

HeadWay

NEWS FOR PHYSICIANS FROM JOHNS HOPKINS OTOLARYNGOLOGY-HEAD AND NECK SURGERY



Christine Gourin's research suggests that some head and neck cancer patients aren't getting care that produces the best outcomes.

Taking a Closer Look at Quality

Much of the talk about health care reform centers on cost, which only continues to grow. According to the Centers for Disease Control and Prevention, the United States spent more than \$2.6 trillion for total health expenditures in 2010, the last year for which data is available—nearly 18 percent of the nation's gross domestic product. In less than a decade, that spending is projected to increase by about 6.2 percent a year, outpacing the country's expected economic growth.

While pundits blame greedy doctors, medical errors and health care system fraud, **Christine Gourin's** research is highlighting another potential cause: care that doesn't lead to optimum outcomes.

For example, clinical trial data suggests that treating larynx cancer with chemotherapy and radiation leads to outcomes similar to surgery. But that's not what Gourin, a head and neck surgeon, and her colleagues were noticing anecdotally in their work. "Increasingly, the surgery we were performing followed nonoperative treatment failure, and often these salvage treatments weren't successful," she says.

To gather real numbers, Gourin retrospectively studied Maryland state data and the Nationwide Inpatient Sample. She found that rates of surgery to treat

larynx cancer were decreasing, and when surgery was performed, it was more likely to be done in patients who already had nonoperative treatment with radiation. Importantly, those "salvage surgery" patients often had more complications and required more complex reconstruction than those initially treated with surgery, with an increase in health care costs.

Gourin then used the SEER-Medicare Linked Database to explore the impact of these trends on survival. She found that, indeed, patients with advanced cancer were more likely to receive chemoradiation than surgery up front, but patients treated with surgery and postoperative radiation had significantly better survival compared with patients treated with chemoradiation.

It's unclear exactly why these findings deviate from those of clinical trials, Gourin says. However, she hypothesizes that clinical trials may not capture a realistic patient population, by leaving out the elderly and those with more complicated care scenarios. In addition, the care delivered may differ between the clinical trial setting and the real world.

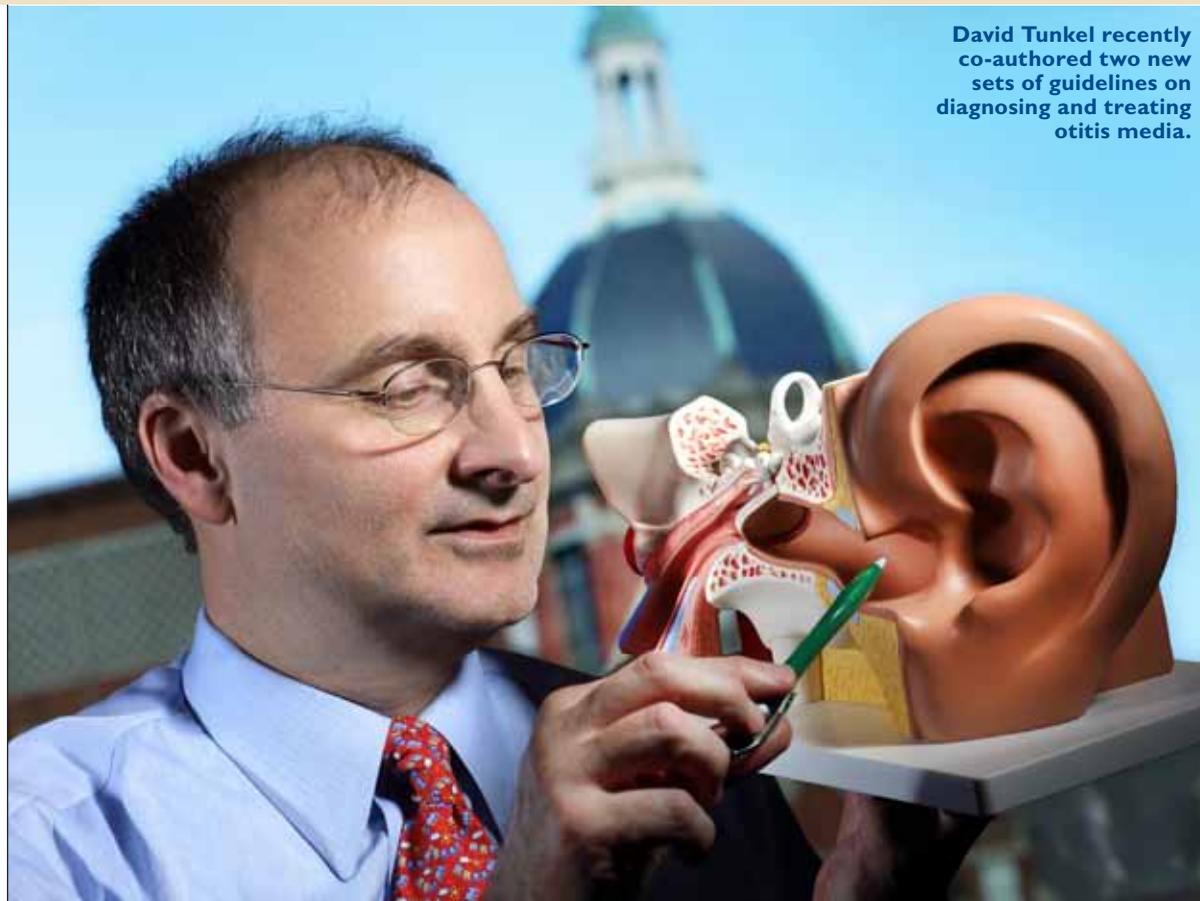
To determine if differences in care quality were responsible for the discrepancy between her findings and clinical trial results, Gourin and colleagues

derived quality indicators based on national treatment guidelines spanning care from diagnosis to the end of life. They found that overall, more than a third of patients received care that deviated from guidelines, and patients who received higher quality care had better survival and lower costs. The exception was for higher quality care for treatment of recurrent disease, which was associated with poorer survival. And yet, after controlling for quality, there was still a survival advantage for surgery with radiation.

These data highlight a pressing need to develop accurate quality measures of cancer care based on real-world outcomes and informed by patient preferences, which has now become the focus of Gourin's research. By delivering the treatments most likely to lead to the best outcomes, Gourin says, both patients and health care payers can benefit, and a focus on improving quality rather than cost-cutting should be the focus of health care reform efforts.

"Quality health care can be thought of as the right care for the right patient at the right time," she says. "Because high-quality care is associated with lower costs, these data show that it's also at the right price." ■

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David Tunkel recently co-authored two new sets of guidelines on diagnosing and treating otitis media.

New Guidelines for Otitis Media, Tympanostomy Tubes

Although every physician practices medicine to diagnose and treat patients with the most benefit and least chance of harm, there can be a wide range of opinions on the best treatment for any given disease. That's why major physicians' organizations are developing clinical practice guidelines that use available evidence to issue action statements to improve quality and outcomes and reduce variations in practices, says **David Tunkel**, director of Johns Hopkins' Division of Pediatric Otolaryngology. Recently, Tunkel joined otologists, pediatricians, nurse practitioners,

OTOLOGY

Lose Hearing, Lose Brain?

Johns Hopkins otologist **Frank Lin** and colleagues have discovered a long list of negative health consequences associated with hearing loss, including increased risk of dementia, falls and hospitalizations, and diminished physical and mental health overall. Now, their latest research adds yet another: The brain atrophy that normally happens with age seems to be fast-tracked in older adults with hearing loss, according to the results of a study by researchers from Johns Hopkins and the National Institute on Aging.

Lin and colleagues used information from the ongoing Baltimore Longitudinal Study of Aging to compare brain changes over time between adults with normal hearing and adults with impaired hearing. The Baltimore Longitudinal Study of Aging was started in 1958 by the National Institute on Aging to track various health factors in thousands of men and women.

Previous research from other studies had linked hearing loss with marked differences in brain structure compared with those with normal hearing, in both humans and animals. In particular, structures that process information from sound tended to be smaller in those with impaired hearing. It was unknown, however, whether these differences occurred before or after hearing loss.

As part of the Baltimore Longitudinal Study of Aging, 126 participants underwent yearly magnetic resonance imaging (MRI) to track brain changes for up to 10 years. Each also had complete physicals at the time of the first MRI in 1994, including hearing tests. At the starting point, 75 had normal hearing and 51 had impaired hearing, with at least a 25-decibel loss.

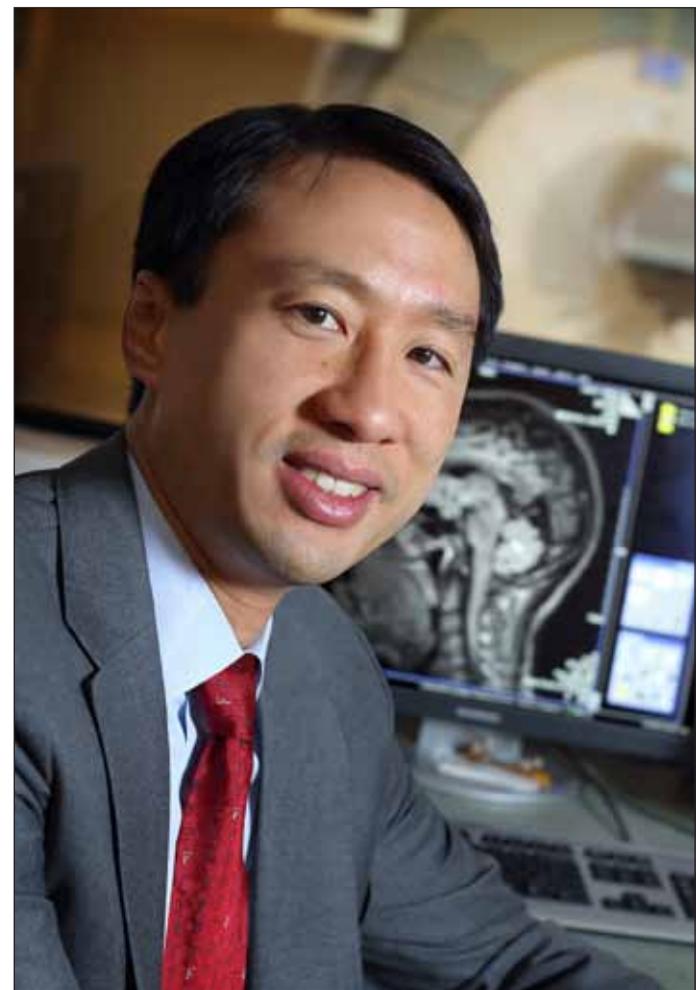
After analyzing their MRIs over the following years, Lin and his colleagues found that participants whose hearing was impaired at the start of the sub-study had accelerated rates of brain atrophy compared to those with normal hearing. Overall, the team showed that those with impaired hearing lost more than an additional cubic centimeter of brain tissue each year compared with those with normal hearing. Those with impaired hearing also had significantly more shrinkage in particular regions, including the superior, middle and inferior temporal gyri, brain structures responsible for processing sound and speech.

That such structures are affected in those with hearing loss wasn't a surprise, says Lin—the shrinkage might simply be a consequence of an “impoverished” auditory cortex, which could become atrophied from lack of stimulation. However, he adds, these structures don't work in isolation, and their responsibilities don't end at sorting out sounds and language. The middle and inferior temporal gyri, for example, also play roles in memory and sensory integration and have been shown to be involved in the early stages of mild cognitive impairment and Alzheimer's disease.

“Our results suggest that hearing loss could be another ‘hit’ on the brain in many ways,” Lin explains.

The study also gives some urgency to treating hearing loss. “If hearing loss is potentially contributing to these differences we're seeing on MRI,” Lin says, “you want to treat it before these brain structural changes take place.” ■

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Frank Lin's research continues to find more and more health consequences associated with hearing loss.

audiologists and other specialists to produce new clinical practice guidelines on two common issues: how to treat acute otitis media and how to care for children who are candidates for tympanostomy tubes.

For acute otitis media, Tunkel joined a group convened by the American Academy of Pediatrics (AAP) to update guidelines last issued in 2004.

The new guidelines emphasize more precise diagnosis of acute otitis media when there is bulging of the tympanic membrane and tympanic membrane erythema in the appropriate clinical setting. Additionally, otitis media is not present in the absence of a middle ear effusion.

These guidelines further clarify when to treat acute otitis media with antibiotics, Tunkel says. When the condition is causing severe symptoms, is bilateral or is causing otorrhea, the document recommends treatment with antibiotics at the time of diagnosis. If these conditions aren't in place, the guidelines suggest taking a wait-and-see approach in children over 2 years of age, with antibiotics used for symptoms that persist after two to three days. Very young children with acute otitis media should be treated with antibiotics at diagnosis.

The AAP guidelines suggest not prescribing prophylactic antibiotics for children with recurrent acute otitis media. They advise that clinicians may offer tympanostomy tubes if patients have frequent infections: three incidences of acute otitis media in the past six months, or four in the last year with at least one incidence in the last six months.

The second set of guidelines, issued by the American Academy of Otolaryngology–Head and Neck Surgery (AAOHNS), deals specifically with issues about tympanostomy tubes.

Adding to the AAP guidelines, those from the AAOHNS suggest that doctors offer tympanostomy tubes to children with recurrent acute otitis media only when middle ear fluid is seen in one or both ears at the time of evaluation, Tunkel says.

The AAOHNS guidelines urge identifying children who might have more substantial problems from ear infections or from the hearing loss associated with middle ear effusion: for example, children with speech and language delays, preexisting hearing loss, visual loss, Down syndrome or autism. Tubes are likely needed more often for children in this “at-risk” group who have middle ear disease.

The AAOHNS guidelines also recommend using antibiotic eardrops instead of oral medications to treat acute otorrhea in children with tympanostomy tubes. Additionally, routine water precautions are not necessary for most children who have tympanostomy tubes in place.

Tunkel notes that the advice in both guidelines is research-based and is usually backed by randomized, controlled trials and systematic reviews. These clinical practice guidelines use a defined guideline creation process that uses analysis of the evidence by experts from multiple disciplines.

“Third parties, not treating physicians, have a growing influence on how we choose diagnostic pathways and treatments,” he says, “so it’s really important that physicians take the lead in producing, understanding and implementing these evidence-based practices.” ■

For information: 443-997-6467

RESEARCH

New Hope for a Cancer Cure

Though researchers have made incredible advances in many cancers—with some treatments extending long-term survival to decades and even rendering many patients cancer-free—treatments for head and neck squamous cell carcinoma still have plenty of room for improvement. At best, available therapies—including surgery, chemotherapy and radiation—cure only about half of these patients.

“Despite the best standard of treatment,” says researcher and otolaryngologist **Young Kim**, “the cure rate is still not sufficient.”

Seeking to turn that around, Kim is researching a one-two punch that would turn off the cancer’s ability to evade the immune system and also enhance the immune system’s ability to fight cancer.

The first part of Kim’s strategy centers on an antibody therapy that got its start at Johns Hopkins in the labs of Drew Pardoll, Suzanne Topalian and Lieping Chen, an immunobiologist now at Yale University. The therapy targets a signaling pathway involving a protein present in T cells called

programmed death-1 (PD-1). This protein normally plays a role in keeping T cell function in check, preventing these immune cells from attacking normal cells. One mechanism that cancer cells use to hide from immune recognition is expressing a protein called programmed death ligand-1 (PD-L1), which binds to PD-1 and prevents T cells from responding as they normally would to kill cancer cells.

Recent clinical trials of an anti-PD-1 antibody in lung cancer patients at Johns Hopkins and elsewhere showed that it boosted T cell response enough to allow the immune system to completely eradicate some cancers—a durable response that hasn’t been seen with many other therapies.

Kim says that these findings have instilled a tremendous sense of optimism in researchers across the oncology spectrum. But there’s just one catch—the number of patients in this clinical trial was still relatively small.

To help boost these numbers, Kim and his colleagues are working on a therapy that will combine anti-PD-1 antibodies and a cancer vaccine he’s



Young Kim is leading research on a new type of therapeutic vaccine for head and neck squamous cell carcinoma.

developing in his lab. The vaccine brings together tumor antigen with a novel adjuvant that radically increases the number of activated antigen-presenting cells.

Kim hopes to eventually bring together anti-PD-1 antibodies with his vaccine, a recipe that he believes has the potential to eliminate cancer in even more patients and significantly increase the cure rate for head and neck squamous cell carcinomas.

“These are patients who have been through the wringer—big surgeries, radiation, chemotherapy—and their cancer keeps coming back,” Kim says. “For the first time, there’s real hope for these patients.” ■

For information: 443-997-6467

Celebrate the Centennial

100 YEARS 1914-2014

JOHNS HOPKINS OTOLARYNGOLOGY- HEAD AND NECK SURGERY

When surgeon-in-chief William Halsted tapped Samuel Crowe to head Johns Hopkins Otolaryngology, he could not have predicted how much the specialty would change over the next 100 years. Come celebrate a century of milestones at the Department of Otolaryngology-Head and Neck Surgery's Centennial Celebration from June 20-21, 2014.

The festivities kick off at 7 a.m. on Friday with a welcome from Paul Rothman, dean of the medical faculty and chief executive officer of Johns Hopkins Medicine. Highlights of the day include a movie about Halsted and his visionary leadership; the new video highlighting departmental milestones; lectures about

Samuel Crowe's appointment as the first director; a panel discussion by department alumni; comments from former directors, Drs. Johns, Cummings, Minor and Eisele; the Charles W. Cummings, M.D., endowed lecture featuring Mark Richardson, dean of the School of Medicine at Oregon Health and Science University; and a resident research symposium. Friday evening, the department will host a gala with a seated dinner at the Four Seasons Hotel Baltimore.

The celebration continues on Saturday with a family picnic on the lawn of Evergreen House at The Johns Hopkins University and a resident and fellow graduation celebration and dinner at Baltimore's Frederick Douglass Museum.

For more information on Centennial Celebration events, please contact Belle Massey at 443-287-2124.

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