of these deaths are related to other chronic medical conditions and that the mortality specific to tracheostomy ranges closer to 0.5-5% (15).

Another well-established effect of tracheostomies is the increased frequency of hospitalization. At one tertiary care facility, tracheostomy readmission rates within 30 days were 22%. This rate is likely high due to comorbidities as acute respiratory illnesses in patients with positive pressure ventilation was found to be a significant risk for readmission (16). There is also concern that these complications rates may be underreported due to patients being lost to follow up.

Because of the complexity of care involved in pediatric tracheostomies, there have recently been efforts to standardize the care of children undergoing this procedure, as there is considerable variation between individual providers as well as between institutions. In 2016, the International Pediatric Otolaryngology Group published consensus recommendations about peri-operative care guidelines for tracheotomy care in children (17). These recommendations, while useful for sedation and nutrition management, were focused on the acute peri-operative care within seven days of the

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operation; no published reports have validated these recommendations to date. Also in 2016, the Global Tracheostomy Collaborative developed a prospective database to start collecting patient variables on pediatric tracheostomies across multiple institutions (18). More recently, Barron CL et al. developed a Pediatric Tracheostomy Care Index to help quantify and monitor the consistency and documentation of tracheostomy care (19). Instead of focusing on "never events" or "near misses", this index combined several small elements of tracheostomy care to give a score of "missed care events." These investigators found that implementation of the index reduced the number of 'missed care events' by 50% (19). The index was used to identify and ultimately eliminate pressure ulcers (an element of the care index). It still remains to be seen whether this index reduces major tracheostomy complications, but the implementation and standardization of tracheostomy care is encouraging and will be indispensable to improve quality.

Although the main indications for pediatric tracheotomy have changed dramatically, it remains an important and often necessary procedure. Pediatric tracheostomy patients are often medically complex with multiple severe comorbidities and their care can be a challenge and weight on caregivers and hospital systems. They have higher mortality and complication rates than adult patients with tracheostomies and there is less standardization in their care. There have been several recent attempts to improve the post-operative care in pediatric tracheostomy patients, but there is still a paucity of data to support successful implementation. Nevertheless, pediatric tracheostomy is an ideal area to focus quality improvement efforts. These efforts should include development of clinical care pathways and standardized protocols, with the goal of decreasing variability of care, which will likely lead to improved patient outcomes.

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