

Human Immune Therapy Center

University of Virginia

"Targeting Cancer with the Immune System"

Summer 2000
Volume 1, Issue 2

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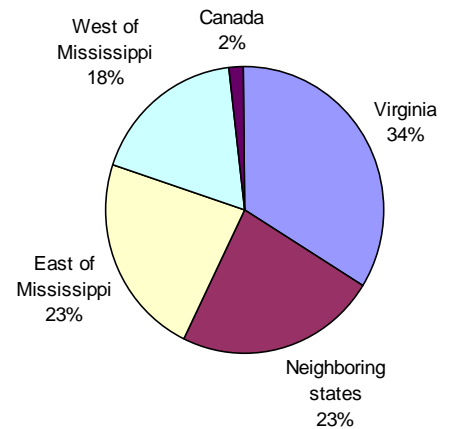
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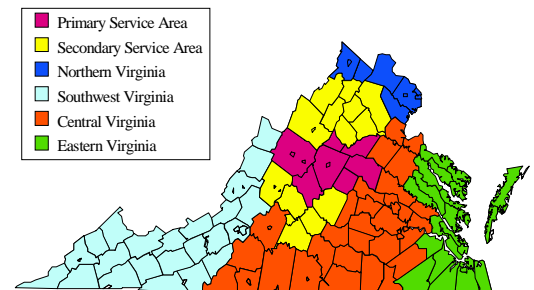
Patient Recruitment for Melanoma Clinical Trials

The Human Immune Therapy Center has been tracking the recruitment pattern of patients who have come to the University of Virginia for treatment in our melanoma vaccine trials. There is a large portion of people, 24%, who come from outside the state of Virginia enrolled in one of our first three trials (Mel 16, 31, 32). One of the fourteen patients from out of state was from Canada. The Center has treated a large number of patients outside of our primary and secondary service area (please see the map of Virginia for the different service areas). The Center is very encouraged by these numbers. The majority of our referral calls (50%) are from outside the state. It shows we are developing a national reputation and national referral pattern for immune therapy for melanoma.

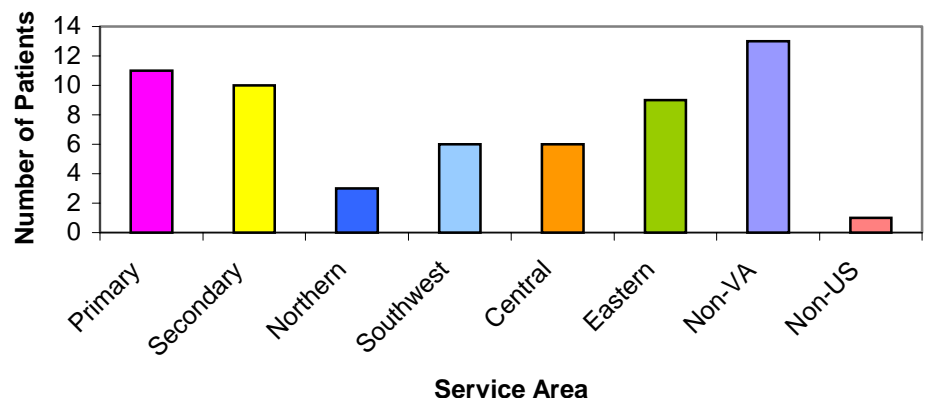
Referrals to Melanoma Vaccine Program
Feb-April 2000
by Region



University of Virginia Service Areas



Recruitment Pattern Mel 31, 32, 16



Two New Vaccine Trials have received Funding through the Cancer Center

The Human Immune Therapy Center worked closely with several investigators to bring two new trials to the University of Virginia. One of the trials that will be starting soon was developed to offer an immune-based alternative to standard of care for patients with ovarian cancer. This trial will use a similar premise of some of the melanoma trials that have been offered to patients at the University of Virginia. A vaccine to help their immune system to attack the ovarian cancer. This vaccine will use the patient's own tumor cells to help create an immune response. Epithelial ovarian cancer represents the most lethal of all gynecologic neoplasms, accounting for more deaths each year than all other gynecologic neoplasms combined. Following traditional surgical debulking and combination cytotoxic chemotherapy, the five-year survival rate for women with advanced stage ovarian carcinoma remains a disappointing 35-38%.

The second trial is for colon cancer patients. The patient's tumor will be used in the preparation of vaccine. There are approximately 160,000 new cases of colorectal cancer diagnosed in the U.S. each year. Despite standard of care treatment, approximately 30,000 Americans die annually from the recurrence of stage II and stage III disease.

In both trials, the patients who enroll into the study will be immunized with autologous tumor cells. The patient's tumor cells will be harvested after surgery

and prepared under sterile conditions. After the cells are prepared in a manner that will make the tumor cell unable to grow as a tumor, they will be given back to the patient in the form of a vaccine along with substances that help to stimulate the immune system to react against the tumor.

Sentinel Node Biopsy and its role in treatment and in Vaccines

Sentinel node biopsy (SNBx) has been used in melanoma patients to determine if the tumor cells have spread to other lymph nodes. Prior to this procedure a complete lymph node dissection was performed which removed all the lymph from either under the arm or in the groin.

The SNBx procedure only removes one lymph node that is found with the help of a radioactive dye that is injected into the skin near the site of the tumor and found with a hand held probe. The lymph node is examined to see if any tumor cells are present in the lymph node. This procedure only takes about 30 minutes to complete as an outpatient. The procedure is 99% accurate. It also has fewer side effects and pain associated with it in comparison to lymph node dissection.

Why look at just this one node? The SNBx is the one that the tumor in that region would drain to prior to it being resected. If the tumor cells had traveled to nearby lymph nodes, they would have to travel through this node. The SNBx acts as the first line of defense prior to going to the major lymph nodes under the arms or in the groin. If tumor is located in this node, there is a good chance that there is tumor located in the other nodes.

This technology now being applied in evaluating the immune response for patients who have had vaccine therapy at

HIT Current Events

April 29, 2000
Villanova University
College of Nursing 11th Annual Alumni Award

Patrice Neese, MSN, RN,CS, ANP received the Medallion Award for her Clinical Excellence in Nursing. It is highest award bestowed by the school for distinguished achievement.

May 9, 2000
National Cancer Institute
Presentation at NCI for a National Multi-center Trial

Dr. Slingluff and several HIT staff members attended a meeting with NCI staff to discuss a new peptide melanoma trial to be preformed at several national sites.

June 3, 2000
Eastern Cooperative Cancer Group (ECOG)
Annual meeting

Dr. Slingluff, Co-Chair of the Melanoma section, will be presenting a proposal for a multi-center trial of a tumor vaccine

the University of Virginia. In this case a SNBx is performed for the vaccine site, rather than the tumor site. The Sentinel Immunized Node (SIN) represents the first node responding to the vaccine. The SIN is evaluated in the research laboratory to determine if the patient had an immune response to the peptide vaccine. The SIN allows direct evaluation of the vaccine immunogenicity. Immunogenicity will allow further development of the vaccine. If no response is seen to one of the peptides, the vaccine can be adjusted to be more effective against the tumor.

Invitation to Conference

Dr. Slingluff was recently invited to a conference between Japan and the U.S. to discuss current advances in Melanoma Immunology in March 2001.