



CANCERcare
Connect[®]

The Future Role of Cancer Vaccines

Presented by

Leisha A. Emens, MD, PhD

Johns Hopkins University

James L. Gulley, MD, PhD, FACP

National Cancer Institute

Peter F. Bross, MD

Food and Drug Administration

Joann Minor, MS, LCPC

Food and Drug Administration

Carolyn Messner, DSW, MSW

CancerCare

Learn about:

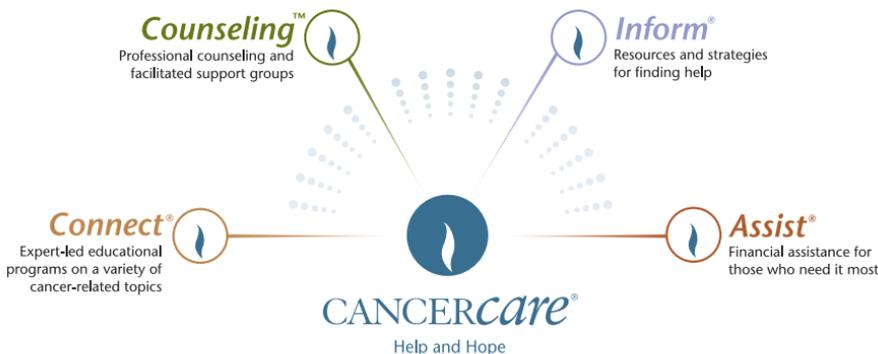
- How the immune system works
- Cancer vaccines
- Clinical trials for vaccine treatments
- Your support and information networks



CANCERcare[®]

Help and Hope

The *CANCERcare*® Constellation of Services



CancerCare's services are provided free of charge to anyone affected by cancer

1-800-813-HOPE (4673) • www.cancercares.org

CancerCare is a national nonprofit organization that provides free professional support services to anyone affected by cancer: people with cancer, caregivers, children, loved ones, and the bereaved. CancerCare programs—including counseling, education, financial assistance, and practical help—are provided by trained oncology social workers and are completely free of charge. Founded in 1944, CancerCare now provides individual help to more than 91,000 people each year, and an additional 1.6 million people visit our websites, www.cancercares.org and www.lungcancer.org, to gain information and resources.

Contacting CancerCare

National Office

CancerCare
275 Seventh Avenue
New York, NY 10001
E-mail: teled@cancercares.org

Administration

Tel: 212-712-8400
Fax: 212-712-8495
E-mail: info@cancercares.org
Website: www.cancercares.org

Services

Tel: 212-712-8080
1-800-813-HOPE (4673)

If you are a health care professional interested in ordering free copies of this booklet for your patients, please use the online order form on our website, www.cancercares.org, or call 1-800-813-HOPE (4673).

The Future Role of Cancer Vaccines

Presented by

Leisha A. Emens, MD, PhD

Assistant Professor of Oncology
Johns Hopkins University

James L. Gulley, MD, PhD, FACP

Director, Clinical Immunotherapy Group
Laboratory of Tumor Immunology and Biology
Center for Cancer Research, National Cancer Institute
National Institutes of Health

Peter F. Bross, MD

Medical Review Officer
Office of Cellular, Tissue, and Gene Therapy
Center for Biologics Evaluation and Research
Food and Drug Administration

Joann Minor, MS, LCPC

Director, FDA Cancer Patient Consultant Program
Office of Special Health Issues
Food and Drug Administration

Carolyn Messner, DSW, MSW

Director of Education and Training
CancerCare

The information in this booklet is based on a November 2006 Telephone Education Workshop conducted by CancerCare in partnership with the American Society of Clinical Oncology, Association of Clinicians for the Underserved, Association of Oncology Social Work, Intercultural Cancer Council, Multinational Association of Supportive Care in Cancer, Research Advocacy Network, and The Wellness Community.

INTRODUCTION

page 2

FREQUENTLY ASKED QUESTIONS

page 9

GLOSSARY (definitions of blue boldfaced words in the text)

page 11

RESOURCES

page 12

This patient booklet was made possible by an educational grant from EMD Pharmaceuticals, Inc.

As researchers conduct clinical trials, hope is emerging that more vaccines will join in the fight against cancer.

Vaccines, also called vaccinations, strengthen the ability of the body's immune system to fight infection and disease. This is the concept behind vaccines such as the flu shot. The immune system is designed to recognize foreign substances such as bacteria and viruses that lead to illnesses. These foreign invaders carry **antigens**, which trigger the immune system to fight against them.

Cells of the immune system called **lymphocytes** detect antigens and destroy the invaders carrying the antigens. By introducing a weakened version of the virus or bacteria, vaccines "teach" the immune system to destroy the invaders. In the case of the flu shot, a weak form of the flu virus is introduced into a person's body to help it prepare to fight a real infection later.

Through research, we know that the same concept can be applied to cancer. Vaccines are beginning to offer one more way to prevent and treat different types of cancer.

Vaccines Used to Prevent Cancer

Cancer prevention vaccines are given to healthy people to protect them against infection with viruses that may eventually lead to cancer.

Already, the U.S. Food and Drug Administration (FDA) has

approved two cancer vaccines that stop the viruses that can lead to two types of cancer.

In 2006, the FDA approved an anti-cancer vaccine called Gardasil, which prevents infection by a virus called human papillomavirus. Some strains of this virus cause most cases of cervical cancer.



The FDA has also approved a vaccine that protects against infection by the hepatitis B virus. Chronic infection with hepatitis B may lead to liver cancer.

Vaccines Used to Treat Cancer

Currently, prevention vaccines are the only types of cancer vaccines approved by the FDA and available to the public. But most cancer vaccines now under study are intended to be used as a treatment for cancer, once it has been diagnosed. These are called **cancer treatment (or therapeutic) vaccines**. Treatment vaccines work by strengthening the body's natural defenses against cancer. They can also prevent an existing cancer from growing, keep a cancer from coming back, or wipe out cancer cells not killed by other treatments. Using vaccines in this way is one of the next steps in the evolution of fighting cancer, along with surgery, radiation, chemotherapy, and **targeted treatments**. Treatment vaccines offer yet another option.

Cancer Vaccines in Development

Currently, there are several hundred clinical trials under way to study various tumor vaccines. Some scientists predict that in the next five years the FDA will approve a treatment vaccine for people who already have cancer. The hope is that the vaccines can be used alone or in combination with other treatments that

already exist to fight advanced disease and reduce the risk for recurrence.

CHALLENGES OF CANCER VACCINE RESEARCH

Researchers know that if they can harness the power of the immune system, it can protect against cancer more effectively. However, by the time cancer cells start to grow and spread quickly, it's often too late for the immune system to get rid of them. In part that's because the immune system is looking for foreign cells—outsiders such as bacteria or viruses. Sometimes, cancer cells—which began as normal cells—slip by unnoticed.

Cancer vaccines are designed to reeducate the immune system to recognize and destroy cancer cells. These vaccines can also teach the immune system to remember which cells are cancerous, so that it will get rid of them if they return at a future date.

But it's a challenge to reeducate the immune system. From the very first months of an infant's life, the immune system is trained *not* to attack the body's own organs or cells. So cancer vaccines must find some target, such as a unique substance on the cancer cell. This type of target would allow the body to recognize the cancer cells as foreign.

What researchers hope to do is boost the ability of several types of lymphocytes, particularly **B cells** and **T cells**, to protect against cancer. Like all lymphocytes, they are trained to recognize antigens, in this case on cancer cells.

WHAT RESEARCH HAS LEARNED SO FAR

So far, cancer vaccines generally have not been able to get rid of tumors by themselves. Research suggests that they need to be paired with other treatments to be most effective against cancer.

From clinical trials, we've learned that patients with smaller amounts of cancer that is progressing slowly may be more likely to benefit from vaccines. Researchers are also looking at new ways to deliver the vaccines, such as injecting them directly into

a tumor. Early results with this approach have been promising.

EXAMPLES OF CANCER VACCINES UNDER STUDY

An anti-prostate cancer vaccine currently being studied may help teach the body to target a substance called prostate-specific antigen (PSA). Excess PSA sometimes signals prostate cancer. Scientists can prepare a vaccine made of a weakened virus that has been created to manufacture PSA. This vaccine can help the body learn to associate PSA with a foreign virus. As a result, the body may start to target and get rid of cancer cells with PSA.

Another strategy is to use MUC1 as a target. This substance is found in patients with breast, lung, or colon cancer.

A number of other vaccines are currently in the final stages of



testing in the United States. For example, several groups of researchers are testing a vaccine called GVAX for treating prostate tumors, leukemia, and pancreatic cancer. This vaccine is made up of modified tumor cells that have been exposed to radiation so they cannot divide and grow. These cells release a substance called granulocyte-macrophage colony-stimulating factor (GM-CSF) in great amounts. GM-CSF boosts the immune system's ability to protect against cancer.

Other researchers are looking at a vaccine called Oncophage as a possible treatment for kidney and skin cancers. This vaccine is specially made for each patient, using a tumor's own "blueprints." Scientists identify what makes the cancer cells in the tumor different from normal, healthy cells. Then, they create a vaccine that trains the immune system to recognize and destroy the cancer cells without harming normal cells.

There are a number of challenges to overcome when making such a vaccine. That's why clinical trials are so important.

The Importance of Clinical Trials

There is no question that clinical trials have led to advances in cancer treatment, creating a brighter future for people with cancer. Clinical trials are the standard by which we measure the worth of new treatments and the quality of life of patients as they go through those treatments. For this reason, doctors and researchers urge patients to take part in clinical trials. Talk to your doctor. He or she can guide you in making a decision about whether a clinical trial is right for you.

Here are a few things you should know about taking part in vaccine clinical trials:

- Before you participate in a clinical trial, you will be fully informed as to the risks and benefits of the trial.
- If a standard treatment exists for your cancer and it is working for you, many doctors advise that you should not choose an experimental vaccine over your treatment. The FDA has not yet approved any cancer vaccine for use as a standard treatment. A vaccine may be an appropriate addition to standard treatment but not a replacement for it. Currently, many cancer treatment vaccines are being used after patients finish standard treatment.
- Some cancer vaccine trials test the vaccine against a placebo (an inactive substance) or in combination with various other treatments, but only when the patient has already received standard treatment.
- You can stop taking part in a clinical trial at any time for any reason.

Another Way to Be Involved

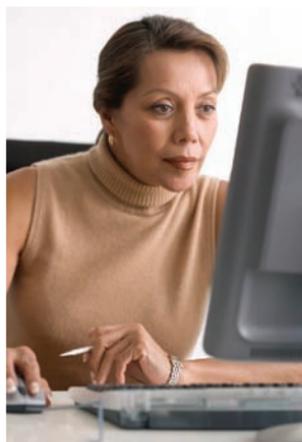
The FDA has created two patient advocate programs designed to involve patients and incorporate their perspective into the drug development review and approval process. Through the Patient Representative Program, patient representatives

have participated as full members in FDA advisory committee meetings for AIDS, cancer, and many other serious diseases. (For more information on becoming involved with the program, see the resource list on page 12.) Currently, 40 patient consultants representing more than 20 different cancers work with the FDA through the Cancer Drug Development Patient Consultant Program. The program recruits patient consultants as needed, working with advocacy organizations such as CancerCare®, the American Cancer Society, and Us TOO.

Your Support and Information Networks

When you are being treated for cancer and are considering taking part in a vaccine clinical trial, you'll want to gather as much reliable information as possible. Your most important information network is your health care team, which can help you sift through what you find, separating facts from fiction. Here are some tips:

- **Identify one person on your medical team** who is in charge of your care and funnel all information through that person.
- **Ask your doctor to recommend books, brochures, and websites.** A reliable website is one sponsored by a reputable organization such as the American Cancer Society, the National Cancer Institute, a nationally known cancer center, or a medical school. *Remember:* The Internet is not a substitute for individual medical care. Use the credible information you find on these sites to help you communicate more effectively with your doctor.
- As you visit different websites or hear about new vaccine clinical trials, **write down questions** as they arise. At your



next medical appointment, bring these questions with you to discuss with your doctor.

- **During your doctor's visits, take notes** or ask a family member to take notes. Also ask your doctor if you can tape record your visits. This will allow you to go back later and listen carefully to all the information presented by your doctor.
- **Find trustworthy educational programs** about your cancer and treatment options available. CancerCare® offers more than 50 free Telephone Education Workshops every year that provide people with reliable information from experts on a range of cancer topics.

You can also turn to these resources:

Oncology social workers and nurse practitioners are specially trained to help you find out more about your treatment options and clinical trials, learn how to navigate the health care system, and get the best care possible. Often, when people are coping with cancer and making decisions about entering clinical trials, they need someone to talk with who can help them and their families sort through the complex emotions and issues that arise. These health care professionals provide emotional support, help you cope with treatment and its side effects, and guide you to resources. CancerCare offers free counseling from professional oncology social workers on staff.

Support groups can reduce the feeling that you are going through cancer alone. These groups provide reassurance, suggestions, insight—a safe haven where you can share similar concerns with your peers in a supportive environment. At CancerCare, people with cancer and their families can take part in support groups in person, online, or on the telephone.

Financial help. A number of organizations, including CancerCare, can provide financial help to cover some costs related to cancer. CancerCare can help with expenses such as transportation to treatment, child care, or help needed around the home. We can also refer you to other resources in your community that provide assistance.

Frequently Asked Questions

Q Do insurance companies help pay the costs of clinical trials?

A Usually the nurse manager of the trial can advise you about this. Most of the time, insurance companies cover standard health care costs such as blood tests and office visits. The research itself—which includes data gathering, purchase of the medications that are being studied, cost of transportation for patients, for example—is covered by the sponsor of the clinical trial, which may be the government or a pharmaceutical company.

Q I've heard that clinics in Europe and the Bahamas already have vaccines to treat existing cancers. Why aren't these vaccines available in the United States?

A It's true that if you go on the Internet, you can find many clinics that offer "immune-based treatments" for cancer. But these treatments have not been rigorously evaluated in clinical trials, so it's best to be cautious. American researchers share information with European agencies that are the counterparts to our U. S. Food and Drug Administration. In that way, everyone is aware of what is going on in terms of legitimate research. By staying in touch with each other, researchers can make vaccines happen faster.

Q How will cuts to the National Cancer Institute's budget affect the progress of vaccine development?

A Certainly we are facing somewhat tougher times in terms of tight budgets for cancer research. But the government is continuing to fund clinical trials for vaccines and other cancer treatments. In addition, researchers receive funding from sources other than the government: advocacy groups, foundations, and pharmaceutical companies all have a stake in supporting this research. People with cancer and their family members and friends have also been extremely effective in raising money for research.

Glossary

antigens Substances on the surface of cells that the immune system recognizes as foreign.

B cells Specialized white blood cells. One of their duties is helping to protect against cancer.

cancer prevention vaccines Injections given to healthy people to prevent infection from viruses that cause cancer.

cancer treatment (or therapeutic) vaccines Vaccines designed to treat already existing cancer by strengthening the body's natural defenses against the disease. Researchers are hoping that treatment vaccines will prevent further growth of an existing cancer, prevent a cancer from coming back, or wipe out cancer cells not killed by other treatments.

lymphocytes Specialized white blood cells that are part of the immune system. There are two major types of lymphocytes—B cells and T cells—whose duties include protecting the body against cancer.

T cells Specialized white blood cells. One of their duties is helping to protect against cancer.

targeted treatments Treatments that zero in on cell mechanisms that supply blood to tumors and promote their growth and division. Rather than killing both healthy and unhealthy cells, as chemotherapy does, targeted treatments attack cancer cells primarily, sparing healthy tissues and causing fewer side effects.

Resources

CancerCare

1-800-813-HOPE (4673)
www.cancercares.org

National Cancer Institute

1-800-422-6237
www.cancer.gov

People Living With Cancer

(Patient Website of the American Society of Clinical Oncology)
www.plwc.org

U. S. Food and Drug Administration

Patient Representative Program

301-827-4460

www.fda.gov/oashi/patrep/patientrep.html#overview

Cancer Drug Development Patient Consultant Program

301-827-4460

www.fda.gov/oashi/cancer/pconback.html

The Wellness Community

1-888-793-9355

www.thewellnesscommunity.org

To find out about clinical trials:

Coalition of Cancer Cooperative Groups

1-877-520-4457

www.CancerTrialsHelp.org

National Cancer Institute

1-800-422-6237

www.cancer.gov/clinicaltrials



CANCER*care*[®]

The information presented in this patient booklet is provided for your general information only. It is not intended as medical advice and should not be relied upon as a substitute for consultations with qualified health professionals who are aware of your specific situation. We encourage you to take information and questions back to your individual health care provider as a way of creating a dialogue and partnership about your cancer and your treatment.

All people depicted in the photographs in this booklet are models and are used for illustrative purposes only.

This booklet was edited and produced by Elsevier Oncology.

© 2007 Cancer Care, Inc. All rights reserved.



From the moment of diagnosis, let the hope begin.

When Fran was diagnosed with cancer, she knew that she and her daughter, Rachel, would need support. Both found help and hope with *CancerCare*.

Since 1944, our professional oncology social workers have provided **free** counseling, education and practical help for anyone touched by cancer. *CancerCare* is with you every step of the way.

If we can help you and your family, please call us at 1-800-813-HOPE (4673) or visit www.cancer.org.



CANCERcare[®]
Help and Hope

1-800-813-HOPE (4673)
www.cancer.org

©CancerCare 2005