

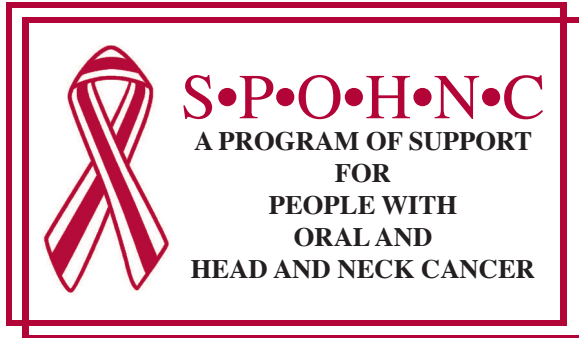
# NEWS FROM S·P·O·H·N·C



VOL. 28 NO. 2

SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER, INC.

OCTOBER 2018



## Acupuncture Following Head and Neck Cancer Treatment

Richard C. Niemtzow, MD, PhD, MPH

### *Xerostomia*

Xerostomia or dry mouth is caused by a disturbance of the salivary glands. This is especially prevalent among head and neck oncology patients who have experienced chemotherapy, radiation and surgery for their head and neck malignancy. Cancer therapy can cause damage to both the serous and mucous cells that compose the salivary glands. Patients who are treated with radioactive iodine for thyroid cancer also experience reduction in saliva and taste.



### *Damage to the Salivary Glands*

The major glands that produce the saliva are found in the sublingual, submaxillary, and parotid glands. Radiation and chemotherapy are most damaging to the serous cells that produce the thin and watery composition of saliva. The mucous cells are more robust and resistant to the impact of cancer therapies. The mucous cells are the thick and sticky components of saliva that manifest due to injury of serous glands in the first few weeks of radiation and/or chemotherapy. The fluid-like dilution of saliva from the damaged serous cells are mostly absent. The patient complains of having a thick saliva that has a sensation of accumulating and gagging in the back of the throat and is difficult to spit out. Patients are forced to drink water to help keep their mouth moist, improve swallowing, eating and talking. Further modifications in taste

also begins shortly after the saliva alteration. The changes can be slight to severe. Some patients even say that “water is not wet.” But most often the combined deficit in saliva and its consistency plus the change in taste can heavily impact on the quality of life. Food may have a bland or aggerated taste and is no longer a source of enjoyment. Lack of satisfaction with eating can add to unintentional weight loss. Patients who are treated with radioactive iodine for thyroid cancer also experience disturbances in saliva and taste by the same mechanism.

### *Other Dry Mouth Consequences*

The impact of dry mouth is even more devastating. Because there is no longer a natural rinse of the teeth and gums from the saliva, an increase in caries and periodontal disease occurs with a significant financial burden. Carbohydrate metabolism that begins in the mouth is affected by the saliva’s poor dilution and breakdown of carbohydrate nutrients and as result, leads to a higher incidence of gastric ulcers. Social interaction becomes compromised as talking turns into a social handicap as the dry mouth necessitates frequent sips of water and degrades speech.

### *Avoiding the Damage to the Salivary Glands*

The use of medical radiation protectors has been advocated to protect the salivary glands from the radiation. For example, Ethyol (amifostine), is a recent new radiation protector approved by the FDA. It is also possible to specifically target the tumor cells and avoid healthy tissue by specialized radiation techniques. Even various techniques of radiation scheduling may prevent some destruction of the salivary glands. Unfortunately, it is beyond the scope of this article to provide details on the radiotherapy. Surgical transposition of the salivary glands outside of the radiation field may be considered and then the glands restored to their proper anatomical location. There are some protocols geared for tumors caused by the human papillomavirus (HPV) that may permit reduction of the radiation and chemotherapy dosages. Proton beam therapy may be more healthy tissue sparing than conventional radiotherapy. Despite the many attempts to spare the salivary glands, many patients still suffer from saliva and taste deficiencies.

### *Failure of Artificial Saliva*

There are a multitude of saliva aids on the commercial market that help keep the mouth moist. Although these are artificial remedies, many patients find them helpful in combatting dry mouth. Other patients do not benefit from artificial saliva with complaints that their dry tongue “sticks” to the roof of their mouth upon awakening. There still remains the constant difficulty in eating and swallowing that requires frequently use of water with every mouthful of food.

ACUPUNCTURE continued on page 2

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*Acupuncture*

Patients inquire whether acupuncture can be effective in improving the xerostomia. The author has treated xerostomia since 1999 to the satisfaction of many patients with a self-styled acupuncture procedure. How does acupuncture work and what are the results? There are few and questionable scientific acupuncture theories. Despite the fact that acupuncture has been around for over 5000 years, little evidence supports acupuncture points or meridians; nevertheless, for centuries, people have been placing needles into these mysterious meridians and points and demonstrated that beneficial physiological effects occur.

*My self-styled acupuncture technique*

At this point I would like to elaborate on my self-styled acupuncture technique. I presented a dry mouth acupuncture technique as a poster demonstration at an acupuncture symposium held by the American Academy of Medical Acupuncture in 1999. In the early 2000s, I demonstrated the technique at MD Anderson Cancer Center in Houston, Texas. Many months later I accompanied my colleagues from MD Anderson to the Cancer Center at Fudan University, Shanghai to further validate this technique on Chinese head and neck cancer patients. I conducted a clinical trial at the Naval Medical Center, San Diego, California while I was on active duty and published in the International Journal of Radiation Oncology and Biophysics. The dry mouth acupuncture technique has made its “rounds” in military and civilian hospitals. The majority of patients that seek my care are oncology patients with dry mouth. I taught the technique to many acupuncturists in this country and overseas. The teaching is still on-going. Many patients state that it is a life changer as the acupuncture technique increases the saliva. The treatment requires 2 sessions; one right after the other so it is a perfect weekend treatment. Saliva usually starts within ten minutes. The treatment does not always work. But in the vast majority of cases, the acupuncture proves helpful. There are quite a few patients who have achieved 10 years of maintaining a saliva flow. Patients who have been dry over many years, may be salvaged. I find this quite surprising as some patients with no saliva for over 15 years have been successfully treated. This is quite curious as the saliva glands remain dormant despite having been damaged for such a long time and the acupuncture treatment “wakes them up.”

The therapy consists of needles on the outside of the ears and in the index fingers. The acupuncture needles in the ear are placed in points named Shen Men that means spirit gate, point zero and salivary gland 2'. The first two points are well known points and help very much with the process. The classical salivary gland point did not seem to work well, so I slowly moved it toward the orifice of the external ear canal such that the needle just abutts the canal at the 6 o'clock position. I call it salivary gland 2'.

Trial and error have demonstrated that this maximizes the production of saliva. Next, needles are also placed near the tip of the index finger about ½ way toward the nail bed in the fleshy tissue. The other two needles are then placed in areas of the

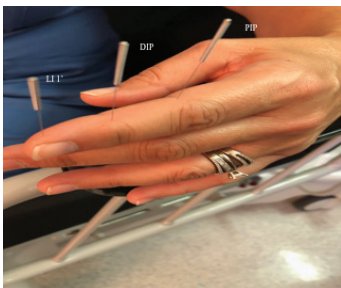


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ACUPUNCTURE continued from page 2

index finger on the distal interphalangeal and proximal interphalangeal joint areas. These index needles align on the “Large Intestine” acupuncture meridian but have nothing to do with our large intestines.

Acupuncturists will question the fact that the needles are not located on acupuncture points. This is a result that the meridians may act as a conductor and needles do not have to be placed just on the acupuncture points to bring about a physiological effect.



I always have the patient dissolve a sugarless mint at the beginning of the treatment to start a parasympathetic saliva stimulation. This aids in the production of the saliva. How long does the treatment take? I usually keep the needles in place for at least 1 to 1½ hours. Considering that the treatment may last for many months to several years, this is very acceptable. Many patients ask about taste. Taste is even more difficult to resolve than the saliva. In many cases taste is improved but never fully. I have had some patients tell me that their taste had become normal, but this is certainly the exception.

In a clinical trial, 18 patients were treated with my acupuncture technique. 9 patients had a robust secretion of saliva and the others had various degrees of lesser secretion. This is very encouraging and as the years have gone by the technique has certainly become refined and the success rate and refinement of the technique has improved. Practice makes perfect. Several years ago, I co-authored an article with my colleagues surveying xerostomia in the research literature. Here are the findings. “Acupuncture may be a helpful adjunct to cancer care for treatment and/or prevention of xerostomia in patients with head and neck cancer, but studies to date have been limited by small sample size and/or lack of blinding. Large phase III trials are currently underway.” It is interesting to note that other reviews in the medical acupuncture literature for dry mouth are inconclusive. There are some trials that are suggestive of a positive effect. I looked at several reviews and there was no mention of the acupuncture technique employed. This is very important as you would not expect positive results if the technique was not optimized.

### *Where Can You Find an Acupuncturist that Treats Dry Mouth?*

The easiest way is to “google.” Some acupuncturists state on their web site medical conditions that are treated. A good source of finding a medical acupuncturist in your area is a service by the American Academy of Medical Acupuncture that is found on the initial page of their web site “Find an Acupuncturist Near You.”

### *Final Remarks from a Head and Neck Cancer Patient*

I too am a cancer survivor having had thyroid cancer treated with radiation. I experienced the dry mouth and loss of taste and appreciate the complaints of my patients. I can truthfully say as a previous practicing radiation oncologist and as a patient, dry mouth and loss of taste is debilitating. Fortunately for me my wife is an acupuncturist and she treated me with my own technique. It does work! What would I do without it?

Many of you may be skeptical in trying acupuncture, but as the recipient of my own treatment I have no doubts of its benefit. I do believe that many cancer treatments centers should offer acupuncture treatments to their patients even for other medical challenges. A patient from England who I treated with acupuncture was so pleased with the results on himself that he started a dry mouth foundation in London. The foundation pays for any patient who cannot financially afford the payment in England. Need I say more? *The opinions and assertions of this article are the private views of the author and are not to be construed as official or as reflecting the views of the United States Air Force Medical Corps, the Air Force at Large, or the Department of Defense. The author indicates that he does not have any conflicts of interest or financial interests.*

*Editors Note: Richard C Niemtow, M.D., PhD, MPH is a graduate of the Faculte de Medecine, Universite de Montpellier, France 1976 and completed a residency in radiation oncology at the University of Texas Medical Branch Galveston, Texas 1980. Graduate of the UCLA /Helms Medical Acupuncture Course in 1995. He has been practicing medicine for over 41 years. He is responsible for initiating the first full time acupuncture clinic in the Armed Forces that today is the Air Force Acupuncture*

*and Integrative Medicine Center at Joint Base Andrews, where he is current director.*

*Editor in Chief of the journal Medical Acupuncture for 20 years and Senior Military Editor of the Journal of Alternative and Complementary Medicine for 12 years. Former President of the American Academy of Medical Acupuncture and the Maryland Medical Acupuncture Society.*

*Military Service: Retired from the United States Air Force in April 2010 obtaining the rank of Colonel after almost 30 years of active duty service. First full time medical acupuncturist in the Armed Forces. Consultant for Integrative Medicine for the United States Air Force Surgeon General. He was the Assistant Secretary of Defense for Health Affairs’ representative to the National Institutes of Health, National Center for Complementary and Integrative Health Advisory Council from 2004 to 2017. Represented the United States Air Force as a NATO committee member on Integrative Medicine. Assistant Professor at the Uniformed Services University of the Health Sciences. “Point of Contact,” Moderator and Co-Author of a \$5.4 million Army, Navy, Air Force and Veterans Administration Joint Incentive Fund to teach Battlefield Acupuncture (Niemtzow). Designer of many acupuncture techniques such as Battlefield Acupuncture, dry mouth resolution in cancer head and neck patients, a concussion headache protocol and acupuncture for degenerative retinal disease (phase 3 study).*

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## HEAD AND NECK CANCER NEWS

### Important Information from Medicare.gov

#### Save on drug costs

If you meet certain income and resource limits, you may qualify for Extra Help from Medicare to pay the costs of Medicare prescription drug coverage.

In 2018, costs are no more than \$3.35 for each generic/\$8.35 for each brand-name covered drug.

Other people pay only a portion of their Medicare drug plan premiums and deductibles based on their income level.

In 2018, you may qualify if you have up to \$18,210 in yearly income (\$24,690 for a married couple) and up to \$14,100 in resources (\$28,150 for a married couple).

If you don't qualify for Extra Help, your state may have programs that can help pay your prescription drug costs. Contact your Medicaid office or your State Health Insurance Assistance Program (SHIP) for more information. Remember, you can reapply for Extra Help at any time if your income and resources change.

Countable resources include:

- Money in a checking or savings account
- Stocks
- Bonds

Countable resources **don't** include:

- Your home
- One car
- Burial plot
- Up to \$1,500 for burial expenses if you have put that money aside
- Furniture
- Other household and personal items

*Apply for Extra Help*

#### Some people automatically qualify for Extra Help

You automatically qualify for Extra Help if you have Medicare and meet any of these conditions:

- Have full Medicaid coverage
- Get help from your state Medicaid program paying your Part B premiums (from a Medicare Savings Program)
- Get Supplemental Security Income (SSI) benefits

Even if you automatically qualify this year, you may not qualify for Extra Help next year.

Changes in your income or resources may cause you no longer to qualify for one of the programs listed above. You'll get a notice (on grey paper) by the end of September if you no longer automatically qualify. Even if you get this notice, you may still qualify, but you need to apply to find out.

- If your copayment amounts change next year, you'll get a notice (on orange paper) in the mail in early October with the new amounts.
- If you don't get a notice from Medicare, you'll get the same level of Extra Help that you got for this year.

#### Paying the right amount

If you're not sure if you're paying the right amount, call your drug plan. Your plan may ask you to give information to help them check the level of Extra Help you should get. Get your plan's contact information from a Personalized Search (under General Search), or search by plan name.

#### Can I get money back if I've been paying too much?

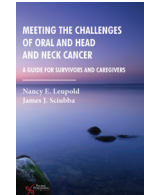
If you paid for prescriptions since you qualified for Extra Help and you aren't enrolled in a Medicare drug plan, you may be able to get some money back. Keep your receipts and call your plan. Or, you can contact Medicare's Limited Income Newly Eligible Transition (NET) Program at 1-800-783-1307 for more information (TTY: 711).

#### Other ways to lower your prescription drug costs

- Look into generic drugs. Ask your doctor if there are generics that will work as well as your current brand-name drugs.
- Ask your doctor about less expensive brand-name drugs.
- Consider using mail-order pharmacies.
- Use the Medicare Plan Finder to compare Medicare drug plans to find a plan with lower costs.
- Find out if your state offers help paying for drug costs.
- Find out if the company that makes your drug offers help paying for it.

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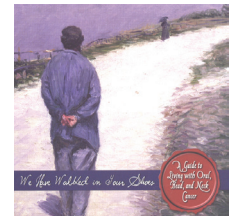
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## HEAD AND NECK CANCER NEWS

### *Oncology Community Expresses Concern About Medicare Advantage Step-Therapy Policy*

September 12, 2018 - More than 90 medical societies have called on the US government to reverse a policy allowing step therapy under Medicare Advantage.

The American Medical Association (AMA), American Society of Clinical Oncology (ASCO), American Society for Radiation Oncology (ASTRO), the American Society of Hematology (ASH), and 90 other medical societies cosigned a letter on September 7, 2018, calling on the US Centers for Medicare & Medicaid Services (CMS) to reconsider its decision to allow Medicare Advantage plans to use “step therapy” or “fail first” cost-control programs for Part B drugs.

Step therapy allows insurers to require physicians to prescribe less expensive medications as a first step; the patient is required to try certain medications before progressing to more expensive treatments.

Participating plans will not be required to submit their step-therapy criteria for affected Part B drugs to CMS and can require off-label use of drugs before allowing access to on-label, FDA-approved treatments when off-label indications are “supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices,” according to a CMS document.

Describing the policy change as part of President Trump’s efforts to negotiate better prices and foster competition in the drug marketplace, CMS announced the change “empowers patients with more choices when picking a Medicare Advantage plan.”

In their letter, the medical societies expressed concern about the use of step therapy to guide treatment decisions, stating that it could endanger patients undergoing treatment for cancer and other life-threatening diseases.

“While step-therapy protocols are problematic for many patients on a variety of therapies, they are particularly concerning where physician-administered drugs are concerned,” the letter states. “In many cases, patients receiving drugs covered under Part B are especially vulnerable, many with serious or life-threatening conditions. Many cancer therapies, for example, are covered under Part B. For cancer patients, selecting the proper personalized treatment as quickly as possible can be critical to survival.”

The new policy would take effect in January 2019. The medical societies asked CMS to abandon the change and stick with a 2012 policy that stops Medicare Advantage plans from using step therapy.

Details are scarce, and it is not yet clear exactly how the policy will be implemented — or what the implications will be for oncology formularies.

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Just before the policy was announced, Department of Health and Human Services Secretary Alex Azar, who oversees CMS, met with ASCO officials and others. He acknowledged that there exists limited drug interchangeability in oncology and said he did not expect to see step therapy be a significant issue for patients with cancer, according to ASCO Vice President of Clinical Affairs Stephen Grubbs, MD, FASCO.

“We’ve had that discussion and he said in no way does he want these policy changes to affect or delay treatment for patients with cancer,” Dr. Grubbs said of his conversation with Azar. “He asked that if we find the policy delays therapy, we [should] report that immediately to him personally.” Particularly with increasingly rapid cancer drug approvals, it will be important to carefully monitor step-therapy restrictions, and to make sure appeals processes are quick, Dr. Grubbs said.

“The physician’s responsibility is to always pick the right drug for the right patient at the right time,” Dr. Grubbs said. “In-class drug difference nuances can make one drug more appropriate for a given patient. Appeals have to be done in a timely fashion.”

Even if those goals are achieved, the policy will add “one more layer of administrative burden,” Dr. Grubbs asserted. “Our [ASCO] membership polling shows that the number 1 issue right now is the work [physicians] do for preauthorization.”

“There’s no question that we have to reign in the costs of drugs. Nobody’s going to argue against that,” said Ramaswamy Govindan, MD, professor of oncology at the Washington University School of Medicine in St. Louis, Missouri. “But we have to make sure that we provide our patients with the best available treatment options based on efficacy and toxicity.”

“Efficacy is foremost,” he said. “We don’t want to offer cheaper therapies that are not as effective for cancer patients.”

In theory, Dr. Govindan said, if there are no issues with efficacy and toxicity between two anticancer drugs, we should use a less expensive therapy. “But in reality, unfortunately, most of the drugs in the same class are priced at the same level,” he added.

Step therapy is “ill-advised” and would delay care by requiring additional steps of

approval and restricted access to the newest drugs, noted oncologist Lucio Gordan, MD, of the Florida Cancer Specialists & Research Institute in Gainesville, Florida. Outcomes and disease control could be “gravely worsened” by step therapy, he said. It could even lead to avoidable toxicities, Dr. Gordan speculated. Ironically, that could increase costs if patients are treated in emergency departments or hospitals to manage those adverse effects.

The new policy would require Medicare Advantage plans to offer a formulary-exception appeals process for patients but that would add a “convoluted review” by middlemen who are less familiar with cancer treatment than the patient’s team, Dr. Gordan said.

The utilization management approach is an attempt to cut costs and improve treatment predictability, said Fred Schnell, MD, FACP, medical director of the Community Oncology Alliance in Washington, DC. “That’s the intent,” Dr. Schnell said. “But the thing that really bothers me about step therapy in cancer is that if it’s a critical decision point at the front end of a patient’s care, and not fifth-line therapy for advanced colon cancer, the choices really can be life-or-death choices. A bad choice can lead to bad outcomes that are not reversible. This isn’t hypertension or diabetes — cancer’s not like that. Patients may never recover from a bad choice.”

Oncology has dealt with step therapy for quite some time on the private insurance side, Dr. Schnell noted. “It’s been a roller-coaster,” he said. “Some companies make it quite onerous and others focus on a few disease sites. None of the oncologists like it because the people making decisions on the payer side are, for the most part, not oncologists.”

Because of their costs, tyrosine kinase inhibitors (TKIs) will “definitely be in the mix” as Medicare Advantage plans adopt step-therapy restrictions, Dr. Schnell predicted.

“Myeloma will be a big target, too, because of the extreme cost of some therapeutics,” he said. Insurers who have adopted step-therapy restrictions for private health insurance plans have focused on myeloma and common, high-volume cancers like breast, colon, lung and prostate cancer, he added.

Biosimilars and supportive care drugs will also likely be affected, Dr. Schnell said. “Supportive antiemesis and growth factors are expensive,” he noted.

“Step therapy also ties up a lot of staff time to launch appeals and overcome objections,” Dr. Schnell said. “That causes delays — it creates roadblocks for implementing care. Decisions can take forever, particularly if you appeal. It’s unclear who will field these appeals or what the timelines will be. Days trickle into weeks. That happens. Weeks trickle into months. And the patient is stuck in the middle.”

For the moment, CMS is “offering suggestions rather than rules” about appeals, allowing Medicare Advantage plan insurers to self-regulate, said Caitlin Donovan of the National Patient Advocate Foundation, in Washington, DC. Without government oversight, plan transparency and the speed of appeals could become a problem, she warned.

Because the Medicare Advantage enrollment period is yearly from October 15 through December 7 — every year it could be difficult or impossible for patients to switch plans when the medication they need is subject to step-therapy restrictions, Donovan and others noted.

The CMS policy proposal could add to already “very significant” pressures for community oncology practices, Dr. Gordan cautioned, hastening a trend of shuttered practices and shifts to cancer care at more expensive health systems.

The policy represents “cookbook medicine,” according to Ted Okon, of the Community Oncology Alliance. “Step therapy isn’t new — it’s used on the commercial side and it’s caused horror stories. It’s not just branded drug vs generic and use the generic first. It puts the insurer in the position of middleman, telling physicians what they have to try first.”

Several states have passed laws that limit step therapy for privately insured cancer patients. But no such protections apply to Medicare Advantage programs, Donovan confirmed.

“This is a new chapter in Medicare Advantage,” said Dr. Grubbs. “It’s something we’ll have to watch very carefully.”

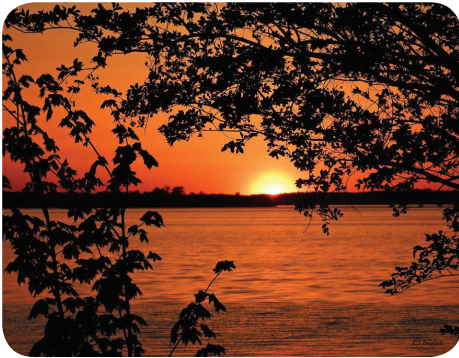
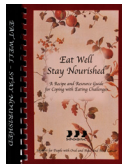


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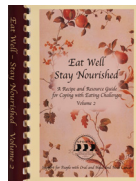


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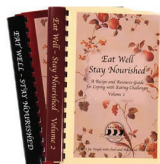
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## Outrageous October Recipes from "Eat Well Stay Nourished: A Recipe and Resource Guide For Coping With Eating Challenges"

Compiled and Edited by Nancy E. Leupold, Survivor, Founder & President Emeritus  
**Easy Cheeseburger Soup (from Volume 2)**

- 1 ½ c. water
- 2 c. cubed, peeled potatoes
- 2 small carrots, grated
- 1 small onion, chopped
- ¼ c. green pepper, chopped
- 1 garlic clove, minced
- 1 Tbsp. beef bouillon granules
- ½ tsp. salt
- 1lb. ground beef, cooked and drained
- 2 ½ c. milk, divided
- 3 Tbsp. flour
- 8 oz. cheese (American or other)



In a large saucepan combine the first 8 ingredients. Bring to boil. Reduce heat, cover and simmer 15 – 20 minutes or until potatoes are tender. Stir in beef and 2 cups milk, heat through. Combine flour and remaining milk until smooth – gradually stir into soup. Bring to a boil. Cook and stir for 2 minutes or until thickened and bubbly. Reduce heat. Stir in cheese until melted. Serves 6 to 8.

328 calories/serving.

~ Becky V.

## Pumpkin Chiffon Pie (from Volume 1)

- 1 9" baked pie shell
- 1 Tbsp. unflavored gelatin
- ¼ c. cold water
- 4 egg yolks
- ½ c. milk
- ¾ c. brown sugar
- 1 ¼ c. pumpkin
- ¼ tsp. salt
- ½ tsp. grated nutmeg
- 4 egg whites
- ½ c. sugar
- 1 c. whipping cream
- 2 Tbsp. confectioners sugar
- ¼ c. chopped nuts (OPTIONAL)
- ½ tsp. cinnamon
- ¼ tsp. ginger
- ½ tsp. allspice



Put egg yolks and brown sugar in top of double boiler and beat until thick. Add pumpkin, milk, salt and spices. Mix well. Cook until thick, stirring constantly. Soak gelatin in cold water for 5 minutes. Add to hot custard, stirring until dissolved. Cool completely. Beat egg whites until stiff, gradually adding ½ c. sugar. Fold into custard. Pour custard into baked pie shell and chill in refrigerator. Whip cream and add confectioners sugar. Spread over pie, Sprinkle with chopped nuts, if desired. Yield 8 servings. 398 calories/serving.

~ Michael W., Arkansas

Visit the SPOHNC website at [www.spohnc.org](http://www.spohnc.org)

## HEAD AND NECK CANCER NEWS

### FDA OK's HPV Vaccine for Adults Up to Age 45

*Previously Approved for Ages 9 to 26 Years*

October 07, 2018 - WASHINGTON -- The FDA expanded the approval of Gardasil 9, the human papillomavirus (HPV) vaccine, to include men and women ages 27 to 45, the agency announced Friday.

"Today's approval represents an important opportunity to help prevent HPV-related diseases and cancers in a broader age range," said Peter Marks, MD, PhD, director of the FDA Center for Biologics Evaluation and Research, in a statement.

The CDC estimates that HPV vaccination can prevent more than 90% of HPV-related cancers, which most commonly include those of the cervix and oropharynx, as well as penile, anal, vaginal, and vulvar cancers.

In all, an estimated 31,000 new HPV-related cases are diagnosed in the U.S. each year. In women, roughly 12,000 new cervical cancer cases are diagnosed each

year and 4,000 die from the disease.

In 2014, the agency first approved Gardasil 9 for individuals ages 9 to 26. It covers nine types of HPV, including seven that can lead to cancer (16, 18, 31, 33, 45, 52, and 58).

An earlier version of the vaccine first came to market in 2006 -- marketed as Gardasil and covering four types of HPV -- for HPV prevention in girls and women ages 9 years to 26. This indication was later expanded to include boys and men in this same age group.

Questions have been raised at various times over the vaccine's safety, but most studies have found the vaccine to be safe, including a study conducted in women during early pregnancy. The FDA reports that the safety of Gardasil 9 was evaluated in roughly 13,000 individuals, with injection site pain, swelling, headaches, and redness

being the most frequently reported adverse events.

The efficacy data for the new approval comes from both earlier studies with the 4-valent HPV vaccine and a study of the newer 9-valent version.

For women ages 27 to 45, the vaccine was studied in roughly 3,200 women who were followed for 3.5 years on average. The vaccine was 88% effective in preventing persistent infection; genital warts; precancerous cervical, vaginal, and vulvar lesions; and HPV-related cervical cancers (for types covered by the vaccine).

In men ages 27 to 45 years, the approval was based on both the efficacy data in women for this age group, the earlier trials in boys and younger men, and immunogenicity data from a trial of 150 men in this older age group.

### Inspire Someone Today



***SPOHNC is seeking your story, to share with those who are just beginning their cancer journey.***

*To find out how you can help a newly diagnosed patient, contact Chris at SPOHNC at 1-800-377-0928, x4 or email [c.leonardis@spohnc.org](mailto:c.leonardis@spohnc.org).*

### SPOHNC wants to share your news!

***Send us your birthdays, good news, Sharing Stories and Chapter News.***



***Send to [info@spohnc.org](mailto:info@spohnc.org)***

## SURVIVOR NEWS

### *Learning more...*

ASCO: "American Society of Clinical Oncology" recently published updated testing guidelines relating to HPV "Human Papillomavirus Virus" in head and neck cancers. These guidelines were discussed by a panel of experts; I was asked to be the patient advocate on this panel. The goal of the ASCO panel was to review past testing guidelines and update these guidelines based upon new research and behaviors of HPV and how it relates to head and neck cancer in 2018.

As a patient advocate on this panel I had little to say but much to learn. Participating in the ASCO panel was a humbling experience. As a silent patient advocate listening to a panel of experts talk about my cancer was and is a real time experience. As survivors, we can be grateful for these professionals who keep asking questions and keep improving ways to diagnose and treat cancer. Link to guidelines at [www.asco.org/head-neck-cancer-guidelines](http://www.asco.org/head-neck-cancer-guidelines)

*~ Jon Thibo, Survivor*



## HEAD AND NECK CANCER NEWS

### MedImmune Trial for HPV Associated Head and Neck Cancer Patients Now Enrolling

MedImmune (a member of the AstraZeneca Group) is conducting a study in Human Papilloma Virus (HPV) associated recurrent/metastatic Head and Neck Cancer patients (clinicaltrials.gov NCT03162224). All patients who meet eligibility criteria will receive treatment. The study treats patients with 2 drugs, MEDI0457 and Durvalumab (two immune-mediated therapies). You may be required to allow the doctor to take a biopsy tumor sample for testing.

#### You may be eligible for the trial if you meet these criteria:

- You have HPV positive head and neck cancer.
- You have been treated with a platinum based chemotherapy (such as cisplatin or carboplatin, or another approved drug, if not eligible for platinum treatment.

- You have not previously been treated with an immune-mediated therapy (such as nivolumab or pembrolizumab).
- You do not have autoimmune diseases or inflammatory disorders (including inflammatory bowel disease [e.g., colitis or Crohn's disease], diverticulitis [with the exception of diverticulosis], systemic lupus erythematosus,

sarcoidosis, or Wegener syndrome [granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc]).

#### Where to find participating doctors:

To find the institution in your city, or nearest to you, please call toll free 1-877-240-9479, or email [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)



Sites open and enrolling are located in Atlanta, GA, Indianapolis, IN, Baltimore, MD, Detroit, MI, St Louis, MO, Bronx, NY, Winston-Salem, NC, Philadelphia, PA and Morristown, NJ. Sites that will be open in the next few months are located in San Francisco, CA, Columbus, OH, Louisville, KY, Orlando, FL, Chicago, IL, Minneapolis, MN and College Park, MD.

## HEAD AND NECK CANCER NEWS

### New nuclear medicine imaging method shows strong potential for cancer imaging

RESTON, VA - A new nuclear medicine imaging method could help diagnose widespread tumors, such as breast, colon, pancreas, lung and head and neck cancer better than current methods, with less inconvenience to patients and with equal or improved accuracy. The study is featured in the September issue of *The Journal of Nuclear Medicine*.

The new imaging method, developed by a team of German researchers, targets cancer-associated fibroblasts, a subpopulation of tumor stroma cells (connective tissue cells). These fibroblasts are an attractive target for diagnostic imaging and therapy, as they are present in more than 90 percent of epithelial carcinomas, including pancreatic, colon and breast cancer.

Cancer-associated fibroblasts (CAFs) have a high expression of fibroblast activation protein (FAP) and are known to be involved in tumor growth, migration and progression. They are also genetically more stable than cancer cells, making them less susceptible to developing therapy resistance.

"The appearance of FAP in CAFs in

many epithelial tumors and the fact that overexpression is associated with a worse prognosis led to the hypothesis that FAP activity is involved in cancer development, as well as in cancer cell migration and spread," said Uwe Haberkorn, MD, professor of nuclear medicine at the University Hospital of Heidelberg and at the German Cancer Research Center. "Therefore, the targeting of this enzyme for imaging and endoradiotherapy can be considered as a promising strategy for the detection and treatment of malignant tumors."

Based on an FAP-specific enzyme inhibitor (FAPI), the team developed the positron emission tomography (PET) tracer gallium-68 (<sup>68</sup>Ga)-labeled FAPI, which was tested first on mouse models then through proof-of-concept PET/CT imaging of three patients. The results showed high tracer uptake by the tumors and fast body clearance, resulting in high contrast images and very low binding to healthy tissue in

both animals and tumor patients.

Haberkorn pointed out, "A comparison to fluorodeoxyglucose [<sup>18</sup>F-FDG]--the common standard in tumor imaging--revealed a clear advantage of our tracer with regard to tumor uptake and image contrast in many tumors."

The fact that radiolabeled FAPIs allow fast imaging with very high contrast in tumors that have a high stromal content makes them versatile, pan-tumor agents. These molecules can be coupled to DOTA or other chelators, allowing labeling not only with <sup>68</sup>Ga, but also with therapeutic isotopes such as lutetium-177 (<sup>177</sup>Lu) or yttrium-90 (<sup>90</sup>Y). As the FAPI tracers contain the universal DOTA-chelator, a theranostic approach also seems feasible.

*"Support from our local SPOHNC helped restore a healing sense of community.*

*THANKS TO ALL!!"*

*~ Carole W.*

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## ***IN MEMORY OF BILL WESP, DEAR FRIEND OF SPOHNC***

SPOHNC is deeply saddened to share news of the passing of a very near and dear friend of our family here. William A. Wesp, of our home group in Syosset, NY, passed away on September 7, 2018. He was born in New York City but grew up in Sea Cliff, NY.

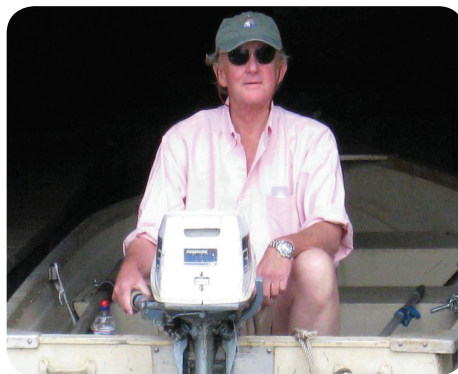
If ever there was a man who fought and never ever gave up, it was Bill. From the moment of his diagnosis, when he began his long and arduous battle with oral, head and neck cancer, he kept a brave face and a positive outlook always. He endured so much pain and suffering throughout his recent years, but he never ever gave up, even in the face of seemingly insurmountable situations, illnesses, side effects and conditions. His beautiful and amazing wife, Anne, had such a gift in her ability to keep things positive, even when it looked as though all hope was lost. Somehow, she managed to keep so many people informed of new developments in Bill's treatment and care, all while maintaining a very positive outlook, and at times, even a sense of humor. Anne was the most supportive, kind, caring and dedicated partner anyone could ever wish for in a wife. She helped Bill fight the battles each and every day, until the very end.

Bill was an avid sailor, a passion that stayed with him throughout his life. He was a longstanding member of the New York Yacht Club, the Centerport Yacht Club and the Explorers Club. His love of the ocean took him on many exciting trips, to exotic places some of us may never even have heard of. His stories of travel to foreign lands were an education, and he was indeed a great storyteller. Bill lived his life with enthusiasm and it showed.

After graduating from Hamilton College, Bill enjoyed a long and very successful career in finance, which included several highly esteemed positions at American Express, Central Federal Savings Bank, Fidelity New York FSB and Lehman Brothers. He was blessed with great wealth throughout his career, however, he remained humble always. His career afforded Bill the opportunity to share his good fortune with others. He was a very generous donor to SPOHNC and enabled our New York Chapters to host several very successful

Taste Events during April Oral, Head and Neck Cancer Awareness month, for quite a few years.

Bill's love of travel and adventure allowed him the gift of visiting all 7 continents. His extensive travel brought him so much joy, and he developed a particular fondness of the high arctic and Antarctica. He loved taking photographs, especially of polar bears and penguins. He also loved to share his passion and stories of his adventures with friends and family, and his stories brought joy and inspiration to the attendees of the SPOHNC, Syosset, New York Chapter Support Group. Whenever Bill attended a meeting, you knew you'd



be entertained with his wit, knowledge and his ability to share his travels with everyone through the stories he shared.

A Celebration of Bill's Life was held following his passing, where attendees were encouraged to share poems and anecdotes. Several survivors from the Long Island area were in attendance, as well as SPOHNC Executive Director, Mary Ann Caputo, who shared some details about the service and beautiful tribute held in Bill's honor. It was said that Bill was "curiosity in action." Truer words were never spoken. Bill was always seeking opportunities to learn and to know more about the world. Despite his challenges, Bill's motto was always "Live Your Life."

Bill was also admired for his honesty, in business, with his friends and family, and especially with his SPOHNC family of fellow survivors. John B., friend and fellow survivor, shared with those in attendance, that Bill always told it like it was at the

meetings. He was not one to sugar coat anything, yet he still shared his experience, thoughts and feelings in a way that helped other in the group to understand, and know that it will be ok, no matter what it is. That was truly Bill. He lived his life by that very example.

A family member in attendance at the Celebration shared stories of Bill's love of bears. While we're sure he admired the bears in the wild, this was more about the cute and cuddly kind. Apparently, Bill enjoyed giving plush bears as gifts, to his nieces and nephews. There were all sorts of bears, given all the time. Bill and Anne never had any children, so they were blessed to share their love and generosity with many nieces and nephews.

The service was a beautiful kaleidoscope of feelings, shared by friends, family, co-workers and many others whose lives were touched by the kindness of Bill. What a tribute to a man who lived his life with such enthusiasm, grace and honor. There were many photos shared of Bill and Anne's great adventures, and the tribute closed, appropriately, with Frank Sinatra's recording of "I Did It My Way."

Bill – you always did it your way, and you were admired and respected for that. Your SPOHNC family will remember you for your spark for life, your kindness and generosity, and your pink shirts and argyle socks. You were a special man to many, and will remain in our hearts and our prayers forever.



*photo courtesy of PJ Jordan,  
Caregiver and NSVN Volunteer*

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*"We are grateful  
that you are there..."*

*~Lewis & Amy B.  
SPOHNC Palm Coast NE, FL  
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