The Oncology Bulletin

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Clinical Innovation: Immunotherapy

The goal to find the cure for cancer has become more exciting over the past decade. A novel form of cancer treatment known as immunotherapy has increased in research over the last five years. Immunotherapy is a unique form of treatment that uses a patient's natural immune system to fight cancer. It stimulates the immune system instead of killing cancer cells directly. Types of immunotherapy include but are not limited to monoclonal antibodies, adoptive cell transfer, and cellular vaccines(1).

The Cancer Research Institute (CRI) developed a program known as the Cancer Immunotherapy Consortium (CIC) to organize and promote the development of immunotherapy. This program has recently made a widespread initiative termed the Cancer Vaccine Clinical Trial Working Group (CVCTWG) "to construct and recommend a paradigm for development of cancer vaccines and related immunotherapies" (see **Figure 1**)(1).

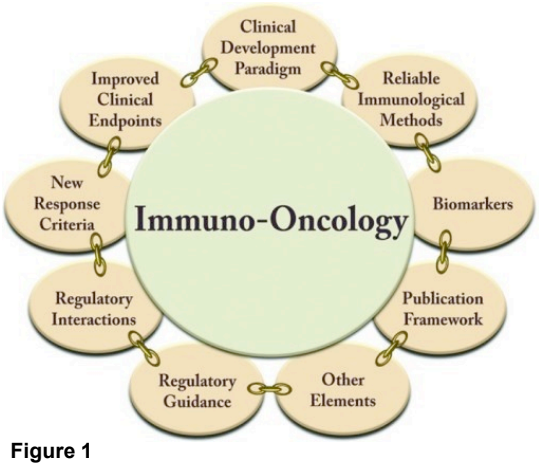

Figure 1

Many differences between immunotherapy and traditional cytotoxic

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In This Issue

Organization Spotlight: HOPA Annual Conference

This past March, the 11th annual Hematology/Oncology Pharmacy Association (HOPA) conference was held in Austin, TX with a record breaking attendance of more than 1,000 participants! This conference offered pharmacists the opportunity to review the most recent developments in treatment guidelines, innovative technology, therapeutic regimens, and findings of clinical trials. The four-day event was an enriching experience for anyone interested in continuing to expand their clinical knowledge and networking opportunities in oncology and hematology (1).

At the HOPA Conference, pharmacists this year participated in discussions at the Oncology Interest Group Meetings, including a session for ambulatory and pediatric providers to converse and interact with other professionals on the issues affecting their fields. Throughout the weekend, research sessions and workshops on topics, such as developing letters of intent and identifying grant opportunities, served as critical learning sessions for attendees. Panels of researchers and providers offered their knowledge and discussed pressing issues affecting their fields from mitigating adverse effects of patients to the naming policy of

Continued on Page 2...

CAR-T CELL THERAPY: A NEW APPROACH TO TREATING CANCER

One area of active research in immunotherapy is enhancing the body's ability to detect cancer cells which have evaded normal immune surveillance. One method of immunotherapy, which is also referred to as adoptive cell transfer (ACT), involves altering a patient's T-cells to identify and then attack their own cancer cells. Following collection, a patient's T-cells are genetically modified to have chimeric antigen receptors (CARs) on their surface. The modified cells are harvested in a laboratory before being infused back into the patient. Once infused, the T-cells proliferate, and the CARs aid the T-cells in identifying specific antigens located on the cancer cells. Once the target cells are identified by the T-cells, this allows the immune system to mount a response against the cancer which had previously evaded the immunesystem.

The POB CAR-T cell clinical trial was conducted that involved 20 pediatric patients with acute lymphoblasticleukemia. Twelve of the patients (60%) had no blasts detected in their bone marrow following CAR T-cell therapy. Ten ofthose patients (50%) have since received a stem cell transplant and continue in remission(1). The Children's Hospital of Philadelphia (CHOP) conducted a trial where 27 out of the 30 patients (90%) with ALL showed a completeresponse in that all signs of cancer were eradicated in those patients after one month. Half a year after initial therapy, the survival rate was 78% along with an event-free rate of 67%(2).

CAR-T cell therapy has shown efficacy in other disease states without the need for immunosuppression beforehand. In the article "Decade-Long Safety and Function of Retroviral-Modified Chimeric Antigen Receptor T-cells," authors discussed the results of three clinical trials that evaluated the use of modified T-cells to treat HIV. They monitored the CD4z CAR in CD4+ and CD8+ T-cells in patients with active viremia or chronic HIV-1 infection. The researchers found 98% of samples contained detectable levels of CAR T-cells for a minimum of 11 years after infusion. The researchers concluded that patients do not have to undergo immunosuppression prior to modified T-cell infusion, because long-term persistence of the modified T-cells will occur regardless(3).

While there seem to be positive outcomes with CAR T-cell therapy, one common side effect is cytokine-release syndrome, where a large amount of cytokines is released into the bloodstream by the infused T-cells, possibly leading to hypotension, a high fever, and a coma. CRS is often treated with etanercept or tocilizumab because they have been proven to help alleviate symptoms without impacting CAR T-cells' activity. Despite the significant side effect of CRS, CAR-T cell therapy has shown incredible efficacy with patients suffering from ALL and others who possessed such an aggressive malignancy that they would have been considered untreatable otherwise(1). This efficacy will lead toeven more research and understanding of CAR-T cells to help save many cancer patients in the future.

1) "CAR T-cell Therapy: Engineering Patients' Immune Cells to Treat Their Cancers." National Cancer Institute. The National Institutes of Health. 16 Oct 2014. <http://www.cancer.gov/cancertopics/research-updates/2013/CAR-T-Cells/>.

2) Maude, S. L., Frey, N., Shaw, P. A., Aplenc, R., Barrett, D. M., Bunin, N. J., ... & Grupp, S. A. (2014). Chimeric antigen receptor T cells for sustained remissions in leukemia. *New England Journal of Medicine*, *371*(16), 1507-1517.

3) Scholler J, Brady TL, Binder-Scholl G, et al. Decade-long safety and function of retroviral-modified chimeric antigen receptor t-cells. Sci Transl Med. 2 May 2012; 4(132): 132ra53.

Contributed by Bliss McMichael

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HOPA ANNUAL CONFERENCE CONTINUED

biosimilar oncology drugs. Attendees were given the opportunities to sign up for committees, work groups, and task forces(1).

HOPA has put together a momentous meeting where attendees leave well-armed with knowledge that can be used to enhance the care of cancer patients. Next year, HOPA sets their sights on Atlanta, Georgia for the 12th annualconference, which will be especially exciting for the UGA College of Pharmacy since Dr. David DeRemer was recently inducted to the HOPA Board of Directors and Dr. Amber Clemmons is the in-coming Chair of the Program Planning Committee for the conference. HOPA continues to excel in expanding professional development, promoting research, participating in patient advocacy efforts and will continue to do so for next year's conference(1).

1) http://www.hoparx.org/education/default/index.html

Contributed by Charity Loput, Pharm.D. Candidate

CLINICAL INNOVATION: IMMUNOTHERAPY CONTINUED

chemotherapy can be noted in terms of pharmacokinetics, anti-tumor response, and time to clinical effect. For example, the effects of chemotherapy are assessed by tumor shrinkage measurements, which were presumed to correlate with long-term outcomes. However, response to immunotherapy can be delayed and may only be seen "after a period of stable disease, after initial tumor burden increase, or after appearance of new lesions" (1). Therefore, standard chemotherapy efficacy endpoints were seen as failures in immunotherapy studies. This required the development of new immune-related response criteria (1).

Based on these findings, the CVCTWG has created guidelines for future safety and efficacy trials. Using these criteria, immunotherapy has seen major success in primary survival endpoints in Phase III clinical trials in the past 3 years. Of note, Sipuleucel-T (Provenge®) is a therapeutic cancer vaccine approved for the treatment of hormone-refractory prostate cancer through its structure involving a prostate-specific antigen that can incite the body's immune system to attack the cancer cells(2). Also, ipilimumab (Yervoy®), a monoclonal antibody that activates T-cells by antagonizing the suppressor receptor, CTLA-4, has shown efficacy in metastatic melanoma(3).

The CIC has also encouraged the streamlining of immunotherapy monitoring. Immune monitoring assays evaluate the "function, phenotype, and frequency of antigen-specific T cells and other immune effectors" to determine if correct biological targets are reached and can correlate with clinical outcomes(1). Monitoring is challenging because the assays are associated with a wide range of variability that contributes to barriers when researching immunotherapy. Immune response assay harmonization, developed by the CIC, provides guidelines to reduce the variability of monitoring in immunotherapy. This program is advancing the progress of immunotherapy, as data is more reliable and structured. "The broad usage of assay harmonization may bring immune monitoring to the forefront of immune biomarker development, support a better understanding of therapeutic modes of action, and guide decision making in clinical development"(1).

In order to advance and learn from the current status of immunotherapy, data must be reproducible, organized, and accurately understood (4). The CIC created the Minimal Information About T-Cell Assays (MIATA) project, which has guidelines published in *Immunity*(4). These guidelines outline data publication for the results of clinical trials(1). More information is now included about the conditions, variables, and results from specific tests. Required information incudes summaries on the sample, assay, data acquisition, results, and laboratory environments(4).

The future of immunotherapy has grown with the changes made by the CIC. The immunotherapy pipeline currently has 641 companies developing 1064 immunotherapy agents in 2994 projects(5). Immunotherapy can be used along with chemotherapy, small molecule targeted therapy, radiation, and surgery to fight cancer. It can also be administered in the outpatient setting to enhance its ease of use(1). Changing the way immunotherapy is researched, monitored, and reported should contribute to its success in treating cancer in the future.

1) Hoos, A., & Britten, C. (2012). The immuno-oncology framework: Enabling a new era of cancer therapy. *OncoImmunology, 1*(3), 334-339. Retrieved April 12, 2015.

2) Kantoff, Philip W., M.D., Celestia S. Higano, M.D., Neal D. Shore, M.D., E. Roy Berger, M.D., Eric J. Small, M.D., David F. Penson, M.D., Charles H. Redfern, M.D., Anna C. Ferrari, M.D., Robert Dreicer, M.D., Robert B. Sims, M.D., Yi Xu, Ph.D., Mark W. Frohlich, M.D., and Paul F. Schellhammer, M.D. "Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer." New England Journal of Medicine 363.5 (2010): 411-22.Web.

2) Hodi, F.S., et al., *Improved Survival with Ipilimumab in Patients with Metastatic Melanoma.* New England Journal of Medicine, 2010. **363**(8): p. 711-723.

4) Hoos, A., Janetzki, S., & Britten, C. (2014). Advancing the field of cancer immunotherapy. *OncoImmunology, 1*(9), 1457-1459. Retrieved April 12, 2015.

5) Immunotherapy in Oncology Drug Pipeline Update 2015. (2015). *Research and Markets,* (1196685). Retrieved April 12, 2015.

Contributed by Hayley Hodgson

IPILIMUMAB: A RECENT CLINICAL PHASE III TRIAL

The American Cancer Society estimates that about 73,870 new cases of melanoma will be diagnosed in 2015. Stage IV melanoma or metastatic melanoma is an aggressive form of skin cancer where the cancer cells have spread to other organs in the body besides the skin cells and lymph nodes. Metastatic melanoma has a high mortality rate with the standard of care being enrollment in a clinical trial due to the aggressive nature of the disease. The 5-year survival rate for metastatic melanoma is between 15-20% and the 10-year survival rate is between 10-15%(1). Decarbazine remains the only chemotherapeutic agent FDA-approved for the treatment of metastatic melanoma. Decarbazine shows tumor shrinkage in 12.5% of these patients with not much efficacy in terms of prolonging survival(2). Ipilimumab is a human monoclonal antibody currently used in the treatment of metastatic melanoma that has shown increased survival. Its mechanism of action is antagonistic toward cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4). CTLA-4 down regulates T-cell activation; therefore the blocking action of ipilimumab increases T-cell responsiveness to attack cancer cells (see **Figure 2**).

In 2010, a randomized, double-blind, phase 3 study reported on 403 patients with a diagnosis of unresectable stage III

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WANTED: ONCOLOGY PHARMACISTS

Oncology is an innovative subspecialty of pharmacy that continues to grow and improve on a daily basis. As the anti-cancer therapeutic pipeline continues to expand with agents that are associated with high cost, significant adverse effects, and improved survival, healthcare will have an increased demand for oncology pharmacists.

Oncology pharmacists can work in inpatient and outpatient settings where they assist medical teams with managing ADRs, choosing chemotherapeutic regimens, managing other comorbidities, educating patients and their caregivers, and assisting with the development of formularies and treatment protocols. With the recent push by many pharmaceutical organizations, including HOPA, for pharmacist provider status under Medicare Part B, pharmacists in the oncology profession may soon be recognized by all payers and insurance companies for these activities especially in medically-underserved communities(1). As of 2008, approximately 1% of registered pharmacists identified themselves as oncology pharmacists(3). To be an oncology pharmacist and practice at such a high caliber today, certain levels of education should be achieved. After completing a four-year doctorate of pharmacy program, it is then necessary to complete one year of PGY1 residency and then one year of oncology/hematology PGY2 residency. Although not required, it is highly recommended to become board certified as well by the BPS as a BCOP(4).

Although the path to become an oncology pharmacist may seem daunting, it is also rewarding. Not only is there an increased job demand, but also oncology pharmacists have a substantial impact on direct patient care. Oncology is an emerging and growing specialty that deserves some consideration for all those interested in the pharmacy practice.

1) http://www.hoparx.org/uploads/Health_Policy/2015/HOPA_-_HR_592_S._314_Fact_Sheet.pdf

3) Butcher, Lola. Demand for oncology pharmacists growing as key role in increasingly valued. Oncology Times 2008; 30: 6, 8.

4) http://www.bpsweb.org/specialties/oncology.cfm

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IPILIMUMAB, CONTINUED FROM PAGE 3

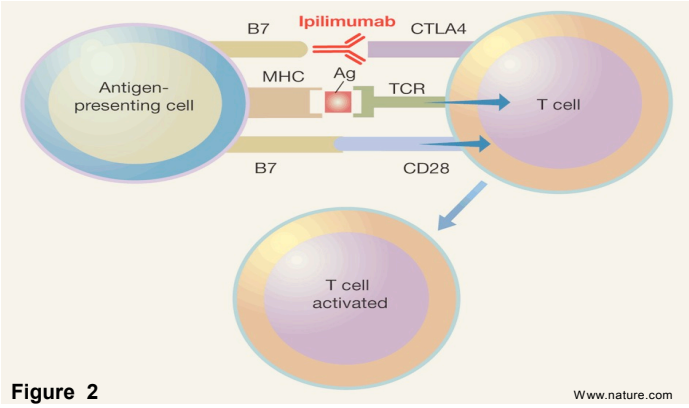

Figure 2

or IV melanoma and HLA-A*0201-positive status that had failed previous treatment. Patients were randomized in a 3:1:1 ratio to treatment groups. The treatment groups included an induction course of ipilimumab (3 mg/kg) with the gp100 vaccine, ipilimumab plus a placebo, and the gp100 vaccine with a placebo. These treatments were administered every three weeks for a total of four treatments. The primary endpoint of median overall survival was 10 months, 10.1 months, and 6.4 months in the ipililumamab plus gp100 group, ipilimumab plus placebo group, and gp100 plus placebo groups, respectively. The hazard ratio for death in the ipilimumab-plus-gp100 group compared with the gp100-alone group was 0.68 with a P-value of <0.001. The hazard ratio for death in the ipilimumab alone group compared with the gp100 alone group was 0.66 with a P-value of 0.003. There was no statistical difference in the overall survival between the two ipilimumab groups with a P-value of 0.76. Of note, ipilumomab did not show clinically significant differences in historical criteria such as a decline in disease progression and response rates.

Adverse events occurred in 60% of patients treated with ipilimumab alone and 32% of patients treated with gp100 alone, including mainly immune-related adverse events such as pruritis, rash, and vitiligo as well as other adverse events, including diarrhea (38.4%), nausea (33.9%), and fatigue (36.1%). These adverse events were managed during the course of the study through the use of corticosteroid regimens and infliximab for severe diarrhea. There were also 14 deaths overall during the study with 7 of those deaths related to immune-related adverse events.

The authors concluded that ipilimumab, used alone or with gp100, was superior in overall survival compared to gp100 alone in patients who had received previous treatment for metastatic melanoma(3). Ipilimumab offers a unique mechanism that should help lower the mortality rate of metastatic melanoma with an increase of its use in these patients.

1) What are the survival rates for melanoma skin cancer, by stage? (2015, March 20). Retrieved April 26, 2015, from http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-survival-rates

2) Chapman, P. B., Einhorn, L. H., Meyers, M. L., Saxman, S., Destro, A. N., Panageas, K. S., .. & Kirkwood, J. M. (1999). Phase III multicenter randomized trial of the Dartmouth regimen versus dacarbazine in patients with metastatic melanoma. *Journal of Clinical Oncology*, *17*(9), 2745-2745.

3) Hodi, F.S., et al., *Improved Survival with Ipilimumab in Patients with Metastatic Melanoma*. New England Journal of Medicine, 2010. **363**(8): p. 711-723.

Contributed by Caroline Cruce, Pharm.D. Candidate

SIPULEUCEL-T: CANCER VACCINE TREATMENT OF PROSTATE CANCER

Prostate cancer is the second leading cause of death from cancer in men. According to the National Cancer Institute, there are 137.9 new diagnoses per 100,000 men per year and the 5-year survival rate is 98.9%(1). Although curative therapies are available in the forms of surgery and radiation, 20 – 30% of patients experience a relapse of cancer after treatment, classified as castration-resistant prostate cancer. Pharmacological agents and steroid treatments can be used to prolong survival for castration-resistant cancer. Currently, docetaxel is the only chemotherapeutic agent with proven efficacy to produce such results when compared to mitoxantrone and prednisone combination therapy. Unfortunately, docetaxel has only shown an increase in overall survival of 2-3 months, leaving the need for other treatment methods to help extend the lives of castration-resistant prostate cancer patients(2).

A phase 3 trial was completed on Sipuleucel-T, which targets castration-resistant prostate cancer. Sipuleucel-T is an autologous active cellular immunotherapy or an "anti-cancer vaccine". The major component of Sipuleucel is an active antigen-presenting cell bound to a recombinant fusion protein titled 'PA2024'. PA2024 is made of a prostate antigen (prostatic acid phosphatase) fused to a granulocyte-macrophage colony-stimulating factor. Sipuleucel-T works to incite the body's immune system to respond to prostate cancer cells. The phase 3 trial was a double-blind, placebo-controlled, multicenter study where patients were assigned randomly in a 2:1 ratio to receive either sipuleucel-T or a placebo. The study had two endpoints with the primary endpoint being overall survival and the secondary endpoint being time to disease progression(2).

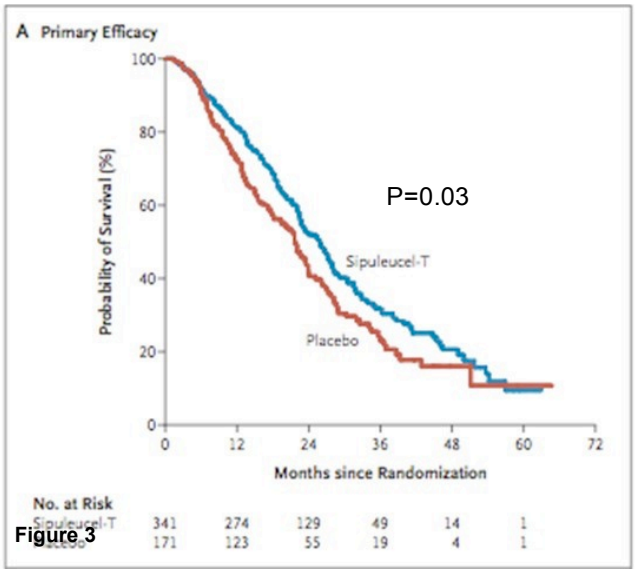

Figure 3

A total of 512 patients participated in the study with 341 receiving sipuleucel-T and 171 receiving the placebo. The results of the study were as follows:

- The median survival was 4.1 months longer in the sipuleucel-T group (25.8 months) than in the placebo group (21.7 months) (**See Figure 3**).
- The median time to objective disease progression was 14.6 weeks (3.7 months) in the sipuleucel–T group and 14.4 weeks (3.6 months) in the placebo group (P=0.63). Similar results were observed for time to clinical disease progression.
- For immune responses, titers of antibodies against PA2024 & prostatic acid phosphatase were shown to be higher in the sipuleucel-T group.

Factors to consider regarding the trial include the use of additional anticancer therapies after study treatment and the adverse events due to sipuleucel-T. APC8015F, a different formulation of sipuleucel-T, was used as salvage therapy in the placebo group. Docetaxel was used as salvage therapy in patients who were enrolled in either arm of the study. Administration of subsequent therapies may confound long-term outcome assessment of overall survival. Adverse events (classified as mild or moderate) that were observed more frequently in the sipuleucel-T consisted of chills (in 51.2%), fever (22.5%), headache (10.7%), influenza-like illness (9.8%), myalgia (9.8%), hypertension (7.4%), hyperhidrosis (5.3%), and groin pain (5%)(2).

Overall, the results of the phase 3 trial revealed sipuleucel-T as a well-tolerated agent with a modest impact on overall survival and insignificant effect on time to disease progression.

1) "Surveillance, Epidemiology, and End Results Program Turning Cancer Data Into Discovery." Cancer of the Prostate. National Cancer Institute, Web. 28 Apr. 2015.

2) Kantoff, Philip W., M.D., Celestia S. Higano, M.D., Neal D. Shore, M.D., E. Roy Berger, M.D., Eric J. Small, M.D., David F. Penson, M.D., Charles H. Redfern, M.D., Anna C. Ferrari, M.D., Robert Dreicer, M.D., Robert B. Sims, M.D., Yi Xu, Ph.D., Mark W. Frohlich, M.D., and Paul F. Schellhammer, M.D. "Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer." New England Journal of Medicine 363.5 (2010): 411-22. Web.

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VACCINATIONS IN CANCER PATIENTS

Immunization in patients with cancer undergoing chemotherapy or hematopoietic stem cell transplant (HSCT) require careful consideration of their vaccination schedule due to the immunosuppression caused by these treatments. One role of the hemotology/oncology pharmacist is to assist providers with selecting appropriate vaccines including theappropriate schedule based on that patient's specific circumstances. In addition to the criteria involved in healthy individuals, the additional criteria are applied for cancer patients. Specifically, consideration must be given to the timing of vaccinationin relation to immunosuppressive therapy(1).

Due to the immunosuppressant effects of chemotherapy and stem cell transplant, vaccination schedules are more complex in cancer patients then in patients with other disease states. An inactivated vaccine would not adequately initiate an immune response if the immune system is weakened, decreasing the vaccination protection that patient should ofreceived(2). For chemotherapy and HSCT therapy, patients can receive inactivated vaccinations at least **2 weeks before** treatment or at least **3 months after** treatment (**6 months after** therapy regimens with B-cell antibodies)(1).

Live vaccinations, even if they are attenuated or weakened, are contraindicated during immunosuppression therapy due to the chance of enhanced viral replication of the vaccine. Live vaccines still contain components of the virus that, if present in a weakened immune system, can possibly infect the patient(2). For chemotherapeutic and HSCT therapy, patients can receive live vaccinations at least **1 month before** immunosuppression therapy and typically at least **3 months after** chemotherapy and **6 months after** transplant for most vaccinations (can be up to **2 years after** transplant for MMR and Zoster vaccinations)(1). Below is a table listing inactivated and live vaccines given to patients (**Table 1**).

HSCT patients generally lose their prior immunities and require re-vaccination regardless of their pre-HSCT status. While HSCT donor immunities may provide some level of protection to the patient, it is unreliable and should not prevent vaccination of the patient. Live vaccines should be avoided in HSCT patients after transplant if they are experiencing active graft-versus-host disease or ongoing immunosuppression(1).

Table 1: Significant Vaccines in Cancer and HSCT Patients

Inactivated Vaccinations	Influenza (IM), Polio, Hepatitis B, Tdap/DTaP
Activated (Live) Vaccinations	Influenza (FluMist®), Measles/ Mumps/Rubella, Rotavirus, Varicella (Chicken Pox), Zoster (Shingles)

Live vaccines are also avoided in cancer patients during chemotherapy. Vaccinations given during chemotherapy should not be considered to be adequate immunization without proof by antibody titers due to decreased immune response. For additional information, see the 2013 IDSA Clinical Practice Guidelines for Vaccination of the Immunocompromised Host(1).

Pharmacists are constantly expanding their scope of practice in providing patients with vaccinations. Knowledge of the proper scheduling and criteria for administering vaccinations to cancer patients is necessary to ensure pharmacists fulfill that responsibility.

1) Rubin, L. G., Levin, M. J., Ljungman, P., Davies, E. G., Avery, R., Tomblyn, M., ... & Kang, I. (2013). 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. *Clinical infectious diseases*, cit684.

2) http://www.cdc.gov/vaccines/pubs/pinkbook/genrec.html

Contributed by Andrea Clarke

Pharm.D. Candidate

CLINICAL CASE STUDY: TEST YOUR KNOWLEDGE

A 65-year-old white male who is going to begin his third cycle of combination cisplatin and vinorelbine therapy in one week for his non-small cell lung adenocarcinoma is requesting information about which vaccinations he should receive. You search for his profile using the GRITS database and notice that he is due for a few vaccinations.

Which of the following vaccinations that you notice he is due would you not recommend for the patient?

A. Zoster (Shingles)

B. Tdap

C. PPSV23

D. Influenza (inactivated)

E. None of the above

See Page 7 for the correct answer!

Contributed by Ben Albrecht, Pharm.D. Candidate

THE ONCOLOGY BULLETIN

SOAP
STUDENT ONCOLOGICAL ADVOCATES IN PHARMACY
COLLEGE OF PHARMACY

SPECIAL THANKS TO ALL THE WRITERS AND SOAP ADVISORS WHO HELPED MAKE THIS ISSUE AND WILL HELP MAKE ALL FUTURE ISSUES OF THE ONCOLOGY BULLETIN POSSIBLE.

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ANY QUESTIONS, COMMENTS, TOPIC REQUESTS?
Email Ben Albrecht at balb3@uga.edu

Stay tuned with upcoming meetings and events of SOAP by joining our Facebook page:

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From the Editor

I am very happy that the Oncology Bulletin has continued since its first issue in December 2013. Oncology is a growing field for pharmacists to develop a significant role in patient care. I am proud to be able to help create a means, for those who are interested, to expand their knowledge of important practices, therapeutics, and policies effecting pharmaceutical oncology services.

-Ben Albrecht, Pharm.D. Candidate

Clinical Case Study Answer from Volume 2, Issue 1:

E: A, B, and D

Clinical Case Study Answer from Volume 2, Issue 2:

A: Zoster (Shingles)

Some Upcoming SOAP Events:

- **SOAP Sponsored Red Cross Blood Drive**
- **Monthly Meetings and Speaker Lectures**
- **SOAP Percentage Nights and other Fundraising Events**
- **Valentines Day Goody Bag Donations to the Winship Cancer Center**
- **Annual Tina Borg 5k**

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