Facial Reanimation Surgery
Following Facial Nerve Injury
Bradley Mons, DO
Otolaryngologist; Head and Neck Surgeon

Nerve injury is one of the most common complications of head and neck surgery. Most of these injuries involve sensory nerves and are almost considered “normal” or an “expected” outcome of surgery. Sensory nerves are those that provide sensation to the skin. That is why it is not uncommon to have numbness or tingling around an incision site for many months and sometimes for many years after surgery. But injuring a motor nerve, or a nerve that controls a muscle often results in disfigurement and can lead to other complications throughout life.

The facial nerve, also known as cranial nerve seven, is a large motor nerve that controls the muscles of facial expression. Almost every muscle that moves on your face is controlled by these two facial nerves (one on each side). These nerves exit the skull from a hole near the mastoid, or the boney prominence behind the ear. Once they exit this hole, they give off a few small branches to muscles in the neck then continue into the parotid glands, which are the largest salivary glands and sit at the angle of the jaw. Within the glands, the facial nerves divide into five branches each.

The two upper branches control the muscles of our forehead and around the eye. The middle branch controls muscles of the cheek. The two lower branches control muscles of the lower lip, chin, and the large sheet-like muscle in the neck, known as the platysma. Therefore, any surgery in front of the ear (most commonly skin cancers and tumors of the parotid gland) carries a risk of damaging one or more of these branches and causing facial weakness on that side.

Facial paralysis can be quite difficult for a patient. The muscle weakness causes facial disfigurement, which worsens with age due to gravity and loss of muscle tone. If half of the mouth cannot move, drooling will occur and eating will be more difficult. If the eyelid cannot close, the eye will dry out, become infected, and can result in loss of vision. Careful and continuous attention to the eye must be taken to keep it moistened. It is also important to keep it closed or covered as the blink reflex is absent and dust and other airborne objects can scratch the eye more readily.

If one branch of the facial nerve is injured or involved with cancer, then only the group of muscles controlled by that branch will be weak or paralyzed. If the main trunk of the nerve is damaged or involved with cancer, then that whole side of the face will be paralyzed. This is different than Bell’s palsy. Bell’s palsy is a diagnosis of exclusion. In other words, when a patient presents with one-sided facial weakness, every cause of weakness needs to be ruled out, or excluded, before a physician can call the weakness “Bell’s palsy.”

Common causes of facial weakness include stroke, head trauma, surgery of the neck or face, severe ear infections known as mastoiditis and brain tumors. When I see a patient with facial paralysis or weakness for the first time, I ask the patient many questions. When did the weakness start? Was there any head trauma at the time of weakness? Was it after neck surgery or radiation? Is there any ear pain, drainage, or vertigo? Has the weakness gotten any better or worse? I also perform a careful physical examination. I look for other nerves not working. I look in the ear. I feel the neck for any abnormal lumps or bumps (masses). I also order radiographic imaging, either a CT or MRI or sometimes both. These images give me a better understanding of what is happening deep into the skin and in the brain. Lastly, depending on how long the muscle has been weak, I may request electric nerve testing. This will show me if there is any muscle function still present and provides prognosis of the weakness.

Skin cancers in their early stages usually do not grow deep enough to involve the facial nerve whereas late stage skin cancers or more aggressive skin cancers can cause facial weakness even before surgery is performed. In the case of early skin cancers, a surgeon must be careful to go deep enough to remove all of the cancer but not too deep so as to avoid cutting or traumatizing the facial nerve. If the cancer has already invaded the nerve before the surgery, the nerve cannot be saved and must be removed during the surgery.

The most common tumors of the parotid gland are benign and do not usually cause facial weakness. However, malignant tumors of the parotid gland, even if really small, can cause facial weakness. Tumors in the parotid gland, even if benign, require
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surgery to remove them. Any surgery of the parotid gland puts the nerve at risk for injury.

Any physician performing surgery around or near the facial nerve should have a strong knowledge of facial nerve anatomy. Adequate training also serves the physician well when performing any surgery. A third tool that is being used more often is nerve monitoring. This device consists of needle probes that are inserted into a group of muscles that are innervated by a particular nerve. These probes are then attached to a computer. If the surgeon stimulates the particular motor nerve, the muscles twitch which then makes a response on the computer. The computer can be set to make an audio signal for the surgeon to hear or a visual one which a technician can see who then alerts the surgeon. These neuro-monitoring systems have not been shown to decrease the incidence of nerve injury but still continue to be used to confirm the integrity of the nerve during the case.

If a patient has facial weakness after a procedure, the surgeon follows a mental algorithm. If the nerve was not identified during the procedure, the surgeon should bring the patient back into surgery as soon as possible to find the nerve and confirm that it was not cut inadvertently during the initial procedure. If it is found to have been damaged, then the nerve should be reconnected in an “end to end” fashion with a fine suture. If the surgeon did identify the nerve during the initial procedure and knows that the nerve was not cut, then the patient is counseled to wait one to two months for the nerve to start working again.

If the nerve does not start working after 2-3 months, or if the nerve had to be removed during the procedure, then there are a variety of options available for the patient. Static procedures pull or tighten the paralyzed muscles. This allows the face to look symmetric as long as the face is at rest, or not moving. There are also options that have the potential to “reanimate” the facial muscles again.

Because the eye is the most important organ to protect when the facial muscles are paralyzed, a gold weight is usually implanted in the upper eyelid of the affected side. Although a gold weight implant is not a true reanimation technique, it does allow the upper eyelid to close. This is because the major muscle group that keeps the eye open is not controlled by the facial nerve, but the muscles that close the eye are. Therefore, placing a gold weight in the upper eyelid will make it heavier, which allows gravity to pull it closed when the lifting muscles relax.

The preferred technique for facial reanimation reconstruction is primary facial nerve grafting. This should be performed at the time of the primary cancer surgery. A nerve graft is harvested from a sensory nerve, usually from the lower leg. This piece of nerve is then gently sutured to the trunk of the facial nerve and then the other end of the graft is gently divided and sewn to the facial branches. This often requires a microscope and occasionally drilling bone away from the hole of the facial nerve in order to provide enough nerve trunk to sew to. Out of all the facial reanimation techniques, this one yields the best functional results.

The next preferred facial reanimation reconstruction is a nerve transfer procedure. For this technique, the surgeon harvests the piece of sensory nerve from the lower leg or the neck. The graft is then tied to a branch of tongue nerve or even a branch of the facial nerve.

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from the other side of the face. The other end of the graft is sutured to the paralyzed nerve. The tongue nerve graft has been more successful and provides better functional results than the cross-facial graft.

The temporalis muscle transposition flap can provide reanimation. This technique takes the temporalis muscle from the side of the scalp, tunnels it under the skin and attaches the tendon to the corner of the mouth. This muscle is one of the muscles used for chewing foods. Using it for facial reanimation does not impact chewing food. However it does allow for facial symmetry at rest and, with practice, can allow the patient to smile by clinching the teeth together. This particular flap is useful for facial paralysis that has been present for longer than a year. This technique is not recommended if post-operative radiation is planned.

Lastly there is a free tissue transfer technique that can be used. A piece of muscle, usually from the leg, is harvested with its blood supply and motor nerve. This graft is then brought up to the face, muscle is sewn to the corner of the paralyzed mouth, nerve is sewn to the remaining facial nerve trunk, then the blood vessels have to be attached in the neck as well. This graft can be disfiguring due to the bulkiness of this muscle in the face. The flap can also die if a clot develops in the blood vessels during the healing process. This technique is also not recommended if post-operative radiation is planned.

There are many controversies when dealing with facial nerve reanimation. The first is the length of time since the injury. The motor end-plates, or connections between the nerves and muscles, start to breakdown when there is no longer nerve stimulation. The nerve grafting procedure as well as the free tissue graft should ideally be performed within 6 months of the facial nerve injury. Historically, it was thought that after one year post facial nerve injury, the motor-end plates would not regenerate and therefore a static sling or transposition flap would be performed. But recent literature has shown that even two years past nerve injury, a nerve graft procedure can be successful. The second controversy is which nerves to re-attach. Some surgeons try to reattach as many branches as possible. This requires splitting the nerve graft into several smaller branches, which can reduce the success of the graft. Other surgeons focus on the lower branches to the mouth and use the gold weight implant for the eye. This allows for larger “branches” of the graft and less synkinesis. Synkinesis is when two or more muscle groups move when the patient only tries to move one group.

During the post-operative reanimation procedure, no matter which technique is performed, therapy is important. Speech and physical therapy provide strengthening and coordination exercises. As the nerves regenerate and the patient develops motion in the once paralyzed muscles, it is important for the patient to practice in front of the mirror several times a day. This allows for feedback to the brain on what stimulation provides what motions.

There are multiple options for facial reconstruction. Facial reanimation is one of them and there are many successful techniques. Even if the paralysis has been present for longer than 2 years, there are options available. The surgeon should have experience performing the desired procedure with acceptable results.

Editors Note: Dr. Mons earned a Doctor of Osteopathic Medicine degree from Oklahoma State University Center for Health Sciences in Tulsa, OK. He then completed a surgical internship and residency at Ingham Regional Medical Center in Lansing, MI, followed by a residency in the Department of Otolaryngology Head and Neck Surgery at the Philadelphia College of Osteopathic Medicine.

Dr. Mons also completed a fellowship in head and neck oncology/microvascular reconstruction in the Department of Surgery at the University of Wisconsin in Madison, WI. This fellowship training, Dr. Mons says, gave him the skills to reconstruct the defects created when removing tumors of the head and neck.

Dr. Mons is board certified with the American Osteopathic Board of Otolaryngology and the American Board of Facial Plastic and Reconstructive Surgery. He is a member of several professional organizations, including the American Osteopathic Association, the American Osteopathic College of Otolaryngology-Head and Neck Surgery, and the American Academy of Otolaryngology-Head and Neck Surgery.

“Thank you so much for all of your support!”
~ Rita A.
TIME FOR SHARING...My Thyroid Cancer Story

My thyroid cancer story is full of firsts and surprises...and lessons. My diagnosis was confirmed several months after a routine spring checkup that led to a neck ultrasound, then a biopsy, and then a surgery that occurred on a day that no one who was old enough to remember it will ever forget.

It wasn’t that my cancer was life-threatening...but a few days after I learned, thirteen days after that first thyroid surgery, that I really did have thyroid cancer, an expert in the field did say that they had “never seen” one that looked quite like mine before. There’s nothing like stumping the experts with cancer!

Did being the first frighten me? Of course, although thyroid cancer had been quite frightening to me for a while, by then. When told, about a month pre-op, that there was about an 80% chance that the small (1.5 by 2 cm.) nodule on the right lobe of my thyroid was malignant, I reacted the way I think anyone would: my first word was “Eighty?!” As in, the endocrinologist who’d done the FNA (fne-needle aspiration biopsy) had told me, a few minutes after getting very preliminary results, that the nodule was probably benign. As in, after getting the pathologist’s report a week later, he’d asked me if I knew what a follicular neoplasm was, and when I’d said I could spell it and wondered what it meant for me, he’d replied that there was about a 20% chance of malignancy. When I’d asked him what I should do, he, a Tennessee native with a laid-back personality and a voice to match it, said he was going to give me a surgeon’s name and number and that I should write them down and see him as soon as I could. Did I say the doctor was laid-back? Not that time!

So I went and saw the surgeon, whose trademark shuffle I heard for the first time as he approached the door of the exam room and knocked softly before one of the three of us—a fourth-year medical student, a friend of mine, or I, said, “Come in!” Sticking out a paw, he said, simply, “Hi, I’m Doug Fraker.” Now, if you’ve ever met Douglas Fraker, you know a few things. One, he’s very tall. Built like a quarterback, and it wouldn’t surprise me if he once was one. Two, he’s a Midwesterner by birth...and, I believe, temperament (I’ve never met a Midwesterner I didn’t like); in other words, he has better things to worry about than his fancy titles. Three, he treats his patients the way I’m sure he’d want to be treated: with respect, with helpful information, with a gentle sense of humor, but without hand-holding pity. He knew I was scared. Scared? No, terrified. My mother had died of cancer at 49. I was fifty. I told him. He nodded. He told me my cancer was very different...I knew, but did I know? Does anyone? (She had inflammatory breast cancer. No matter: she was my mother, she was 49, I was 50. He knew.) And he said, “Not a hundred per cent. Eighty.” Not to be reassured so easily, I retorted, “Are you a gambler?” “No,” he answered, shaking his head, still looking right at me. “Neither am I. Get that thing the hell out of me.”

I shocked myself with the words, barked as an order to a total stranger—a surgeon!—but I didn’t care. And he drew a picture of the surgery for me, and I suggested he keep his day job, and we laughed, just a little. A bunch of forms for me to sign included one that meant, as I put it, “if I die I don’t sue you,” and he laughed, just a little.

Concerned about possible vocal damage, I told him as much: I’m a passionate amateur singer, and at that time, music was one of the few things keeping me steady. He assured me that the risk was very slight. “When do you want to do this?” I asked. He offered me September 18 (it was August 8 then), by which time he’d be back from a conference abroad. I asked for the previous Tuesday, since Tuesday the 18th was Rosh Hashanah, the Jewish New Year, a celebration, and he’d just said I’d probably be up and about within a week after surgery. “Sure,” he answered. “I get horribly dry if I have to go all night without water,” I continued, having read some of the instructions on the forms. “Can we do this early in the morning?” He nodded: I could be his first patient of the day:

~ September 11, 2001 ~ 
Even on the morning of the 11th, I didn’t know whether or not I had cancer. I was sure I did, but that meant little. All I knew was that the sky was that perfect, cloudless blue that can only be seen safely through protective sunglasses, and that I shouldn’t be in a hospital, waiting to be anesthetized and operated on; I should be flying somewhere, in a sky that bright. It was what I called a flying day. I was terrified. And then a nurse, who’s also been with me during three subsequent neck surgeries, came to gently and kindly ask me a lot of questions, and then there were the two good-natured anesthesiologists, one of whom stuck a needle in the back of my hand and began infusing solutions. First a saline, and then....

Then I was in the recovery room, and a TV screen opposite my bed, and near a clock that read 9:03, showed me the Twin Towers of the World Trade Center, one with heavy smoke at its summit, and an airplane, sailing across that perfect blue sky into the other Tower, the South Tower. Bad movie, I thought, I’m going back to sleep. Goodnight...and I drifted off....

And then I woke up again, and this time I saw a mushroom cloud of things coming down. Banging on the side of the bed, I demanded, repeatedly--“What happened? What happened?”—until a nurse turned to another and said I was in shock. “No, look!” I insisted, repeatedly, pointing at the TV screen. Eventually they realized I was neither kidding nor in shock, and turned around, and saw.

The rest of the day’s elective surgeries were cancelled in the belief that the staff would be called upon to treat the many injured men, women and children they thought would need their help. It was afternoon before we realized that the thousands were not injured, but dead.

At 6 PM my surgeon came to see me, and gave me the good news that his and an expert pathologist’s examination of the excised right lobe of my thyroid had indicated no malignancy, so he doubted very much that the left lobe would have to be removed. That was a huge relief to me, but what thrilled me even more was the knowledge that I would still be able to sing.
and in March 2014, another parathyroid within a year or two my PTH was climbing, fine, endocrinologically speaking, but for a while after that, everything seemed very high parathyroid hormone (PTH) level. In a year's time and a blood test disclosed a gland had to be removed in late April 2003, I'd been born with five? The supernumerary vital glands, which make the hormone that majority of us have four of those little but parathyroids were normal, since the vast tissue my surgeon had been unable to remove. At the time he thought all my parathyroids were normal, since the vast majority of us have four of those little but vital glands, which make the hormone that regulates calcium metabolism, and the four he saw were, indeed, normal. Who knew I’d been born with five? The supernumerary gland had to be removed in late April 2003, after my serum calcium was elevated twice in a year’s time and a blood test disclosed a very high parathyroid hormone (PTH) level. For a while after that, everything seemed fine, endocrinologically speaking, but within a year or two my PTH was climbing, and in March 2014, another parathyroid was removed. I hope that’s it...as I told him on one occasion, I like my neck...I’m very attached to it! (A line he has wisely ignored.)

Back to my thyroid cancer: In August 2003 I had a scan to see if the surgeries and ablation had successfully wiped out all my thyroid tissue. This scan followed some hypothyroid weeks that were far worse than those that had preceded the ablation...because, as I realized afterwards, I had absolutely no thyroid tissue by then! This beautifully, blissfully negative scan has remained the last of its kind for me, thanks to regular--and regularly negative--tests for thyroglobulin, a protein made only by thyroid tissue. For at least some time after that August 2003 scan, I remained the first live patient ever seen with a suspicious but ultimately benign nodule plus multifocal microcarcinomas, which are commonly seen in autopsies. I suppose I was a pioneer, albeit an unwilling one.

And the lessons? There was the example of the people who made sure I was as healthy as they could make me, and who treated me with the utmost respect, kindness, humor and even tenderness. Do I dare call it love? Most of them were still total strangers to me on that flying day in September 2001. One of them, still not much more than a stranger, took such pains that, far from damaging my voice, he improved it for me. I suppose there were a total of about twenty of them: doctors, surgeons, nurses, nurse-practitioners, nursing assistants, and my friend who was with me the day I met Doug Fraker.

On September 11, about the same number of people--very different people--chose instead to demonstrate murderous hatred. As it turned out, beginning that spring and down to the minute, they had made calamitous use, planning and executing that terrorist attack, of the same length of time that I had spent with various doctors and nurses. Which is more important--making sure that saving just one life means everything, or proving how destructive hate can be? I know the answer; I learned it through a sequence of eerie coincidences. And another lesson: Sometimes it’s good to be an unwilling pioneer. I didn’t save any lives, but, with no recurrences or metastases since the negative scan of 2003, a case like mine proves that a cancer that looks

~ Barbara Pilvin
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HEAD AND NECK CANCER NEWS

Silk and stem cells may help engineer salivary glands for dry mouth

July 30, 2015 - Millions of people in the US suffer with dry mouth, a very uncomfortable feeling of insufficient saliva in the mouth that can lead to serious health problems. Now, there is the promise of relief, as a new study shows how - with the help of silk fibers - it may be possible to generate new salivary glands out of stem cells.

There are currently no treatments for dry mouth, where the salivary glands do not produce enough saliva.

Dry mouth is the result of low-producing or non-functioning salivary glands. The often devastating condition - known as xerostomia - has a number of causes, including medication use, radiation treatment for head and neck cancers, autoimmune diseases, diabetes and the process of aging. There are currently no treatments, and salivary glands have little capacity to renew themselves, highlighting a need for cell-based therapies that can grow new tissue and restore gland function.

In the journal Tissue Engineering Part A, a team from the University of Texas at San Antonio describes how they used silk fibers to provide salivary gland stem cells with a 3D scaffold on which to grow a matrix of salivary gland stem cells.

Senior author Chih-Ko Yeh, a professor in comprehensive dentistry who runs a lab focusing on salivary gland research, says: “The cells had many of the same characteristics as salivary gland cells that grow in the mouth.” The achievement is significant because “salivary gland stem cells are some of the most difficult cells to grow in culture and retain their function,” he explains.

Most of us do not give it a second thought - but the saliva we produce in our mouth is critical to good health. As well as initiating digestion, keeping bits of food off our teeth and preventing oral infection, saliva helps us swallow and speak. Insufficient saliva can lead to bad breath, tooth decay, gum disease and infections in other parts of the body.

Silk is a ‘good choice’ as a scaffolding for stem cells

The findings bring promise to 4 million Americans with an autoimmune disease called Sjögren’s Syndrome - a condition where the body attacks its own tear ducts and salivary glands. They also bring hope to thousands of others who have poor salivary function as a result of radiation treatment for head and neck cancer, and the 50% of older Americans whose medications can cause dry mouth.

For their study, the team made a silk framework from purified silk fibers, populated it with stem cells from rat salivary glands and added a nourishing medium to encourage growth. Prof. Yeh describes what happened: “After several weeks in culture, the cells produced a 3D matrix covering the silk scaffolds.” Prof. Yeh explains that silk is a good choice as a scaffolding for the stem cells because it is a natural product, it biodegrades and is flexible and porous. These properties help oxygen and nutrients reach the growing cells easily, and do not lead to inflammation, which has been a problem with other scaffolding materials, he adds.

‘Great potential’ for research and cell-based therapies

Because of the small number of salivary glands in the human mouth, the team is going to continue using rat salivary glands to fine-tune the method. Eventually, they hope to use stem cells harvested from human bone marrow or umbilical cord blood to regenerate human salivary glands.

Looking further into the future, Prof. Yeh believes that within the next 10 years, we will be repairing damaged salivary glands in patients by transfusing stem cells, or engineering artificial salivary gland tissue to replace damaged glands. He concludes: “This unique culture system has great potential for future salivary gland research and for the development of new cell-based therapeutics.”

Earlier this year, Medical News Today learned of another study where an injectable hydrogel boosted stem cell transplantation to help brain recovery after stroke and partially reverse blindness in mice. The team, which included researchers from the University of Toronto in Canada, said the hydrogel did more than hold the stem cells together - it directly promoted stem cell survival and integration.

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Visit the SPOHNC website at www.spohnc.org
In Memory...

SPOHNC was deeply saddened to learn of the passing of LeAnn Dragano, longtime facilitator of the SPOHNC, Augusta, GA Chapter. LeAnn was an asset to her community as she volunteered in so many capacities, helping others in any way she could. LeAnn was a dedicated volunteer for Cub Scouts, Little League Baseball, School PTO and Church Service, in addition to SPOHNC.

LeAnn’s history with SPOHNC began in 2008, when she, as a survivor of oral, head and neck cancer, spoke with her friend, Lori Burkhead Morgan, about starting up a Chapter at the Medical College of Georgia. As is said – the rest is history.

LeAnn’s husband, Glen, wrote to SPOHNC recently, telling of how she never asked for recognition for anything in her life. She did so much, in addition to running the SPOHNC Augusta Chapter with Lori. From 2006 when she was diagnosed with her first cancer, LeAnn also learned sign language, so she could communicate with others who were not able to speak, and also to assist those in the deaf community and she ran a bible study group at her church. Most important was her contribution to GRU, where she lectured medical students on the care of chronically ill patients and their caregivers. LeAnn made a huge difference, no matter where she was.

Lori Burkhead Morgan, Co-Facilitator of the Augusta, GA SPOHNC Chapter, also shared some deeply personal sentiments about LeAnn, with SPOHNC. As LeAnn’s battle with head and neck cancer intensified, she eventually lost her ability to speak, but that never stopped her from living, and helping others. “Actually, LeAnn didn’t need words at all – her life and actions were so powerful and were definitely her strength. Her actions in this world were filled with so much love, strength and selflessness. LeAnn’s faith was faith in action.”

As we keep LeAnn’s family and friends in our thoughts and prayers, SPOHNC is forever grateful for the leadership, commitment and compassion she showed to all around her, even as she fought her own battle. As Lori so eloquently put it into words…”We are better because we’ve known LeAnn, and the world is a better place because she was in it.”

SPOHNC Welcomes 3 New Chapters

Welcome to SPOHNC’s newest addition to our Texas family of support - Austin, Texas. Thanks to Dr. Ryan Tierney, Radiation Oncologist, for spearheading the effort. Having knowledge of SPOHNC, he presented the idea to Lauren Brandt, MSW at Texas Oncology - Austin, and the rest is history. Lauren is a licensed Master Social Worker, certified in oncology social work. She has worked in healthcare for nine years and facilitates several support groups, workshops and classes about survivorship, caregiving and the emotional impact cancer has on patients and family members. All of her experience will no doubt make her a kind and caring facilitator for our new Texas Chapter.

Welcome to SPOHNC’s 4th Michigan Chapter!

SPOHNC is pleased to welcome Warren, Michigan to our family of ever growing SPOHNC Chapters. Tammy Cass, RN, BSN, and Carlos Ramirez, MD, DDS will be facilitating this new group. Tammy brings a wealth of volunteer, as well as professional experience with her as the Nurse Navigator for Head, Neck and Maxillofacial Reconstructive Surgery at St. John Providence Health System. Dr. Ramirez has extensive specialized training in reconstructive surgery for head and neck cancer patients. This unique combination of professional knowledge will surely bring help and hope to newly diagnosed patients, survivors and their families throughout their cancer journey.

SPOHNC’s Florida Family Is Growing!

Tampa, Florida is the home of our newest warm weather SPOHNC Chapter. SPOHNC welcomes Elizabeth Korman, Oncology Dietician, and Bob Ciappetta, head and neck cancer survivor, as its dedicated and committed facilitators. Elizabeth brings unique experience to her group, as she previously facilitated the Lancaster, PA Chapter of SPOHNC. Bob’s enthusiasm, experience and willingness to support others who are just beginning their journey, makes this team of facilitators a very special one.

Contact SPOHNC at 1-800-377-0928 for more information.
As an Advisory Board member for the University of Rochester Geriatric Assessment study, Valerie Targia, Facilitator of the San Diego, CA Chapter of SPOHNC was invited to attend the May 2015 U-13 conference in Chicago, IL. The University is developing a standardized, pretreatment Geriatric Assessment for cancer patients over 70 years of age. The ultimate goal of the GA, when implemented nationally, is to enhance the quality of life and survivorship of elderly cancer patients. Various sites in medical institutions were randomly, computer selected. Physicians, oncology teams, and patients are currently being enrolled.

The 3-day national conference was sponsored by NIH, U of R, PCORI, CARG, and various national cancer-patient, advocacy organizations. It was convened to illustrate the need for a standardized, pretreatment geriatric cancer patient assessment. Because of comorbidities, or other functional declines, older cancer patients are historically under served by clinical trials or studies, in case they alter the hoped-for results.

The wide-ranging, talented field of conference speakers from prominent universities and medical institutions included oncology doctors, clinical researchers, psychologists, social workers, patient advocates, etc. - an amazing group of fully-involved professionals.

A wide range of relevant subjects were covered. Just a few included:

- The need for a standardized, pretreatment Geriatric Assessment;
- Priorities for better treatment outcomes and survivorship for geriatric cancer patients;
- Recommendations to close key gaps in knowledge concerning geriatric cancer patients;
- What is missing in clinical trials for geriatric cancer patients;
- How to build an interdisciplinary team and share information;
- Translating research results, and disseminating information to the community at large.

After each speaker, everyone participated in discussions, relevant to that subject, and the U of R Advisory Board cancer survivors, were asked to give their perspective on each subject.

Over three days, the conference was an overload of educational information, and collaboration. It was invaluable, and so worthwhile regarding an issue that Valerie is passionate about. It is a necessary project that she considers “a no-brainer”, and a national standardized geriatric assessment should have been implemented years ago.

Valerie came away from the conference with the impression that there is so much more work to be done, and there were more questions raised than answers. However, she is hopeful that this will come to fruition because of the dedication of so many compassionate people she met while there, who are working towards implementing this need for the geriatric cancer population.

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ASC0 Issues Recommendations for the Inclusion of Older Adults in Clinical Trials

Over 60% of cancers diagnosed in the U.S. occur in people aged 65 years or older. However, this population remains underrepresented in clinical trials, therefore leading to a lack of evidence to inform treatment decisions for this population, according to a press release.

“Older people living with cancer often have different experiences and outcomes in their treatment than younger cancer patients,” Julie M. Vose, MD, MBA, FASCO, chief of the division of hematology and oncology in the department of internal medicine at the University of Nebraska Medical Center and president of ASCO, said in the release. “As we age, for example, the risk of adverse reactions from treatment significantly increases. Older adults must be involved in clinical trials so we can learn the best way to treat older cancer patients resulting in improved outcomes and manageable toxicities.”

Julie M. Vose

Two articles — both published in Journal of Clinical Oncology — outlined ASCO’s recommended guidelines for the inclusion of older patients with cancer in clinical trials. One of the papers — by Edward S. Kim, MD, chair of solid tumor oncology and investigational therapeutics at the Levine Cancer Institute in Charlotte, North Carolina, and a HemOnc Today Editorial Board member, and colleagues — described the need to modernize eligibility criteria for molecularly driven trials. In the other paper, Arti Hurria, MD, associate professor of medical oncology and population sciences and director of the Cancer and Aging Research Program at City of Hope, Comprehensive Cancer Center, as well as HemOnc Today’s geriatric oncology section editor, and colleagues sought to outline ways to improve the evidence base for treating older patients with cancer.

Edward S. Kim

Hurria and colleagues wrote that overly restrictive clinical trial eligibility criteria often lead to the exclusion of representative populations of older adults.

“There is growing recognition that eligibility criteria in clinical trials could be relaxed without compromising scientific rigor,” Hurria and colleagues wrote. “From 1999 to 2005, the median number of eligibility criteria per trial increased from 31 to 49. In addition, it is estimated that only 20% to 40% of patients treated at cancer centers are eligible to participate in clinical trials, primarily as a result of stringent eligibility criteria.”

Other strong recommendations from Hurria and colleagues included:

• Leveraging research designs and infrastructure to improve the evidence base for treating older adults, including the use of innovative trial designs;
• Increasing the authority of the FDA to incentivize and require research including older adults, including congressional requirements requiring drug or biologic marketing applications to contain a plan to gather data and develop dosing recommendations germane to older adults;
• Increasing clinical recruitment of older adults to clinical trials, including the development and promotion of educational materials for clinicians and researchers to encourage greater recruitment of older adults; and,
• Using journal policies to incentivize researchers to consistently report on the age distribution and health–risk profiles of study participants, including the requirement that authors submit detailed reports on age distribution by decade of the study population and the inclusion of geriatric oncology experts in the pool of editorial board members serving as peer reviewers.

“We need to see clinical trials that mirror the age distribution and health–risk profile of patients with cancer,” Hurria said in a press release. “ASCO has laid out a multi-pronged approach to expand the participation of older adults in clinical trials, ensuring that all patients will receive high-quality, evidence-based cancer care.”

Further, Kim and colleagues highlighted the need for the inclusion of older patients in molecularly driven clinical trials. The article focused on the refinement of eligibility criteria to be more representative of the entire patient population.

Although researchers seek to streamline drug development and approval processes of molecularly targeted agents to hasten drug access, the use of narrow populations in clinical trials may lead to questions about the agents’ generalizability, according to the authors.

“There are many eligibility criteria that are grandfathered into clinical trial protocols, not because they are appropriate for the trial, but because they were carried over from previous protocols written for previous study populations,” Kim and colleagues wrote. “As the pressure of speeding up approval of promising drugs mounts, there may be a tendency to include a greater number of eligibility criteria as smaller numbers of patients are evaluated, efficacy signals are more readily detected, and patient safety is more carefully scrutinized.”

The authors reviewed the eligibility criteria from 26 clinical trials including phase 1 to phase 3 industry and cooperative group non-molecularly targeted and molecularly targeted trials before issuing their recommendations.

Recommendations from Kim and colleagues included:

• The development of eligibility criteria focused on the scientific objectives of the study, excluding criteria unrelated to the scientific objectives or key safety considerations;
• That the study patient population be generalizable to the nonstudy but clinically eligible patient population;
• Using the specific toxicity profile of the drug and its mechanism of action to drive the selection of inclusion and especially exclusion criteria; and,
• The regular review of eligibility criteria through the protocol development process and in situations where an active study experiences poor accrual.

“Understanding the risks and benefits of a treatment in the intended patient population is the fundamental goal of clinical trials,” Kim said in a press release.

*Enrollment into clinical trials has not been continued on page 10

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optimal and needs urgent reassessment. The era of molecularly-targeted therapy is an exciting one and requires us to re-evaluate how we meet this primary objective in order to expedite approval of promising drugs into the clinic.” — by Cameron Kelsall

Disclosure: Hurria reports research funding from Celgene and GlaxoSmithKline and consultative roles with Boehringer Ingelheim, GTx and Seattle Genetics. Kim reports research funding and honoraria from and consultative roles with Celgene, Eli Lilly and Myriad Genetics. Vose reports no relevant financial disclosures. Please see the full articles for a list of all other authors’ relevant financial disclosures.

The number of 13 to 17-year-old boys and girls getting the human papillomavirus (HPV) vaccine increased slightly for the second year in a row, according to data from CDC’s 2014 National Immunization Survey-Teen (NIS-Teen), published in this week’s Morbidity and Mortality Weekly Report (MMWR).

Despite these increases, 4 out of 10 adolescent girls and 6 out of 10 adolescent boys have not started the recommended HPV vaccine series, leaving them vulnerable to cancers caused by HPV infections. Persistent HPV infections can cause cancers of the cervix, vagina, and vulva in women; cancers of the penis in men; and cancers of the anus and oropharynx (back of the throat, base of the tongue, and tonsils) in men and women. CDC recommends the vaccine for girls and boys at age 11 to 12 years.

The latest estimates show that 60 percent of adolescent girls and 42 percent of adolescent boys have received one or more doses of HPV vaccine. This was an increase of 3 percentage points for girls and 8 percentage points for boys from the 2013 NIS-Teen survey estimates. While there was a 3 percentage point overall increase nationally for first-dose HPV vaccine coverage among adolescent girls, a handful of state and local areas achieved much larger increases in coverage.

“The large increases in these diverse parts of the country show us it is possible to do much better at protecting our nation’s youth from cancers caused by HPV infections,” said Dr. Anne Schuchat, assistant surgeon general and director of CDC’s National Center for Immunization and Respiratory Diseases. “We are missing crucial opportunities to protect the next generation from cancers caused by HPV.”

Some of the promising strategies that have been effective in combination at increasing receipt of HPV vaccine include:

- Establishing links between cancer organizations and immunization organizations to emphasize HPV vaccination is cancer prevention;
- Health care provider education initiatives, including reminding doctors and nurses to take every opportunity to strongly recommend HPV vaccine, especially when they recommend the two other vaccines recommended at age 11 to 12 years (the quadrivalent meningococcal conjugate and Tdap vaccines) and the annual flu vaccine;
- Practice-based quality improvement efforts by state and local health departments, such as assessment of a clinic’s HPV vaccination coverage levels and providing feedback on how to improve coverage;
- Public communication campaigns; and,
- Reminder-recall interventions, such as using immunization information systems to send reminders to parents about vaccinations for which their child is due.

The relatively large increases in HPV vaccination seen in some states mask the lack of progress in other states. Every year, about 27,000 women and men in the United States are diagnosed with a cancer caused by HPV infection. HPV vaccination could prevent the majority of these cancers from ever developing. “HPV vaccine prevents cancer,” said Dr. Schuchat. Research shows that an effective recommendation from a healthcare professional is crucial to a parent’s decision to get the HPV vaccine for their child. CDC encourages clinicians to recommend HPV vaccine the same way and same day they recommend other vaccines for adolescents.

Preteens need four vaccines at ages 11 or 12 years to protect against serious diseases: quadrivalent meningococcal vaccine to protect against meningitis; HPV vaccine to protect against HPV infection and HPV cancers; Tdap vaccine to protect against tetanus, diphtheria, and pertussis, or whooping cough; and an annual flu shot to protect against seasonal flu. A second dose of meningococcal vaccine is needed at age 16.

CDC encourages parents and caregivers to talk to their child’s doctor or nurse at their next healthcare encounter. If a preteen or teen has not received all doses of these vaccines, make an appointment to get him or her vaccinated.

The NIS-Teen is a random-digit-dialed survey of parents and guardians of teens 13–17 years old and in 2014, included data for more than 20,000 adolescents. The telephone survey is followed by a mail survey that collects vaccination information from health-care providers.
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"My diagnosis was 5 years ago, and my SPOHNC Chapter meetings and newsletters have been a great help and resource."  
~ Claire N.
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