

EMBARGOED FOR RELEASE

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NCI Issues Clinical Announcement for Preferred Method of Treatment for Advanced Ovarian Cancer

The National Cancer Institute (NCI), part of the National Institutes of Health, today issued an announcement encouraging treatment with anticancer drugs via two methods, after surgery, for women with advanced ovarian cancer. The combined methods, which deliver drugs into a vein and directly into the abdomen, extend overall survival for women with advanced ovarian cancer by about a year.

The clinical announcement to surgeons and other medical professionals who treat women with ovarian cancer was made with the support of six professional societies and advocacy groups. The announcement coincides with publication in the *New England Journal of Medicine*^{*} of the results of a large clinical trial by Deborah Armstrong, M.D., medical oncologist and an associate professor at Johns Hopkins Kimmel Cancer Center in Baltimore, Md., and her colleagues in an NCI-supported research network known as the Gynecologic Oncology Group (GOG). This is the eighth trial evaluating the use of chemotherapy delivered into the abdomen for ovarian cancer. Together, these trials show a significant improvement in survival for women with advanced ovarian cancer.

The two treatment methods are called intravenous, or IV, for chemotherapy delivered into a vein and intraperitoneal, or IP, for chemotherapy delivered into the abdominal, or peritoneal, cavity. The Armstrong trial involved 429 women with stage III ovarian cancer who were given chemotherapy following the successful surgical removal of tumors. It compared two treatment regimens: 1) IV paclitaxel followed by IV cisplatin, to 2) IV paclitaxel followed by IP cisplatin and the subsequent administration of IP paclitaxel.

“Americans look to NCI—and to all of the institutes that constitute the National Institutes of Health—for unbiased research studies and sound counsel. This clinical

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announcement is a demonstration of that commitment,” said NIH Director Elias A. Zerhouni, M.D.

“The National Cancer Institute wants to make certain that the results of clinical research are rapidly disseminated to both health care providers and patients, in order to ensure that life-enhancing cancer treatments are widely available,” said NCI Director Andrew C. von Eschenbach, M.D.

"IP therapy is not a new treatment approach, but it has not been widely accepted as the gold standard for women with ovarian cancer," said Armstrong. "There has been a prejudice against IP therapy in ovarian cancer because it's an old idea, it requires skill and experience for the surgery and for the chemotherapy, and it's more complicated than IV chemotherapy. But now we have firm data showing that we should use a combination of IP and IV chemotherapy in most women with advanced ovarian cancer who have had successful surgery to remove the bulk of their tumor."

Standard treatment for women with stage III ovarian cancer has been surgical removal of the tumor (debulking), followed by six to eight courses of IV chemotherapy given every three weeks with a platinum drug, such as cisplatin or carboplatin, and a taxane drug, such as paclitaxel. The new NCI clinical announcement recommends that women with advanced ovarian cancer who undergo effective surgical debulking receive a combination of IV and IP chemotherapy. IP chemotherapy allows higher doses and more frequent administration of drugs, and it appears to be more effective in killing cancer cells in the peritoneal cavity, where ovarian cancer is likely to spread or recur first.

“In our trial, women who received part of their chemotherapy via an IP route had a median survival time 16 months longer than women who received only IV chemotherapy,” said Armstrong. The 205 women treated via the IP route fared better, even though most of them received fewer than the six planned treatments. Complications associated with the abdominal catheter used to deliver the IP chemotherapy were the main reason only 86 of the women completed all six IP treatments. Women who received IP chemotherapy had more side effects than those treated with IV chemotherapy alone, but most side effects were temporary and easily managed. One year after treatment, women in both study groups had the same reported quality of life.

“Randomized, multicenter clinical trials, including this most recent study, clearly show the value of IP chemotherapy—an extended life for women with advanced ovarian cancer,” said

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Philip DiSaia, M.D., chairman of the GOG.

"For most women who have had successful surgical removal of tumors to less than one centimeter in size, we now know that the longest survival may be achieved by giving their chemotherapy directly into the abdomen," said Beth Karlan, M.D., president of the Society of Gynecologic Oncologists and director of Gynecologic Oncology and the Gilda Radner Ovarian Cancer Program at Cedars-Sinai Medical Center in Los Angeles, Calif.

In response to this announcement, the Ovarian Cancer National Alliance's outgoing president, Ginger Ackerman, and its executive director, Sherry Salway Black, said the Alliance would widely disseminate this information on IP therapy to their patient community. "We welcome the results of the recent trial that demonstrates increased survivorship," said Salway Black.

"It is important for women to have the facts about when it is appropriate to consider IP chemotherapy," said Karl Podratz, M.D., Ph.D., chairman of the board of the Gynecologic Cancer Foundation (GCF) and professor of obstetrics and gynecology at the Mayo Clinic, Rochester, Minn. "GCF looks forward to working with NCI and the ovarian cancer community to educate women about the results of this very important clinical trial, and what it means for women with advanced ovarian cancer."

Karen Stanley, R.N., M.S.N, president of the Oncology Nursing Society, and Susan Vogt Temple, R.N., president of the Society of Gynecologic Nurse Oncologists, noted that their societies have plans in place to teach oncology nurses and women with ovarian cancer how IP chemotherapy can be given safely and reliably.

More studies are needed to determine the best IP drug regimen and the optimal number of IP treatments. Future trials also will address how to reduce toxicity associated with IP administration.

In addition to continued research to improve ovarian cancer treatment, NCI is funding studies to identify disease markers and develop improved screening techniques, enabling earlier detection and treatment of the disease. An estimated 22,220 women in the United States were diagnosed with ovarian cancer in 2005. It causes more deaths in the United States than any other cancer of the female reproductive system, with an estimated 16,210 women dying from the disease in 2005. The most recent statistics show that only 45 percent of women survive five years after being diagnosed with ovarian cancer; the rate increases to 94 percent when the disease is diagnosed before it has spread. However, women with ovarian cancer frequently have no symptoms or only mild symptoms until the disease is advanced. As a result, only 19 percent of all cases are detected at that

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early, localized stage.

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- For Questions and Answers about IP treatment for advanced ovarian cancer, after 5 p.m. EST on Jan. 4, 2006, please go to <http://www.cancer.gov/newscenter/pressreleases/IntraperitonealQandA>.
- The clinical announcement regarding treatment for advanced ovarian cancer will be available online after 5 p.m. EST on Jan. 4, 2006, at <http://ctep.cancer.gov/highlights/ovarian.html>.
- The article in the *New England Journal of Medicine* can be viewed online after 5 p.m. EST on Jan. 4, 2006.
- To obtain accompanying video footage, please contact the NCI Media Relations Branch at (301) 496-6641 or ncipressofficers@mail.nih.gov.
- Additional information on IP chemotherapy, including administration, as well as other resources for clinicians and patients can be obtained at <http://www.gog.org>, <http://onsopcontent.ons.org/Toolkits/Chemotherapy/> and <http://www.ons.org/patientEd/Treatment/chemotherapy.shtml>.
- For a digest of information on IP chemotherapy, please visit <http://www.cancer.gov/clinicaltrials/developments/IPchemo-digest>.
- For more information about ovarian cancer, please go to <http://www.cancer.gov/cancertopics/types/ovarian/>.
- For more information about clinical trials for ovarian cancer, please go to <http://www.cancer.gov/search/clinicaltrials/> and <http://www.cancer.gov/clinicaltrials/ovarian-cancer-updates>.
- For more information about cancer, please visit the NCI Web site at <http://www.cancer.gov> or call NCI's Cancer Information Service at 1-800-4 CANCER (1-800-422-6237).

Professional Societies and Advocacy Groups

- Gynecologic Cancer Foundation: <http://www.thegcf.org>
Contact: Marsha Wilson, (301)320-3342
- Gynecologic Oncology Group: <http://www.gog.org>
Contact: Marsha Wilson, (301)320-3342
- Oncology Nursing Society: <http://www.oncologynursesociety.org> (more)
Contact: Karen Hochberg, (412) 326-1100

- Ovarian Cancer National Alliance: <http://www.ovariancancer.org>
- Contact: Sharon Flynn, (202) 331-1332

- Society of Gynecologic Nurse Oncologists: www.sgno.org
Contact: Susan Temple, (334)728-0355

- Society of Gynecologic Oncologists: <http://www.sgo.org>
Contact: Marsha Wilson, (301)320-3342

* Armstrong DK, Bundy B, Wenzel L, Huang HQ, Baergen R, Lele S, Copeland LJ, Walker JL, Burger RA. Intraperitoneal cisplatin and paclitaxel in ovarian cancer. *NEJM*, January 5, 2006, Vol. 354, No. 1, pgs. 34-43.