Clinical research leading to new cancer treatment options

Patients receiving a cancer diagnosis are faced with a difficult and often overwhelming experience. From a medical standpoint, there are a variety of treatments that include surgery, chemotherapy, radiation, immunotherapy, hormone therapy, or blood and marrow transplants. Determining which option, or combination of options, is the best course of treatment requires a team-based approach and a personalized plan for every patient.

A multidisciplinary oncology group from the Department of Otolaryngology – Head and Neck Surgery cares for hundreds of head and neck cancer patients each year. The group includes clinicians who are also head and neck cancer researchers, placing them at the forefront of medical breakthroughs. Increasingly, these physicians and their patients are turning to clinical trials and research studies to test the latest treatments and drugs not widely available to the public.

Dozens of trials involving head and neck cancer are going on at the nationally recognized University of Iowa Holden Comprehensive Cancer Center, each aimed at improving the quality of life or increasing the chances of survival. Trials are carefully monitored and regulated to safeguard patient safety and privacy, and to ensure data integrity.

One example is a pilot project that Nitin Pagedar, MD, assistant professor of otolaryngology – head and neck surgery, and Richard Hoffman, MD, MPH, professor of internal medicine, are pursuing with support from a grant by the Alliance for Clinical Trials in Oncology (ACTO). The alliance’s award program supports pilot projects in cancer prevention, risk assessment, screening, symptom intervention, surveillance, health outcomes research, or specific population groups.

Pagedar is co-leader of the head and neck cancer research team at the Holden Center, which is using the ACTO award to ask how lung cancer screening guidelines apply to head and neck cancer patients. “We’re looking at if and how patients from our survivorship clinic are getting screened for lung cancer during their head and neck cancer survivorship follow-up period,” states Pagedar. “This includes how physicians and patients are jointly determining the appropriate lung cancer screening and treatment options.”

“New treatments” continues on page 2

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In another case, clinician-researchers are participating in an important nationwide study of the connection between HPV-related cancers and the use of robotic surgery as a treatment option. Research has shown there has been a link to some head and neck cancer and Human Papillomavirus (HPV). The trial is investigating how well transoral surgery followed by low-dose or standard-dose radiation therapy works in treating patients with HPV positive stage III-IVA oropharyngeal cancer.

Rodrigo Bayon, MD, assistant professor of otolaryngology, is directing UI Hospitals and Clinics efforts as part of the Eastern Cooperative Oncology Group (ECOG). He and researchers at other participating sites are studying why HPV is underlying a large number of cancer cases. They are studying how robotic surgery combined with additional treatment after surgery compares to standard treatments available to patients today. Their approach is unusual for cancer trials involving surgery. Typically, surgeons conduct surgery only, whereas in the case of this trial, organizers like Bayon are conducting surgery in a very specific way while maintaining certain quality standards among participants. The focus is on determining the appropriate combination of radiation therapy with chemotherapy to kill any tumor cells remaining after surgery. Findings are being compiled with results to be published at a later date.

“The ECOG 3311 trial is an exciting opportunity for us to assess whether it is possible to de-escalate treatment in patients with HPV-related cancers of the tonsil or tongue base,” says Bayon. “This trial allows us to reduce radiation and eliminate chemotherapy in carefully selected patients who currently would receive chemoradiation following an operation. In turn, this should hopefully result in better swallowing outcomes for our patients.”

Trials and studies such as these have contributed to improved care rates for head and cancer patients as survival rates have improved 55-66 percent from 1992. While these rates are encouraging, physicians like Pagedar and Bayon seek to push rates even higher and improve the quality of life that patients experience during and after treatment.

More information about head and neck cancer care at the University of Iowa Holden Comprehensive Cancer Center at uihc.org/head-and-neck-cancer-program

For information about clinical research taking place, visit uihc.org/cancer-clinical-research
Twelve-year-old Madelynn Higbee loves to sing, play the flute, and run track. You’d never know she almost lost the ability to do all of these things.

In summer 2014, Madelynn began experiencing swelling and pressure in her neck and throat. She was initially diagnosed with tonsillitis, but Madelynn’s parents, Emily and Brian, worried it was more serious. She was referred to a local ear, nose, and throat specialist, where a CT scan revealed two large non-cancerous masses—lymphatic malformations—in her esophagus. These masses, known as macrocysts, were caused by the abnormal development of Madelynn’s lymphatic system and made it difficult for her to swallow and breathe.

“This is something that normally occurs in utero (before birth),” says Brian. “We have no idea how this popped up when Madelynn was 10.”

Madelynn was referred to University of Iowa Stead Family Children’s Hospital, where a team of specialists was waiting.

“It’s an amazing relief to know you’re not the one in charge anymore, to know that other people are taking care of you and your daughter, to where you can step back and trust their expertise,” says Emily.

Many lymphatic malformations are more external, but Madelynn’s were in a delicate, more internal area of her neck. Due to their size, they pushed into her trachea and esophagus, and their placement made surgery a dangerous option, risking permanent deformities. Her parents and the care team decided that a drug developed in Japan, OK-432, was the best course of action.

“The first of many blessings was the realization that we are only two hours away from what’s basically the hub of this coordination [in the United States] of the OK-432: Iowa City,” says Brian.

Fluid was first drained from Madelynn’s two macrocysts and then the OK-432 drug was injected into them. The goal of the drug is to cauterize, or scar, the inside of the macrocysts to remove the threat of more fluid buildup.

During the scarring process, the masses swell, making swallowing and breathing more difficult. Madelynn underwent a tracheostomy (trach)—a surgical incision into the windpipe—to keep her airway open as the drug worked. Emily and Brian learned how to care for Madelynn’s trach during her 15-day stay in the Pediatric Intensive Care Unit.

“We know that we feed our children, clothe them, and provide them with memories and moments,” says Emily. “But to know that you’re responsible for her airway…it’s a big undertaking.”

Madelynn’s doctors advised that the drug would likely need to be administered multiple times. But six weeks later, the Higbees learned the OK-432 therapy worked on the first try. Additionally, Madelynn no longer needed her trach.

The Higbees are thankful for Madelynn’s care team, including associate professor of otolaryngology Jose Manaligod, MD, and Diane Burke, RN, BSN, who helped their daughter. Burke shares, “The love and appreciation and cooperation this family gave to us was a key factor in the outcome. Madelynn continues to do well with her trach out and we’ll follow up with her lymphatic malformation to ensure her continued health and success.”

“We are just very grateful for each and every person who has played a role in Madelynn’s journey,” remarks Emily. “We have been given the opportunity to remain a family.”

Learn more about the Kid Captain program and view Madelynn’s story at uichildrens.org/kid-captain/2016
Hearing loss is the most common sensory deficit in humans. It is diagnosed in one in 500 newborns and affects half of all octogenarians. Although causality is multifactorial, in developed countries a large fraction of hearing loss is genetic and non-syndromic.

A team of researchers led by the Sterba Hearing Research Professor of Otolaryngology Richard J. H. Smith, MD, received a competitive renewal grant from the National Institute on Deafness and Other Communication Disorders/National Institutes of Health to continue their investigation into the causes of deafness. The five-year award of $3.2M supports the project titled Optimizing Genetic Testing for Deafness for Clinical Diagnostics.

Identifying a genetic cause of deafness is not always straightforward. Smith and his colleagues currently are able to provide a genetic diagnosis in about 45 percent of patients with hearing loss. While this is greatly improved compared to previous technologies, it is still not as high as they would like it to be. Goals of the new grant include improving the ability to provide a genetic diagnosis to those affected by hearing loss.

Researchers are using the patient’s exact type of hearing loss (audiometric data) to inform their analysis of deafness genes and better characterize progression of hearing loss over time. They are looking for genetic modifier genes that may have a drastic effect on the severity of hearing loss. For example, two patients may have the same genetic change causing deafness, but one may have a mild hearing loss and one may have a severe hearing loss.

Successful completion of the research will lay the foundation for more refined studies focused on the identification of genetic modifiers – both positive and negative – associated with complex hearing loss phenotypes including noise-induced and age-related hearing loss. Findings will allow Smith and his team to enhance and expand the OtoSCOPE™ genetic testing platform that is available to patients experiencing hereditary hearing loss.

Learn more about research involving the genetics of hearing loss and OtoSCOPE™ genetic testing at medicine.uiowa.edu/MORL

“It is extremely gratifying to work with such a dedicated team to improve the diagnostic approach used to help persons with hearing loss. We have changed clinical care by showing that comprehensive genetic testing is the best test to order in the evaluation of hearing loss. This new grant will offer new insights by enabling us to improve our ability to relate genetic findings to their clinical consequences. This type of genotype-phenotype understanding should help us identify new approaches to the preservation of hearing.” –Richard Smith, MD
University start-up nets key early stage funding and recognition

Cochlear implants have fundamentally changed the treatment of hearing loss. Despite the progress in device quality over the years, more than 50 percent of implant recipients experience additional hearing deterioration after initial implant surgery. Implants cannot be repositioned to account for the additional hearing loss, which leads to a diminished quality of life for patients who can no longer experience the quality and range of sounds they once enjoyed.

Start-up company iotaMotion is addressing this medical need by developing a revolutionary implantable robotic system to assist surgeons in performing cochlear implantation for improved hearing outcomes. The company has created an accessory that seeks to solve the problem by remotely moving the cochlear implant to a position of improved hearing quality. This will allow physicians and their patients to adjust for post-surgical hearing decline without the need for additional surgery. Additionally, it will enable many more patients with hearing loss to retain their hearing capacity much longer over their lifetimes.

Co-founded by professor of otolaryngology Marlan Hansen, MD, and otolaryngology resident physician Chris Kaufmann, MD, MS, the company is supported by UI Ventures, a part of the University of Iowa Office of the Vice President for Research and Economic Development that offers information and resources to University start-up companies.

The technology is in the early stage of development, but the company has conducted initial proof-of-concept testing and has patents pending. It also garnered the attention of the National Science Foundation (NSF) in June 2016. The company won a highly competitive, $225,000 NSF Small Business Innovation Research Phase I grant to further develop its implantable robotic-assistive surgical system for improving cochlear implant hearing outcomes. This technology may also facilitate commercial opportunities for the use of an implantable robotic system in other applications where an implantable electrode/wire requires precise and dynamic remote position adjustments.

Hansen remarks, “NSF SBIR funding has allowed us to further develop and validate our prototype in preparation for large animal studies. It has been critical to moving this technology forward. Ultimately, we anticipate that this

Dr. Chris Kaufmann presented to a group of investors and business professionals at the Iowa Connect Medical Technology Symposium. Kaufmann is co-founder of iotaMotion and currently an otolaryngology resident physician. Image courtesy of iotaMotion

iotaMotion has had success pitching its business model, as well. In late 2015, the company won first place at the Iowa Connect Medical Technology Symposium’s pitch competition. The competition featured six regional teams giving five-minute company pitches. In addition, iotaMotion won the Rising Star award at the Early Stage Symposium in Madison, Wis., coming in second place among 17 entries in the elevator pitch competition. Elevator pitches were evaluated by investors and business professionals from across the country.

More about the company and its recent success at iotamotion.com

"Start-up" continues on page 6
New grant allows study of biomarkers in oral cancer

The University of Iowa Holden Comprehensive Cancer Center awarded an American Cancer Society Institutional Research Grant to Steven Sperry, MD, clinical assistant professor of otolaryngology – head and neck surgery. These one-year, cancer-focused research awards permit the initiation of promising new projects or novel ideas necessary to obtain preliminary results for junior faculty like Sperry to successfully compete for national research grants.

Sperry’s project seeks to identify the biomarkers in oral cavity squamous cell carcinoma (OCSCC) associated with outcomes after surgical treatment of the disease. He and his colleagues will assemble hundreds of tumor samples using a technology called tissue microarray, which allows high-throughput evaluation of the samples by immunohistochemistry. The process uses antibodies designed to recognize the expression pattern of specific proteins in the tissue. Their research aims to identify protein biomarkers associated with recurrences in good prognosis patients, as well as biomarkers associated with positive margins in poor prognosis patients.

From extensive study of patients with OCSCC treated with surgery at UI Hospitals and Clinics, it is known that certain clinicopathologic characteristics are associated with recurrence and survival, with the surgical margin and the presence of node metastasis being the most important factors (see Figure). In a recently published report (Buchakjian et al. JAMA Oto 2016), UI researchers concluded that assessment of the surgical margin from the tumor specimen was the best predictor of recurrence outcome rather than standard thinking that the assessment by intraoperative frozen section margins from the tumor bed periphery was the appropriate indicator.

Despite achieving negative margin surgery and having no node metastasis, recurrences still occur in some patients, which dramatically affect survival from the cancer. UI researchers are questioning why this small number of patients who should have a good outcome do not. They believe that further investigation of the molecular characteristics of their patients’ specific tumors may shed some insight.

Furthermore, for patients who do have a positive margin at the time of surgery, researchers do not completely understand why this occurs. The surgeons embark on the procedure with the objective of resecting the tumor with widely clear margins, so a microscopically positive margin is usually a surprise. While this could be viewed as a technical error by the surgeon or a factor of the anatomic limitations of surgery, experts in the head and neck oncology division at UI Hospitals and Clinics do not consider those to be satisfactory explanations. They contend a positive microscopic surgical margin may simply be a characteristic of the biological aggressiveness of the tumor.

According to Sperry, “The identification of biomarkers which have prognostic importance in OCSCC will benefit patients with more accurate information, clinicians with specific biologic information useful for counseling patients and tailoring treatment, and researchers with insight to develop future research studies and new therapies.”

iota Motion and Dr. Hansen were featured among a group of companies that have utilized UI Ventures and UI Research Foundation to help take their ideas out to the marketplace. Watch http://bit.ly/2f8jqOL
Event celebrates professorship of craniofacial abnormalities

Faculty and staff joined donors and friends of the department to celebrate the creation of the Paul N. Johnson Professorship in Craniofacial Abnormalities. The professorship was made possible through a generous gift from Barbara and Norm (’71BBA) Johnson. Their gift honors Mr. Johnson’s father, who had cleft palate.

The professorship was awarded to Deborah S. Kacmarynski, MD, clinical associate professor of otolaryngology. Kacmarynski specializes in the treatment and research of cleft lip and cleft palate in pediatric patients. She is part a multidisciplinary team of surgeons, audiologists, speech therapists, orthodontists, genetic counselors, and others who treat patients at UI Hospitals and Clinics and through outreach clinics abroad.

TOP RIGHT: Barbara and Norm Johnson (3rd and 2nd from right) celebrated the awarding of the new professorship with Kacmarynski (center), department chair Bruce Gantz, MD (far right), and other leaders from the UI Carver College of Medicine and University of Iowa.

RIGHT: Kacmarynski accepts her professorship medallion from Vice President of Medical Affairs Jean Robillard, MD.

Remembrance

The University of Iowa and the Department of Otolaryngology – Head and Neck Surgery lost a dear friend and key supporter. Harold John Dane, Jr. passed away in July from complications following surgery.

He and members of the Dane family have supported research into the genetic causes of hearing loss and the development of clinical diagnostic tests. In addition, he helped create the Dane Family Professorship in Auditory Science within the department.

The University of Iowa Foundation

There are many ways to make a difference through charitable donations. To learn more about how philanthropic support helps advance the important work of the UI Department of Otolaryngology—Head and Neck Surgery, please contact:

Sean Matthys
Associate Director of Development
University of Iowa Foundation
319-467-3649 or 800-648-6973
sean-matthys@uiowa.edu

The UI acknowledges the UI Foundation as the preferred channel for private contributions that benefit all areas of the university.

For more information or to make a donation, visit the UI Foundation’s secure website at givetoiowa.org/OTO
The 2016 graduates

Residents and fellows who graduated from the University of Iowa this year are off to pursue their next medical career moves.

Graduating residents (pictured left to right):

- **Stephanie Hulstein Burger, MD**: pursuing private practice position with Wagner Ear, Nose and Throat, Sioux City, Iowa
- **Scott Owen, MD**: pursuing facial, plastic and reconstructive surgery fellowship at Vanderbilt University School of Medicine, Nashville, Tenn.
- **Iram Ahmad, MD**: remaining at University of Iowa Hospitals and Clinics for pediatric otolaryngology fellowship
- **Jarrett Walsh, MD, PhD**: continuing with rhinology and endoscopic skull base surgery fellowship at the University of Miami Miller School of Medicine

New colleagues

**Residents:**

- **Zaid H. Al-Qurayshi, MD, MPH**: MD, University of Baghdad College of Medicine, Iraq
  MPH, Tulane University School of Public Health and Tropical Medicine
- **Daniel Lee, MD**: BS, St. Olaf College, Northfield, Minn.
  MD, University of Iowa Carver College of Medicine
- **Joseph Peterson, MD**: BA, Brigham Young University, Provo, Utah
  MD, University of Texas, School of Medicine, San Antonio, Texas
- **C. Blake Sullivan, MD**: BS, Lipscomb University, Nashville, Tenn.
  MD, Oregon Health and Science University, Portland, Ore.
- **Huan Zhang, MD**: BA, University of California, Berkeley, Calif.
  MD, Case Western Reserve University School of Medicine, Cleveland, Ohio

**Fellows:**

- **Chris Kandl, MD** – Head and Neck Oncology
  MD, Medical University of South Carolina College of Medicine, Charleston, S.C.
  Residency, Parkland Health and Hospital System, Kansas City, Kan.
- **Daniel Sun, MD** – Neurotology
  MD, Johns Hopkins University School of Medicine, Baltimore, Md.
  Residency, Johns Hopkins University School of Medicine, Baltimore, Md.

**Fellows:**

- **Oluwafunmilola Okuyemi, MD**: Head and Neck Fellow: joining faculty at the University of Nevada in Las Vegas
- **Ala Sharif, MD**: Rhinology Fellow: pursuing position in the Ministry of Health Hospitals in Amman, Jordan
- **Joseph Roche, MD**: Neurotology Fellow: joining faculty at the University of Wisconsin in Madison
Resident receives teaching award

Medical students from the University of Iowa Carver College of Medicine selected six resident physicians from a field of nearly 800 individuals to receive a Humanism and Excellence In Teaching Award. Among those selected was Department of Otolaryngology – Head and Neck Surgery resident physician Adam Schwalje, MD.

Schwalje remarked, “I was honored and humbled to be selected for the award. For me, the award is a reminder that medicine is personal. It is relational. It is direct. While computer screens beckon with ever-increasing demands for ‘indirect’ patient care, the challenge is to remember that with every encounter comes opportunities to ease a patient’s fears, to support a budding doctor, or to connect in even a small way.”

The award, presented by the Arnold P. Gold Foundation, goes to those individuals who demonstrate the foundation’s and the Carver College of Medicine’s ideals of commitment to teaching and compassionate treatment of patients and families, students, and colleagues.

Iowa Head and Neck Course prepares for “golden anniversary”

A long-standing education tradition is reaching a milestone! The Department of Otolaryngology – Head and Neck Surgery is hosting the 50th annual Iowa Head and Neck Reconstructive Surgery Course May 22-26, 2017.

This five-day course provides a comprehensive review of current techniques in the management and reconstruction of head and neck neoplasms. Cadaver dissection under the supervision of the faculty is offered to those taking the five-day course. Enrollment is limited so sign up early.

Guest speakers include:

Jonathan C. Irish MD, MSc, FRCSC, FACS
The Kevin and Sandra Sullivan Chair in Surgical Oncology
Professor, Department of Otolaryngology-Head and Neck Surgery
University of Toronto

Theodoros (Ted) N. Teknos, MD
Professor and Chair, Otolaryngology – Head and Neck Surgery
The Ohio State University

Brian O’Sullivan, MD
Professor, Radiation Oncology
University of Toronto

Randal S. Weber, MD
Professor and Chair, Head and Neck Surgery
University of Texas MD Anderson Cancer Center

Mark J. Jameson, MD, PhD (’07F)
Associate Professor, Otolaryngology
University of Virginia

Contact otocourses@uiowa.edu or 319-356-1744.
More information at medicine.uiowa.edu/oto/education/conferences-and-events/
Gantz chosen to co-chair search for UI leadership position

University of Iowa President Bruce Harreld named co-chairs for the search committee charged with finding a replacement for Jean Robillard, MD, vice president for medical affairs and dean of the UI Carver College of Medicine.

Bruce Gantz, MD, head of the Department of Otolaryngology–Head and Neck Surgery, joins Carroll Reasoner, vice president of UI legal affairs and general counsel, as co-chairs of the 17-person search committee comprised of leadership from across UI Health Care and University of Iowa.

Robillard is stepping down from his role overseeing UI Health Care, which comprises the UI Carver College of Medicine, University of Iowa Hospitals and Clinics, and University of Iowa Physicians. He will continue to serve as vice president and dean until a new leader is named.

Otolaryngology nurse acting in key role

Cindy Dawson, MSN, RN, CORLN, is providing interim leadership to the Department of Nursing Services and Patient Care at UI Hospitals and Clinics where she is serving as interim chief nursing officer.

Dawson has more than 40 years of experience at UI Hospitals and Clinics, beginning as a staff nurse in the Department of Otolaryngology in 1975 and moving into leadership roles soon after. She is a frequent presenter at regional and national meetings, and the author or co-author of many articles and book chapters focused on clinical care and evidence-based practice.

Dawson is a member of several professional societies, including the American Organization of Nurse Executives, the American Academy of Ambulatory Care Nursing, Society of Otorhinolaryngology and Head-Neck Nursing (SOHN), and the Honor Society of Nursing, Sigma Theta Tau International. She held several leadership roles within SOHN, including president. Among the awards she has received during her career is being named as one of the 100 Great Iowa Nurses.

College recognizes Van Daele for early career achievement

The University of Iowa Carver College of Medicine recognized five exemplary graduates for their outstanding contributions to the field of medicine. Among them was Douglas Van Daele, MD (‘96MD, ‘97F, ‘99F, ‘03R). Van Daele, a professor of otolaryngology – head and neck surgery, received the College’s 2016 Early Career Achievement Award.

During his time with the UI, Van Daele has emerged as a respected voice in conversations surrounding innovations in health care delivery. His appointments to vice dean for clinical affairs in the UI Carver College of Medicine and executive director of UI Physicians came as he developed an international reputation in teaching, research, and clinical excellence in otolaryngology – head and neck surgery. He played a crucial role in the institutional transition to electronic health records and has positioned UI Health Care as a leader in data-driven practice.

Van Daele (left) accepts the Carver College of Medicine’s 2016 Early Career Achievement Award from Vice President of Medical Affairs Jean Robillard, MD.
Alumni gather in San Diego

The coastal city of San Diego served as the location for the 2016 AAO-HNSF Annual Meeting & OTO Expo. Alumni, faculty, and friends of the Department of Otolaryngology – Head and Neck Surgery gathered at The Fish Market for the annual Iowa alumni reception.

Neurotology fellow alumni also gathered for their annual dinner where they shared stories from their training and careers.

Next year’s annual meeting will take place in Chicago Sept. 10-13, 2017. Watch for reception details and plan to join us in the Windy City!
LOUD&CLEAR EVENTS

Mark your calendars

May 19-20, 2017  Functional Endoscopic Sinus Course, Iowa City

May 22-26, 2017  50th Head and Neck Cancer Reconstructive Surgery Course, Iowa City

June 9-10        UI Carver College of Medicine Alumni Reunion, Iowa City (Classes of ’47, ’52, ’57, ’62, ’67, ’72, and ’77)

June 15-16      25th Annual Management of the Tinnitus Patient, Iowa City

June 17         Research Day and Resident/Fellow Graduation, Iowa City

July 5 to August 4  Basic Science Course, Iowa City

Sept. 10-13     AAO-HNSF Annual Meeting & OTO Experience, Chicago

Sept. TBD    Iowa Alumni Reception, date and location pending

Educational meeting information with dates and details can be found at medicine.uiowa.edu/oto/education/conferences-and-events