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THE NEWS CENTER FOR THE CANCER CARE TEAM

## The Frustratingly Slow Pace of Quality Improvement in Cancer Care

Dr. Joe Simone asks: After the proliferation of "quality" committees, alliances, and working groups in the last several years, what true progress has been made? What are the reasons for the delay, and what can be done?

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**Books: Review of Nurture Nature/ Nurture Health: Your Health and the Environment**

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### Medicare Part D: More than 21 Million Enrolled in First Month of Signup—But Only 1 Million Did So on Own

Also: Update on Medicare Reimbursement Changes & Challenges for 2006

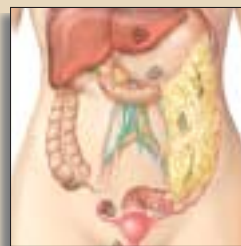
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### NCI Clinical Alert Gives Stamp of Approval for IP as Well as IV Chemo for Advanced Ovarian Cancer

Also: Promising Results for IP Therapy Presented at Chemotherapy Foundation Symposium, including as Consolidation Therapy

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**ADVOCACY INSIGHT: 'Why I am resigning from the NCI Director's Consumer Liaison Group' By Eric Rosenthal**

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### Chemotherapy Foundation Symposium:

(1) Antiangiogenesis Agent Active in Advanced Ovarian Cancer; (2) Finding the Best Sequence for Colorectal Cancer Therapies; (3) Albumin-Bound Paclitaxel Promising for Melanoma

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## AACR-NCI-EORTC Conference on Molecular Targets & Cancer

# Pancreatic Cancer Vaccine Produces Promising Results in Phase II Study

By Devon Schuyler

**A** vaccine for use in patients with pancreatic cancer is producing encouraging results, according to an early analysis of a Phase II study from researchers at Johns Hopkins University. The survival rate with the vaccine is 88% at one year and 76% at two years, a significant improvement over the expected survival rates of 63% and 42%, respectively.

The results were presented at the Molecular Targets and Cancer: Discovery, Biology, and Clinical Applications international conference sponsored by the American Association for Cancer Research, the National Cancer Institute, and the European Organisation for Research and Treatment of Cancer.

"It's quite exciting, since we know how devastating pancreatic cancer is, to have these preliminary survival results," said the moderator of a news conference that featured the study, Frank J. Rauscher III, PhD, Professor and Deputy Director of the Wistar Institute in Philadelphia.

The 56 patients included in the analysis are part of an ongoing study, explained the lead researcher, Dan A. Laheru, MD, Assistant Professor of Oncology at Johns Hopkins. "It is important that we continue to follow these patients so we know how this treatment will work in the long term."

### Re-educating the Immune System

The prostate cancer vaccine, which was developed by Elizabeth Jaffee, MD, the Dana and Albert "Cubby" Broccoli Professor in Oncology and Pathology at Hopkins, was designed to overcome

the ability of cancer cells to evade normal immune surveillance cells.

"A key premise of the vaccine is that the immune system is intact; it just needs to be re-educated to recognize the pancreatic cancer cells as foreign," said Dr. Laheru.

The vaccine is made from cancer cells extracted from two donors. The donor cells are first genetically modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF), and then irradiated to create a killed vaccine. When the vaccine is injected into a patient, the GM-CSF attracts immune cells to the vaccine site, where the immune cells encounter antigens.

"Then, these newly armed immune cells patrol the rest of the patient's body, destroying remaining pancreatic cancer cells with the same or a similar antigen profile," Dr. Laheru said.

He explained that using the patient's own cells to produce a vaccine is not a viable option at this time because not enough of the vaccine can be made for all five injections.

When the vaccine was tested in a Phase I trial of 14 patients, three remained cancer-free more than seven years later. The Phase II trial used the highest bioactive vaccine dose identified in the Phase I study.

### Five Doses

In the study, which finished enrolling patients in January 2005, researchers administered five doses of the vaccine to 60 adults who had undergone a Whipple procedure at Johns Hopkins.

Patients received the first dose of the vaccine eight to 10 weeks after



**Dan Laheru, MD: "A key premise of the vaccine is that the immune system is intact; it just needs to be re-educated to recognize the pancreatic cancer cells as foreign."**

surgery. Within a month of vaccination, patients began treatment with fluorouracil and radiation therapy. If patients were free of disease one month after completing chemotherapy and radiation, they received a second, third, and fourth dose of the vaccine, spaced one month apart. The fifth, final booster dose of the vaccine was given six months after the fourth dose.

In an interview, Dr. Laheru explained that the vaccines were scheduled as far as possible after chemotherapy and radiation because chemoradiation blunts the immune response.

The interim analysis included one-year follow-up on 56 patients and two-year follow-up on 36 patients; the median follow-up was 32 months.

The vaccine appeared to be safe and well-tolerated. The main treatment-

related side effect was injection-site reactions such as redness, swelling, itching, and pain, none of which lasted more than 10 days. There were no systemic reactions such as fever, chills, or systemic rash.


Systemic levels of GM-CSF were evaluated in order to indirectly measure the longevity of vaccine cells at the immunizing site. GM-CSF levels peaked at 48 hours after the first and second vaccinations, about 24 hours after the third and fourth vaccinations, and 48 hours after the fifth vaccination.

### Limitations & Future Studies

Dr. Laheru said that an important limitation of the vaccine is the fact that researchers don't know which proteins play a role in pancreatic cancer. If the specific proteins could be identified, it would be possible to create a vaccine that contained high levels of just those proteins.

Dr. Laheru said he and his colleagues plan to follow the patients in this study for at least three years. In addition, Steven Piantadosi, Professor of Oncology at Hopkins, is completing a planned case-control study to compare the patients in this study with other Hopkins patients undergoing treatment for pancreatic cancer.

Drs. Laheru and Jaffee hope to begin a Phase III trial later this year or early in 2007 that would compare the vaccine plus chemotherapy and radiation with chemotherapy and radiation alone.

Dr. Laheru noted that although other researchers are also developing vaccines for pancreatic cancer, this is the only one being studied for use in the adjuvant setting. 

## Books

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People for the Ethical Treatment of Animals (the notorious PETA).

Gaynor says he plans to follow this book with "a footnoted textbook version" and "online teaching materials...continuously updated [for] universities, law schools, and medical schools." Only a complete rewriting, however, will make it useful to professionals.

### A Disclosure

Some related disclosures about ourselves: David wrote the chapter on toxins and environmental pollutants for a previous edition of *Merritt's Textbook of Neurology*, and this year he underwent

*"Despite our criticisms, we compliment the author for his willingness to take on such a daunting task. There is little doubt that his perceptions are, in the main, correct."*

removal of a kidney and ureter for urothelial carcinoma, possibly attributable to many years of second-hand exposure to tobacco smoke. He sought and benefited from Dr. Gaynor's advice while deciding, reluctantly, to undergo treatment with therapeutic toxins. At


David's request, Dr. Gaynor sent him a review copy of his book.

Peter, who has a long-time interest in toxicology, is a recent graduate of a public health program in environmental and occupational health. As the owner of a nine-hole golf course, he is licensed to use pesticides and does so, reluctantly, in accordance with government regulations and practices acknowledged to be safe.

### An Optimistic Note

Despite our criticism of the work, we compliment the author for his willingness to take on such a daunting task. There is little doubt that his perceptions are, in the main, correct.

He ends optimistically, suggesting that, "if each of us performed just one...simple act of conservation, such

as decreasing our use of bleached paper or eating organic foods...we could, literally, help restore the atmosphere, prevent illness, and save lives." We hope so. 

**M**itchell L. Gaynor, MD, is Assistant Professor of Medicine at Weill-Cornell Medical College and the founder and president of Gaynor Integrative Oncology ([www.gaynoroncology.com](http://www.gaynoroncology.com)). *Nurture Nature/Nurture Health* is his fourth book, and publicity materials for it describe it as being underwritten by Nurture New York's Nature, Inc., a not-for-profit collaboration of corporations and environmental organizations in New York City.