# NEWS FROM S•P•O•H•N•C

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S•P•O•H•N•C
A PROGRAM OF SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER

***April is Oral, Head and Neck Cancer Awareness Month***

*This issue of* ***"News from SPOHNC"*** *is dedicated to SPOHNC's Founder, Nancy Leupold, in memoriam...*

## Cell Free HPV DNA: A new diagnostic and predictive test for HPV oropharynx cancer


Marshall Posner, MD &
Eric Genden, MD, MHCA, FACS


A large shift in the causes and natural history of head and neck cancer has radically changed the prognosis and survival of a significant fraction of patients in the last two decades. This has been driven by the identification of human papilloma virus (HPV) as the major causative factor in oropharynx cancer (OPC). HPV-related OPC is now so common and the biology and prognosis are so different from environmentally and smoking related head and neck cancers that it has a specific designation - HPVOPC. HPV is a transmissible virus which is passed among people by exchange of bodily fluids usually associated with sexual activity. Living virus does not enter into the blood stream and cannot be transmitted by blood transfusion or exposure. Many people are infected in their teenage years or in young adulthood by sexual or intimate acts that transmit bodily fluids. The virus is highly infectious and is likely transmitted by kissing or exchange of saliva in teenagers and adults. Fortunately, the development of an HPV vaccine may reduce the incidence of this cancer. The impact of preventitive HPV vaccines on later cancer development will not be realized for about 30 more years as the vaccinated population matures. While HPV infection is nearly ubiquitous, very few people develop an HPV-related cancer. In fact, the vast majority of those infected will not develop HPV-associated malignancy and may asymptomatically carry the virus. Nonetheless, HPV-associated OPC now represents about 60-70% of all head and neck oropharynx cancer seen in the United States and it is expected that there will be more than 30,000 cases a year by 2025. We have also found that HPV is implicated in significant fraction of sinus cancers and a small fraction of nasopharynx cancers. Outside of the head and neck HPV is associated with anal, cervical, vulvar, and penile cancers.

Unlike tobacco-related head and neck cancer, HPV OPC is very responsive to radiation or chemotherapy and cure rates for patients range between 65% and 95% - as opposed to 30-45% for tobacco-related head and neck cancer. While biomarkers such as invasion of blood vessels, nerves, and lymphatics are considered poor prognostic factors in tobacco-related disease, these biomarkers are less indicative of a poor outcome in HPV-associated cancer. These findings support that HPV-associated disease is fundamentally different than tobacco-associated disease.

Because cure rates are high in HPV associated oropharyngeal cancer, more emphasis has been placed on treatment toxicity. This is especially important because, in general, the patients develop this disease at a younger age than patients afflicted with tobacco associated disease. They will survive for decades after treatment. The long-term consequences of therapy have become an important consideration in this population of patients. Therefore, the goal of reducing aggressive therapy and thus the significant late toxic effects of chemo-radiation and surgery have to enter into the equation of management and decision making. Radiation carries the greatest burden of acute toxicity effects and significant long-term consequential toxicity. Reducing the dose of radiation, while preserving high survival rates would have a significant impact on quality of life in this highly curable disease. Additionally,


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surveillance and follow-up are critically important to identify recurrent disease early in the process so that salvage treatment can be instituted. There is a need to develop better diagnostic and prognostic tests that are accurate and cost effective. With increasing numbers of survivors, there is an increasing need for noninvasive surveillance. Positron emission tomography (PET) scan is one of the best diagnostic tests available for this disease. Unfortunately, it is costly and is associated with a relative high radiation dose compared to other radiologic methods and may be associated with unexpected toxicity and consequences over time. Nonetheless, finding recurrences or identifying persistent disease early after initial treatment can lead to successful salvage treatments. As more patients achieve cure, surveillance testing becomes increasingly necessary and expensive. Second, a pre-therapy prognostic test that identifies patients who will most likely achieve cure with a reduced dose of radiotherapy or chemotherapy would help to facilitate risk based reduction in these treatments. Reducing primary treatment, especially radiation therapy, will improve long-term consequences and morbidity as well as improve survival for patients. Third, a post radiation or postoperative test that accurately identified patients who need more therapy because of persistence or residual disease would allow early intervention with additional therapies including vaccines and immune modulators. Evaluation of patients in the immediate postoperative or post radiation setting is very complicated by tissue inflammation and swelling. Having a highly sensitive or specific test would improve identification of persistent disease where additional treatment may be beneficial.

Recently, a new test has been developed which has some characteristics that would appear to meet some or all of these needs. This biomarker test is based on the fact that in HPV OPC, human papilloma virus is present in all HPV OPC tumors and that measuring virus in blood may serve as a highly specific biomarker of HPV cancer. Because the virus is necessary for the tumors to maintain a malignant state it is both a target for therapy and a diagnostic biomarker test for the cancer and for prognosis. It has now been shown by academic laboratories (Dana Farber Cancer Institute; Mount Sinai Medical Center; Johns Hopkins University School of Medicine; Case Western Reserve; MD Anderson Cancer Center; University of North Carolina) that it is possible to detect cell free fragments of HPV viral DNA in the blood of patients who have active HPV OPC [1-6]. There is also least 1 commercial entity (Naveris) which provides commercial clinical testing. This test is in the early stages of development and the technology is relatively expensive and not routinely available. It is, however, very promising. The concept makes good rational sense and is currently being investigated to see if the promise of a specific and usable plasma test can be realized. We now know that cell free HPV DNA (cfHPVDNA) as a blood test is highly specific to HPV caused cancers. Thus, it may be an excellent test to screen patients who might be at high risk for developing a cancer, predict who might do well with surgery, chemotherapy or radiation and identify recurrences in patients who have been treated for cure and who are in surveillance.

Several studies have shown that the detection of cfHPVDNA can predict recurrence in patients with HPVOPC who have been treated for cure after surgery and chemoradiotherapy. These results are very promising although preliminary. In one study 100% of

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recurrences were identified by a first-time positive test. Many of those patients were initially negative after curative therapy and became positive during repeated testing in follow up. A large fraction of patients, 43%, had an initial false-positive that on repeat testing became negative and only 6% with 2 positive tests did not have recurrence identified. However, the remaining patients, all with 2 positive tests (94%), were found to have a recurrence[2]. These early results are very exciting. There are many details that have to be worked out for physicians to know how to use cfHPVDNA and for routine testing to become a standard of care[6]. One clear conclusion from the data is that many patients were negative after definitive treatment and then developed a positive test indicating that there is a minimum volume threshold necessary to identify persistent or recurrent disease. This leads to a number of questions on how to utilize the test: for example, how often to do testing. Should it be every month for the first 6 months or year after surgery or radiation therapy or perhaps only in the first 6 months and then quarterly after that? How truly sensitive and accurate is the test? Does this become a confirmatory test for a positive scan or the primary diagnostic test? Are we finding tumors early enough in recurrence and how much of a threshold of volume is necessary to be positive – and might they be found by physical exam or appear on PET scans earlier when they are still small and below a cfHPVDNA threshold? There may not be a direct correlation of cfHPVDNA to volume. The biology of each cancer in each person might be unique and might impact on the sensitivity of the assay to recurrence. A positive cfHPVDNA does not tell the physician if this is a local or metastatic spread. This may confound decisions about regional versus systemic salvage treatment. Finally, in our unpublished experience we found that some HPVOPC patients developed late second cancers that were HPV negative and may have been secondary to life style causes such a smoking or to prior radiation therapy. These second cancers can be shown to be molecularly distinct and not HPV related by molecular diagnostic studies. These latter events support lifelong follow-up in patients who smoked or were treated with radiation.

One potential use of the test would be to select patients after surgery who would benefit from postoperative radiotherapy or immunotherapy. This testing could take place in the 6 week window in which postoperative chemoradiotherapy is optimally started. It might also be possible for those patients getting primary chemoradiotherapy to do a midcourse test and evaluate whether they are having a sufficient response such that more or less radiation would be indicated. Pretreatment testing will also be important. There is some very preliminary data that suggests lower levels of cfHPVDNA fragments prior to therapy may be predictive of a poor prognosis biology and early recurrence although this is not consistent[6]. It is possible that molecular characteristics of the fragments might give information on the prognosis as well. These changes could suggest a more resistant form of HPV in the cancers. In patients with locally advanced disease who receive chemotherapy prior to chemoradiotherapy or primary chemo radiotherapy evaluating the velocity of decrease - the rate at which the levels of cfHPVDNA decrease or if they reach 0 during therapy- might help select patients for even further reductions in chemoradiation therapy.

Many of these questions have not been addressed as of yet. However, this is a very exciting new technology which holds great promise for helping improve the outcome in patients. Getting sufficient data through clinical trials to optimally use this test will take some time. However, as our understanding and utilization of the test unfold we will hopefully be able to apply it to improve the quality of life, cost of treatment, treatment toxicity, and anxiety of our patients.

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## *Your Cancer Story...*
### *Real Letters. Real People.*

As Merck and SPOHNC continue their partnership, which began with ***Your Cancer Game Plan***, and continued with the ***With Love, Me*** campaign we are excited and proud to present to you...***Your Cancer Story***...the latest initiative of this program designed to share help, and hope, with those who have been affected by the diagnosis and treatment of oral, head and neck cancer.

"Just do your best – whatever that means in the moment." Julia, a cancer survivor, shares impactful advice about what she wishes she'd known at the start of her #cancer journey. Hear from others by visiting @Merck's Your Cancer Story. #MerckPartner


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*Editors Note: Dr. Marshall Posner is Professor of Medicine Icahn School of Medicine at Mount Sinai, NY. He is Medical Director of the Head and Neck Oncology Program, Associate Director of the Center for Personalized Cancer Therapeutics, and co-Director of the Cancer Clinical Investigation Program for the Tisch Cancer Institute. Dr. Posner has published over 275 peer-reviewed laboratory and clinical studies. He has been principal investigator of NIH grants in immunology and has been principal investigator of multiple Phase 1, 2 and 3 clinical trials. He has a strong clinical and clinical research focus on Immunotherapy, HPV oropharynx cancer and salivary gland cancers.*

*Dr. Eric Genden is a member of the Icahn School of Medicine at Mount Sinai faculty since 1988. Dr. Genden is an internationally recognized expert and innovator in the management of head and neck cancer, microvascular reconstruction of the head and neck, and transplantation. He is the Dr. Isidore Friesner Endowed Professor and System Chairman of the Department of Otolaryngology – Head and Neck Surgery and a Professor of Neurosurgery and Immunology. His many leadership roles at Mount Sinai include Senior Associate Dean for Clinical Affairs at the Icahn School of Medicine at Mount Sinai. Dr. Genden plays a leadership role with the Mount Sinai Doctors Faculty Practice and a he is a Senior Vice-President for Ambulatory Surgery Development.*

# *Medical Advisory Board News*

SPOHNC is pleased to announce that Robert Ferris, MD, PhD, FACS has accepted our invitation to serve as a member of our Medical Advisory Board. Dr. Ferris is a world renowned head and neck cancer physician, and SPOHNC is honored and grateful for his acceptance of this position.

Robert L. Ferris, MD, PhD is Hillman Professor of Oncology and Director, UPMC Hillman Cancer Center and Co-Director of the Tumor Microenvironment Center. Since 2007 he was Co-Leader of the Cancer Immunology Program and Associate Director for Translational Research at the University of Pittsburgh Cancer Institute (UPCI). Dr. Ferris received his medical and graduate training in Immunology at Johns Hopkins, then completed his residency and subspecialty training in head and neck surgical oncology in 2001. In 2006, he received the Excellence in Clinical Investigations award at UPCI and was elected to the American Society for Clinical Investigation (ASCI) in 2008.

Dr. Ferris has also been active in the Society for the Immunotherapy of Cancer (SITC) for 15 years. He is also a Section Editor of the *Journal of ImmunoTherapy of Cancer* (JITC) and serves on the Editorial Boards of *the Journal of Clinical Oncology*, *Clinical Cancer Research* and *Cancer Immunology Research* and as Associate Editor for *JNCI*.

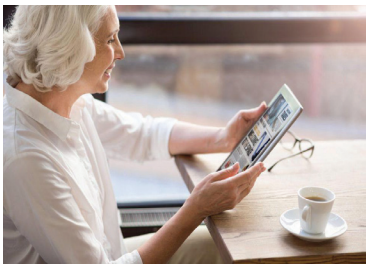
Dr. Ferris' research interests include Cancer Immunotherapy, TransOral Robotic Head and Neck, Surgery Video Assisted, Thyroid/Parathyroid Surgery, Cybernife/ Stereotactic Radiosurgery, Endoscopic Partial Laryngectomy.

Dr. Ferris has been a good friend to SPOHNC for many years, authoring articles for "News from SPOHNC" and sharing his expertise with our audience on several webinars and at conferences as well.

We welcome Dr. Ferris, and SPOHNC appreciates his unwavering commitment to those who have been affected by the diagnosis and treatment of oral, head and neck cancer.



***Do you have a topic of interest that you'd like to see covered in a future feature article in "News from SPOHNC"?***



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## *Medical Advisory Board News*

SPOHNC is pleased to welcome Dan P. Zandberg, MD, to our Medical Advisory Board.

Dr. Zandberg is the Director of the Head and Neck and Thyroid Cancer Disease Sections, Division of Hematology/Oncology and Medical Oncology, and Co-Leader of the UPMC Hillman Head and Neck Cancer Program. He is also the Physician Lead for the second floor Hillman Cancer Center Clinic and an Associate Professor of Medicine.

His main research focus is in the development of clinical trials with immunotherapy to improve patient outcomes. His recent awards include the 2019 National Cancer Institute (NCI) Cancer Clinical Investigator Team Leadership Award, 2020 Leo Criep, M.D. Excellence in Patient Care Award, and 2020/2021 Castle Connolly Regional Top Doctor.

Dr. Zandberg has been a friend to SPOHNC for several years, authoring a feature article for "News from SPOHNC" in 2018, and most recently, speaking on a webinar co-presented by SPOHNC, entitled *Exploring Clinical Trials in Head and Neck Cancer.*

Thank you, Dr. Zandberg, for your consideration of our request. We look forward to a long and continuing relationship.


*"We all need hope and to know there are others like us. It may not be an easy path all the time but we can certainly do it. Just knowing we're not alone is a huge help."*

*~ Pat L.*

## *SPOHNC's Resources*

SPOHNC's most popular resource for newly diagnosed patients is now available as a digital edition!

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*by Nancy E. Leupold & James J. Sciubba, DMD, PhD*

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**Lou Scarpino** *by* Alan Workinger

**David Schultz** *by* RoseAnne Pagac

**Howard Starr** *by* Jan Starr

**Ronald Sturgeon** *by* Harry August, Paula & Linda Bowman, Crestwood Association, Deborah Feairheller, Gregory Korzen, Nick Masciantonio, Mr. & Mrs. Potochnik, Paul Rominski

**Patrick Szerletich** *by* Ron's Produce Co., Inc.

**Karen E. Testa** *by* Wendy Testa

**William Wesp** *by* Anne Wesp

**Bob Wine** *by* Ellen Hauptman, Louise Plate

## *WHY JOIN SPOHNC??*
### *The benefits of becoming a member...*

Right now, you're probably thinking... "but I am a member of SPOHNC! I get this newsletter a couple of times a year." Or maybe you're saying to yourself... "Oh, I'm already a member because I am part of a SPOHNC Chapter support group."


Did you know that you're receiving this issue of "News from SPOHNC" because you're part of a family of people that has been helped by SPOHNC?

If you have ever called us, e-mailed us or have ever been touched by SPOHNC in any way, we like to thank you, by sending you this complimentary April issue of "News from SPOHNC." In fact, you receive another one in October… but you are missing out on 6 additional issues, because you are not a member of SPOHNC.

SPOHNC members are already receiving the benefits listed here. If you haven't joined SPOHNC as a member, please consider doing so, and gain the "MEMBERS ONLY" benefits offered just for you. Membership is $30 annually. If you're not already a member, you're missing out on some great resources that have been designed with care, to help you. SPOHNC wants to provide you with all that you need. We are here to support you, because Together We Heal!

• Are you still dealing with side effects from your treatment? SPOHNC's 42 page PRODUCT DIRECTORY is here! Full of product suggestions and how they can help you, the book also tells you where to find them. This book is a must for anyone who is seeking relief.

• "News from SPOHNC" Feature articles written by distinguished healthcare professionals, sharing stories written by survivors, current head and neck cancer news, survivor and chapter news, human interest stories and more. Receive 8 issues per year.

• Access to SPOHNC's more than 100 Chapter Support groups.

• Access to SPOHNC's National Survivor Volunteer Network of more than 225 survivor and caregiver volunteers, ready and willing to serve as a mentor to a newly diagnosed patient or caregiver.

• Opportunities to connect with patients and survivors. Contact SPOHNC to find out how.

• Insider information about special programs and resources. You will be the first to know.

• Access to additional resources through direct contact with SPOHNC's Outreach Staff.

# CHAPTERS OF SPOHNC

*Contact SPOHNC at 1-800-377-0928 for Chapter information & Facilitator contact information.*

*PLEASE NOTE: Chapters are not holding meetings in person at this time due to COVID-19.*

**Many groups have found other creative ways to support one another during this time of need.**
**Please call to SPOHNC to find out more information.**

**ALABAMA**
BIRMINGHAM, MOBILE

**ARIZONA**
CHANDLER, GILBERT
PHOENIX (2), SCOTTSDALE

**ARKANSAS**
FAYETTEVILLE

**CALIFORNIA**
ARROYO GRANDE, LOS ANGELES
NEWPORT BEACH,
ORANGE-UCI,
SOUTH SAN FRANCISCO, SANTA MARIA,
STANFORD, VENTURA

**COLORADO**
DENVER

**DC**
GEORGETOWN

**FLORIDA**
DEERFIELD BEACH, FT MYERS,
JACKSONVILLE (2), NAPLES,
PALM COAST/NORTHEAST,
WINTER PARK

**GEORGIA**
ATLANTA, MACON,
SAVANNAH

**IDAHO**
MOSCOW

**ILLINOIS**
EVANSTON,
MAYWOOD, MORRIS, SPRINGFIELD

**INDIANA**
AVON
SOUTH BEND

**IOWA**
DES MOINES

**KANSAS**
KANSAS CITY

**LOUISIANA**
BATON ROUGE, NEW ORLEANS

**MARYLAND**
BALTIMORE-GBMC, BALTIMORE-JHMI,
LIBERTYTOWN

**MASSACHUSETTS**
BOSTON, CAPE COD, DANVERS

**MICHIGAN**
ANN ARBOR, SAGINAW, WARREN

**MINNESOTA**
MINNEAPOLIS, ST. PAUL

**MISSOURI**
ST. LOUIS/DPCC

**MONTANA**
MISSOULA

**NEBRASKA**
LINCOLN, OMAHA/MCC

**NEW HAMPSHIRE**
CONCORD

**NEW JERSEY**
CAMDEN, ENGLEWOOD,
LONG BRANCH, MORRISTOWN
PRINCETON/UMC

**NEW YORK**
BAY SHORE, BUFFALO,
MANHATTAN/BI, MANHATTAN, LH
MANHATTAN/MSDUS,
MANHATTAN/NYU, MIDDLETOWN,
NEW HYDE PARK,
ROCHESTER, SOUTHAMPTON,
STONY BROOK , SYOSSET, WHITE PLAINS,

**NORTH CAROLINA**
DURHAM

**OHIO**
DAYTON

**OREGON**
SOUTHERN OREGON

**PENNSYLVANIA**
DUNMORE,
HERSHEY, LANCASTER, LEBANON
PHILADELPHIA/UNIV. PENN HOSPITAL,
YORK

**SOUTH CAROLINA**
GREENVILLE (UPSTATE)

**TENNESSEE**
KNOXVILLE, NASHVILLE

**TEXAS**
DALLAS/BAYLOR
DALLAS/IRVING
SAN ANTONIO

**UTAH**
SALT LAKE CITY

**VIRGINIA**
CHARLOTTESVILLE, FAIRFAX,
NORFOLK, MECHANICSVILLE

**WASHINGTON**
KIRKLAND

**WEST VIRGINIA**
MORGANTOWN

**WISCONSIN**
APPLETON

*"SPOHNC is a wonderful organization and worthy of national note."*

*~ Mitch*

# SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER (SPOHNC)

**MEMBERSHIP APPLICATION**
**SUPPORT FOR PEOPLE WITH ORAL AND HEAD AND NECK CANCER, INC.**
**P.O. Box 53, Locust Valley, NY 11560**
Membership includes subscription to eight issues of *News From SPOHNC & FREE Product Directory*

Name_____Phone (_____)_____

Address_____Email Address_____

Address_____

City_____State_____Zip_____

Please Check: Survivor ____Friend ____Health Professional (Specialty) _____

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**ANNUAL MEMBERSHIP**
❑ $30.00
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**CONTRIBUTIONS**
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❑ Patron, $500+ ❑ Benefactor, $1,000+ ❑ Founder, $5,000+
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Call 1-800-377-0928
to become a member and make a contribution by credit card or order online at www.spohnc.org

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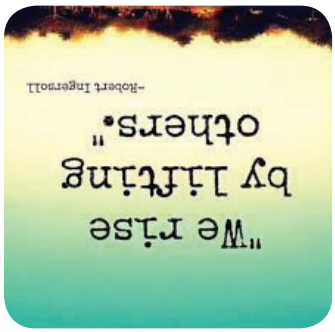


*Together We Heal*
*For your convenience, your appeal envelope is enclosed*

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