

St. Peter's Hospital
Cancer Care Center
Annual Report 2014

OVARIAN CANCERS



St Peter's Hospital

Cancer Care Center

ST PETER'S HEALTH PARTNERS

Mission Statement

The mission of St. Peter's Cancer Care Program is to provide quality cancer care. Guided by the spirit of the Sisters of Mercy, the values that provide direction to the program include:

- Ministry with compassion and caring to the physical, psychological and spiritual needs of cancer patients
- Respect for human life and the dignity of the individual

Dedicated to offering a continuum of services to support the optimal well-being of patients and their families, St. Peter's Cancer Care Program is committed to the promotion of:

- The art of caring, balanced with technology
- Continuous improvement and innovation
- Prudent use of resources
- Excellence through collaboration with existing community organizations
- Facilitation of access to care
- Community and professional education



St Peter's Hospital

Cancer Care Center

ST PETER'S HEALTH PARTNERS

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Chosen date 2015

Dear Colleague:

I am pleased to forward to you the St. Peter's Cancer Care Center's Annual Report for 2014, focusing on the diagnosis and treatment of ovarian cancer.

Since 1985, St. Peter's has been continually accredited as a Comprehensive Community Cancer Program (CCCP) by the American College of Surgeons Commission on Cancer. In its most recent reaccreditation survey, the Commission specifically commended St. Peter's program in the areas of clinical trial accrual, public reporting of outcomes and the quality of its data submission. The Cancer Center pursues a comprehensive quality improvement program and engages in a range of prevention and early detection activities in the community.

St. Peter's program is fully comprehensive, encompassing state-of-the-art screening and diagnostics, and a full range of surgical, medical and radiological oncologic treatment options. Services include external beam and brachytherapy as well as Novalis® Shaped Beam stereotactic radiosurgery and radiotherapy. RapidArc® is used to deliver intensity modulated radiation therapy (IMRT) with speed and precision. St. Peter's full service medical oncology practice offers evaluation and treatment of oncologic and hematologic conditions including systemic therapies, genetic counseling and outpatient infusion.

Multidisciplinary treatment planning is supported by a wide range of ongoing cancer conferences.

If you would like additional information regarding the services offered at St. Peter's, call our Cancer Information Line (518-525-1547) or visit our website at www.sphcs.org/CancerCareCenter.

Finally, I would like to thank all those involved in making this publication possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Wayne Holmen".

Wayne Holmen
DIRECTOR, CANCER CARE SERVICES

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A SURVIVOR'S STORY: OVARIAN CANCER GAVE ME MY GROOVE BACK



MICHAEL DEMARS AND KELLY QUIST-DEMARS, OVARIAN CANCER SURVIVOR

Kelly Quist-Demars was a healthy and active 30-year-old, looking forward to starting a family with her husband, Michael. She started having an urgent need to urinate that was very painful. She thought she might have an infection, so she went to her gynecologist's office.

Initially, Quist-Demars' nurse-midwife felt she was young and healthy, and because her symptoms had subsided by time of the appointment, they were thought to be benign. Quist-Demars kept pushing for more tests, and an ultrasound discovered a 10 cm cyst on her left ovary. It was very low risk to be anything bad, they felt, but since she wanted to get pregnant, surgery was recommended to remove the cyst.

When Quist-Demars awoke from surgery, she learned that her surgeon did not like the look of the cyst up close. He called in Dr. Daniel Kredentzer, a gynecologic oncologist with Women's Cancer Care Associates, who agreed it was abnormal. Her ovary had been removed and the cells were sent to pathology.

"When my follow-up was scheduled in just two weeks instead of the normal four, I knew something wasn't right. And that morning, I could see the surgeon was building up to

something. It must be very difficult to tell a patient they have cancer. It is certainly heart-stopping to hear. He cried, I cried, my husband cried," she remembered.

She was referred to Dr. Heidi Godoy at Women's Cancer Care Associates.

Quist-Demars had a family history of breast cancer, and at the time, didn't know about the connection between breast and ovarian cancers.

"I always thought breast cancer would be in my future, so I'd always inform doctors of my family history," said Quist-Demars. "Ovarian cancer was never on my radar."

Quist-Demars had a mucinous ovarian tumor, which is a slow-moving cancer. She had surgery to determine the stage and whether or not more cancer was evident.

"Dr. Godoy said this may be a stage II or stage III cancer, which changed the game completely," said Quist-Demars.

Her omentum, appendix and lymph nodes were removed to help ensure the cancer didn't have anywhere to hide. The tumor was graded as a stage IC, which meant there

was a break in tissue that could have allowed cancer cells to spread beyond the ovary. Thankfully, no evidence of cancer was found.

After presentation to St. Peter's Tumor Board, and a second opinion at Dana Farber, Quist-Demars underwent four rounds of chemotherapy that were very effective. She lost her hair and suffered from extreme exhaustion, but was able to continue working with time off when she needed it.

"The doctors said I would have a rough six months and then it would be over."

Quist-Demars has been cancer-free for two-and-a-half years. The possibility of having children still exists for her and her husband, and she's looking forward to a long, healthy life with her family. She is also involved with ovarian cancer advocacy and education, and is hoping to be part of finding a cure someday.

Quist-Demars is very thankful for her relationship with Dr. Godoy and St. Peter's Hospital.

"She was only a couple years older than me, so we had a bond," she remembers tearfully.

"She was so honest, which I appreciated. She's so bright and intelligent and I knew she'd take good care of me. She's never let me down."

"I would recommend St. Peter's hospital to anyone," she continued.

"Everyone, from the person who cleaned the rooms, to the highest-level surgeons, were so warm and inviting and took time to talk to me and my family."

Quist-Demars says cancer has taught her that the time to start living is NOW.

"You only get one shot at this 'life' thing, so live your truth right away. I already knew how wonderful my husband and friends and family were, but I certainly learned that on a deeper level. My husband says, 'cancer gave me my groove back!'"

Quist-Demars says women really have to take charge of their health.

"Your concerns are valid, even if they seem minor," advised Quist-Demars. "Keep asking questions, and set up a consultation with a gynecologic oncologist if you think something is abnormal. Get a lot of support."

2014 CANCER PROGRAM ACTIVITY REPORT

St. Peter's Cancer Care program continues to offer a comprehensive range of cancer care services to adults in the community and the region. In its most recent complete reporting year (2013), St. Peter's diagnosed and/or treated 2,349 new (analytic) cancer cases and participated in the care of an additional 711 (non-analytic) cases. St. Peter's Cancer Committee continues to provide direction and oversight to the program.

Among the recent accomplishments of the program are:

- Implemented an acuity scheduling template for the medical oncology infusion practice for better throughput and maximizing capacity
- Improved documentation of Eastern Cooperative Oncology Group (ECOG) performance status and advanced directives

Arthur Sunkin, MD
ATTENDING PHYSICIAN
CANCER COMMITTEE CHAIR
ST. PETER'S MEDICAL ONCOLOGY



Cancer Program Goals for 2015:

- Improve cancer research opportunities through research with National Research Group
- Ensure state-of-the-art radiation oncology care through re-accreditation survey with American College of Radiation Oncology
- Ensure nationally recognized breast care through the National Accreditation Program for Breast Centers
- Expand breast cancer treatment options through use of a prone breast board in radiation oncology

CANCER DATA MANAGEMENT ACTIVITY REPORT

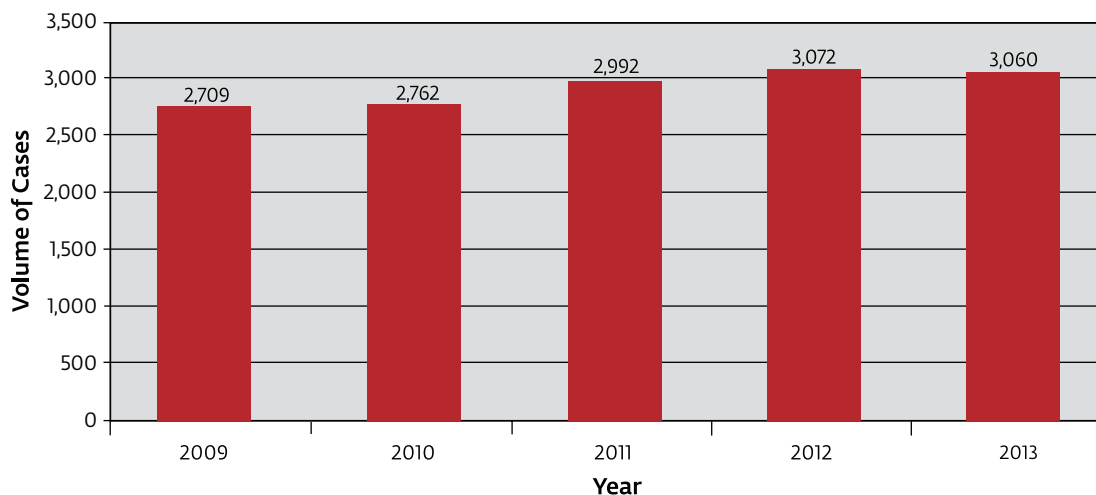
Evelyn Hamm, BS, CTR

CANCER REGISTRY
ST. PETER'S CANCER CARE CENTER

St. Peter's Hospital Cancer Registry is a data collection department that identifies, abstracts and follows patients with a malignant diagnosis treated at our facility. Two full-time certified tumor registrars maintain the daily functions of the registry and continuously review data for accuracy and areas of improvement in accordance with standards set forth by the Commission on Cancer. One full-time tumor board coordinator manages more than 100 multidisciplinary cancer conferences annually. A five-person per-diem staff of certified tumor registrars performs abstracting, casefinding and quality improvement tasks as assigned. Collectively, the St. Peter's Hospital Cancer Registry team provides more than 90 years of professional cancer data management expertise.

During 2013, the registry collected data on 3,060 new cases. This case volume represents a negligible decrease over the previous year's volume of 3,072. In 2013, improvements in casefinding techniques, coupled with enhanced access to electronic medical records, allowed registry staff to accurately deem 360 cases as non-reportable. The following graph indicates the five-year growth in all accessioned cases.

5-Year Cancer Registry Activity



Registry data are submitted weekly to the New York State Central Cancer Registry and annually to the Commission on Cancer's National Cancer Data Base.

St. Peter's Hospital Cancer Committee is a multidisciplinary team comprised of physicians, oncology nurses, social workers, palliative caregivers, program administrators, quality improvement managers and certified tumor registrars. The committee provides direction and oversight of cancer program activities, and implements goals for efficiency and quality. The quality improvement manager oversees the day-to-day operations of the department and assigns responsibilities as set forth by the committee.

Cancer Registry Activities

Cancer registry data is at the forefront of the cancer program. It is used by the cancer committee to determine areas of need, and establish program goals and objectives. The Cancer Care Quality Improvement program relies on registry data to assess program-specific disease incidence and to document the efficacy of treatment outcomes. Community outreach efforts are also data-driven. The need for educational programs and screenings, participation in regional events, and requirements for new technology are supported by registry incidence data. All registry data abstraction is performed by tumor registrars certified through the National Cancer Registrar's Association.

In addition to maintaining an up-to-date cancer data base, the department also facilitates regular cancer conferences—multidisciplinary forums for prospective case presentation, AJCC staging discussion, and treatment planning. Current conferences focus on breast, gastrointestinal tract, genitourinary tract, gynecological, hepatobiliary and thoracic cancers, as well as a general forum. Surgeons, radiation and medical oncologists, diagnostic radiologists and pathologists, as well as other practitioners, attend cancer conferences. In 2013, 627 patient cases were discussed at 114 cancer conferences.

Quality of Cancer Data

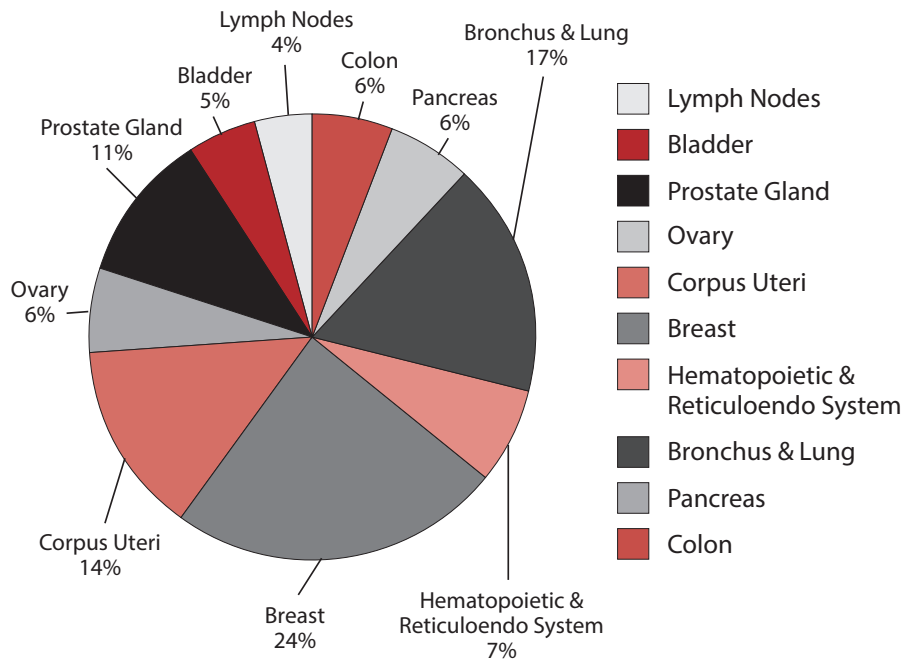
The quality of cancer data abstraction is monitored and reported regularly to the cancer committee. Registry quality monitoring activities include:

- Physician review of a minimum of 10 percent of annual analytic abstracts. These audits identify additional training and resource needs.
- Timeliness of case abstraction and completion is monitored and reported to both the cancer committee and the New York State Cancer Registry.
- Annual follow-up of at least 90 percent of all active cases to ensure that up-to-date health status and survival information is in the data base.
- Regular coding edit checks for format accuracy. Inter-field edits ensure internal data consistency within records.
- Registrar attendance at continuing education and training sessions.

SPH Cancer Incidence 2013

Of the new cancer cases seen in 2013, breast cancer continues to be the most commonly occurring cancer at SPH representing 24 percent, followed (in descending order) by bronchus & lung (17 percent), corpus uteri (14 percent), prostate (11 percent), hematopoietic & reticuloendo system (7 percent), colon (6 percent), pancreas (6 percent), ovary (6 percent), bladder (5 percent), and lymph nodes (4 percent). Relative proportions of cancer sites are shown below:

Top 10 Sites 2013



The role of the cancer registry is multifaceted. Members of the St. Peter's Hospital Cancer Registry team are proud to provide accurate and complete cancer data to support our nationally accredited cancer program.

Diagnosis, Radiology

Ovarian Cancer

Imaging plays a significant part in the workup and management of ovarian cancer. It is important in everything from diagnosis to pre-treatment planning and post-treatment follow-up. Ultrasound, CT, MRI, and PET/CT each have specific and complementary roles to play.

While there is no validated screening test, transvaginal ultrasound has become the modality of choice for initial detection. It is high resolution, inexpensive, widely available and free of ionizing radiation. Unfortunately, sensitivity and specificity vary considerably, likely because it is operator-dependent, susceptible to artifact, and can be limited by body habitus. Furthermore, a great deal of overlap exists between benign, malignant and borderline masses on ultrasound. If findings are inconclusive or an indeterminate mass is identified, patients are often referred for contrast-enhanced MRI for further characterization.

The typical appearance of ovarian cancers on ultrasound and MRI are similar — they are predominately cystic masses with internal solid components such as mural nodules, septations and/or papillary projections. MRI, however, provides additional information. Enhancement of internal components, the presence or absence of fat, and other signal characteristics can help distinguish benign lesions from potentially malignant lesions, and aid in risk stratification.

Once a patient is diagnosed with ovarian cancer, it is important to identify the extent of disease in order to guide proper management. While staging is surgical, CT can play a critical role in defining the extent of disease in order to determine the likelihood of successful surgical intervention, and to warn the surgeon of potential complications. Spread of disease is manifested by enlarged lymph nodes, ascites, extent and location of tumor implants within the abdominal and pelvic cavities, and direct extension into the pelvic organs or pelvic sidewall.

With improved success in treatment, patients with ovarian cancer are living longer; but, with increased survival comes an increased incidence of relapse. While the biochemical marker CA-125 is often used to indicate the possibility of recurrence, it does not provide information about location or extent of disease. PET/CT has been found to be comparable to laparoscopy for the restaging of disease following treatment, and to add both accuracy and confidence to the detection of lesions as compared to CT alone. It has become a useful adjunct to biochemical markers in assessing for residual or recurrent malignancy.



Christine Iseman, MD

RADIOLOGIST
MEDICAL IMAGING
ST. PETER'S HOSPITAL

In summary, imaging is a useful tool in the diagnosis and management of ovarian cancer. From initial detection, to characterization and

risk stratification, pre-treatment planning, and post-treatment evaluation, imaging can greatly assist every step along the way.

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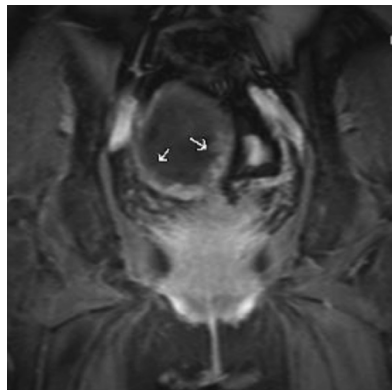


Figure 1
Coronal T1 post contrast

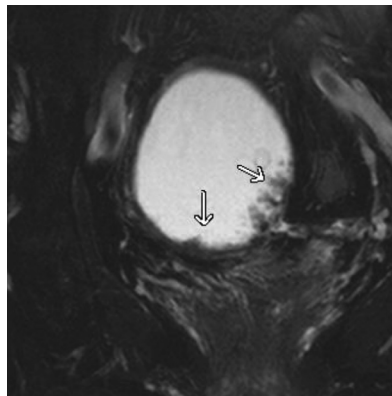


Figure 2
T2 weighted MRI showing a cystic lesion with enhancing papillary projections (arrows) in a papillary serous borderline tumor

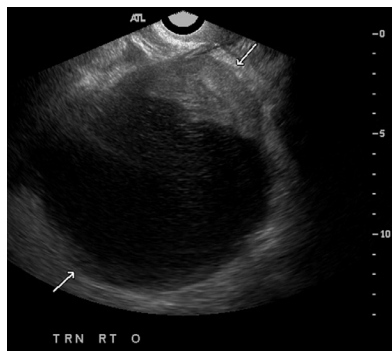


Figure 3
Mixed solid and cystic right ovarian mass highly suspicious for ovarian carcinoma.

Pericardiophrenic lymphadenopathy

Abdominopelvic ascites

Subdiaphragmatic tumor

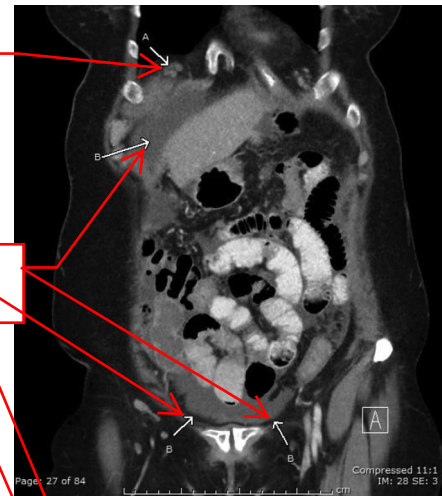


Figure 4
Coronal contrast enhanced CT showing (A) Pericardiophrenic lymphadenopathy, (B) Abdominopelvic ascites, and (C) Subdiaphragmatic tumor implants.

Surgical Intervention and Systemic Therapies in Ovarian Cancer

Theodore T. Chang, MD

ATTENDING SURGEON
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CAPITAL REGION UROLOGY



Ovarian cancer is the second most common gynecologic malignancy with approximately 22,000 new cases annually in the US. However, ovarian cancer is the most common cause of gynecologic cancer death, and the 12th leading cause of cancer death in the United States with roughly 14,750 women dying each year. The majority of ovarian cancer patients (80 percent) present as advanced stage 3/4 disease. With disease confined to the ovary, five-year survival rates are over 90 percent. However, with advanced stage disease, five-year survival rates are approximately 30 percent. The median age at diagnosis is 63, with most women diagnosed between the ages of 45 and 75. The incidence of ovarian cancer has been falling by 1.1 percent per year over the past 10 years, yet the overall five-year survival at five years has remained steady at 40 percent over the past 10 years.

The majority of ovarian malignancies are adenocarcinomas of epithelial cell origin. The remainder arise from other ovarian cell types (germ and sex cord-stromal tumors). Recent studies have shown that epithelial ovarian carcinoma, fallopian tube and primary peritoneal carcinomas have a shared clinical origin. Serous carcinomas, the most common histologic type, is felt to originate in the distal

fallopian, and secondarily involve the ovary and peritoneal cavity. Endometrioid and clear cell carcinomas appear to arise from endometriosis.

The symptoms associated with ovarian cancer are vague and nonspecific, and may be confused with gastrointestinal, urologic or other benign gynecologic conditions. Therefore, the majority of women present late with a large tumor burden. Women often report vague GI symptoms such as heartburn, dyspepsia and early satiety. As the disease progresses, they note increasing abdominal or pelvic pain, and a change in bowel and bladder habits. On presentation, many patients complain of abdominal swelling or bloating which is related to accumulation of fluid in the peritoneal cavity (ascites). Although the symptoms are nonspecific, any symptoms that are new in onset, coexist with other symptoms, occur almost daily and are more severe than expected warrant further investigation.

Unfortunately, there are no effective screening methods for ovarian cancer; neither ultrasound nor CA-125 blood testing have shown to be effective. Ten percent of ovarian carcinoma is hereditary with the BRCA gene being the most common; this gene is present in one to two percent of the general population, but is

present in 40 percent of Ashkenazi Jews and can be seen in other ethnic groups. There may be a role for ultrasound and CA-125 screening in this population with an elevated risk of ovarian carcinoma, however, it is still under investigation.

The initial treatment of epithelial ovarian carcinoma utilizes a combination of surgery and chemotherapy. Maximal tumor reductive surgery followed by platinum-based chemotherapy has been the standard treatment for advanced ovarian cancer.

Primary surgical treatment includes hysterectomy with bilateral salpingo-oophorectomy, pelvic and para-aortic lymph node dissection, and omentectomy. Cytoreductive surgery is performed when metastases are evident. Laparotomy is generally used, but laparoscopic or robot-assisted approaches are used by some surgeons for selected patients. Most recently, for those patients not felt to be surgical candidates either due to the extent of disease or other other illnesses, upfront chemotherapy followed by interval surgery has shown to be effective.

Staging of ovarian cancer is based on the surgical and pathologic findings in accordance with the International Federation of Gynecology and Obstetrics (FIGO) staging for ovarian carcinoma, 2014. Staging has implication fo treatment and prognosis. Stage I disease is confined to the ovaries and often times is cured with surgical removal of affected organs. Stage II disease means the cancer is in one or both ovaries or fallopian tubes and has spread to other organs (such as the uterus,

fallopian tubes, bladder, the sigmoid colon, or the rectum) within the pelvis. It has not spread to lymph nodes or distant sites. Stage III disease means the cancer is in one or both ovaries or fallopian tubes, and one or both of the following are present: has spread beyond the pelvis to the lining of the abdomen or has spread to lymph nodes in the back of the abdomen (retroperitoneal lymph nodes). Stage IV is the most advanced stage of ovarian cancer. In this stage, the cancer has spread most commonly to the pleural space or liver.

Experts have recommend that patients see a gynecologic oncologist for surgery and for management of chemotherapy. Gynecologic oncologists are specialists who have training and experience in treating, staging and debulking ovarian cancer. Improved outcomes are associated with surgery performed by a gynecologic oncologist as compared to general surgeons or gynecologists.

The past 30 years has had a significant trend toward maximal surgical cytoreduction with no gross residual tumor left at completion of surgery. The volume of residual disease remaining after cytoreductive surgery correlates inversely with survival.

Unfortunately, preoperative CA-125 levels, computed tomography (CT) scans, and physical examinations are often not reliable to predict the intraoperative findings. As a result, as many as 30 percent of patients taken to the operating room will not be rendered optimal.

The terminology regarding extent of cytoreduction is:

- Complete cytoreduction – cytoreduction to no grossly residual disease.
- Optimal cytoreduction – residual disease that is ≤ 1 cm in maximum tumor diameter.
- Suboptimal cytoreduction – residual disease that is >1 cm in maximum tumor diameter.

The impact of cytoreduction on survival was illustrated in a systematic review of 11 retrospective studies that found suboptimal (>1 cm) versus optimal (<1 cm) cytoreduction was associated with a significant improvement in overall survival. There was a greater improvement in survival with complete cytoreduction compared with optimal cytoreduction.

Following tumor debulking surgery, treatment with cytotoxic chemotherapy is to be initiated usually within two to four weeks. Data suggests poorer outcomes in patients delaying chemotherapy longer than one month from the time of surgical debulking. This is confounded, however, by possible medical co-morbidities, surgical complications, and delayed wound healing.

For women requiring adjuvant chemotherapy for epithelial ovarian carcinoma, the standard intravenous (IV) regimen utilizes platinum and taxane agents. The mainstay of therapy is carboplatin and paclitaxel, although cisplatin and/or docetaxol may be substituted in certain settings. Treatment is continued for a minimum of six cycles. The combination of platinum and taxane is now considered the standard of care for management of epithelial ovarian carcinoma, with response

rates of 65-70 percent, progression-free survival of 16 to 21 months and overall survival ranging from 32 to 65 months.

The two treatment modalities used in the postoperative treatment of newly diagnosed EOC are IV chemotherapy alone, or a combination of IV and intraperitoneal (IP) chemotherapy (IV/IP therapy). Of note, the administration of IV/IP therapy should be restricted to women with no residual or <1 centimeter of residual disease (defined as an optimal cytoreduction). IP treatment should not be administered to women with residual large volume disease because IP administration of chemotherapy results in limited penetration into larger tumors and reduced effectiveness of treatment.

IP chemotherapy has demonstrated improved overall survival and progression-free survival. The Gynecologic Oncology Group, an NCI-sponsored cooperative group, has done three randomized trials of IP chemotherapy. In the latest study, GOG 172 (phase III trial), in spite of the majority of patients stopping the IP treatment after only two cycles, there was a prolonged survival in the intraperitoneal therapy arm compared to the arm of intravenous therapy (65.6 and 49.7 months respectively; $P = 0.03$). Also, progression-free survival was better in the IP-therapy arm than in the IV-therapy group (23.8 versus 18.3 months, $P = 0.05$). However, it has not been universally adopted as standard of care due to increased side effects including: catheter-related problems, gastrointestinal and hematologic toxicities and diminished quality of life surrounding treatment.

Evaluation of women after chemotherapy varies, depending upon physician preference. At the completion of treatment, a thorough history and physical (including pelvic) examination is performed, along with a screening for tumor marker CA-125. If the results of the post-treatment evaluation are normal, then a patient is considered to have a clinical complete response. The patient is then followed with physical examination and CA-125 screening every three months to assess for recurrence, and for evaluation of toxicities associated with chemotherapy. However, the role of post-treatment CA-125 is controversial and does not lead to increased overall survival. It may also cause increased intervention, and anxiety surrounding the surveillance visit.

Unfortunately, the vast majority of patients with ovarian cancer will have recurring disease and will ultimately die of their cancer. If surveillance indicates recurrence either by physical findings or a rising CA-125, second-line treatment would be tailored to the individual patient. If the patient is potentially platinum sensitive with recurrence greater than six months from her prior treatment, repeat platinum-based treatment can be utilized. If not, other treatments can be instituted, tailored to minimizing toxicity and maximizing quality of life. Occasionally, secondary cytoreductive surgery is utilized. Clinical trials are available to help delineate optimal care. Supportive care is imperative throughout the course of therapy for patients with ovarian cancer; quality of life should always be stressed, and end-of-life discussions should be addressed with the patient and her family to ease transitions.

Diagnosis, Pathology

Role of the Pathologist in Early Detection of Ovarian Carcinoma



Melanie Hawver, MD

PATHOLOGIST
MAPLEWOOD PATHOLOGY

Ovarian Cancer Risk Assessment

The lifetime risk of developing ovarian cancer in the United States is about two percent. Among women with mutations in the tumor suppressor genes BRCA1 and BRCA2, the estimated risk is 20 percent to 50 percent¹. Germline mutations in BRCA1 and BRCA2 account for approximately 90 percent of cases of hereditary ovarian epithelial cancers. Most ovarian malignancies diagnosed in women with BRCA mutations are high grade serous carcinomas of advanced stage². Identifying women at risk for ovarian cancer, and those who should undergo genetic risk assessment, can be achieved with attention to the number of family members affected, age of onset, ethnicity (especially Ashkenazi Jewish descent), and breast cancer in young women or males of any age.

Ovarian Cancer Screening

Although non-invasive methods of ovarian cancer detection such as pelvic examination, ultrasound, and biomarker screening are often utilized, each has limitations of sensitivity and specificity. For example, a lack of sensitivity is seen with pelvic exam: A 15-year study of pelvic exam alone uncovered only one ovarian cancer in more than 18,000 exams of 1,319 women³. A lack of specificity is demonstrated by the use of the biomarker CA-125, since CA-125 elevations are associated with a range of other intra-abdominal disorders. Ultimately, the nature of ovarian cancer itself makes screening difficult, as more than two-thirds are high-grade serous carcinomas that have spread to other pelvic organs by the time of diagnosis. Despite these limitations, there are opportunities for the pathologist to participate in the early detection of ovarian cancer. One is by routine

analysis of the distal fallopian tube in women undergoing procedures for benign disorders. Intraepithelial (noninvasive) carcinomas at this site are occasionally discovered, and will initiate a thorough workup of the patient. The other role for the pathologist is systematic analysis of fallopian tubes from women who are at risk for ovarian cancer, such as those with known inherited BRCA1 or BRCA2 mutations.

Prophylactic Surgery and the Pathologist's Role in Early Detection

Bilateral salpingo-oophorectomy in women with BRCA mutations reduces the risk of developing pelvic serous carcinomas by greater than 90 percent⁴. Thus, for women with known BRCA mutations, or those with a family history consistent with one of the genetic syndromes associated with ovarian cancer, this surgery offers women a significant risk reduction. However, prophylactic surgery does not protect women against the subsequent development of serous carcinoma of the peritoneum.

When the Pathology Department receives a prophylactic salpingo-oophorectomy, the entire specimen is submitted and examined histologically. The distal end of the fallopian tubes (the fimbriae) is sectioned longitudinally to allow for the most extensive examination, because the majority of early serous tumors occur in this area. The remainder of the tube is cross-sectioned (see Figure 1).

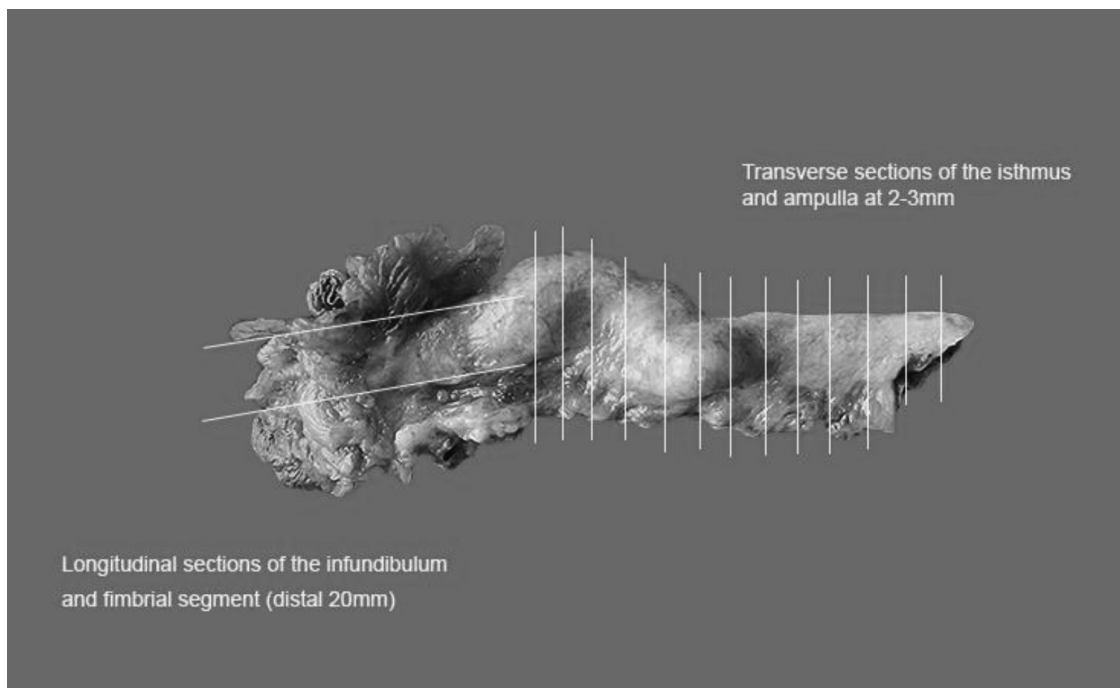


Figure 1
Image from The Royal College of Pathologists, Australia.

Five to 10 percent of surgical specimens from these prophylactic surgeries will demonstrate an early tubal intraepithelial carcinoma (TIC) upon histologic examination. The neoplastic epithelium will appear thickened and darkened, due to cellular stratification and high nuclear to cytoplasmic ratio. Rounded enlarged nuclei with prominent nucleoli are common. Exfoliation of cells into the lumen is also characteristic (see Figure 2).

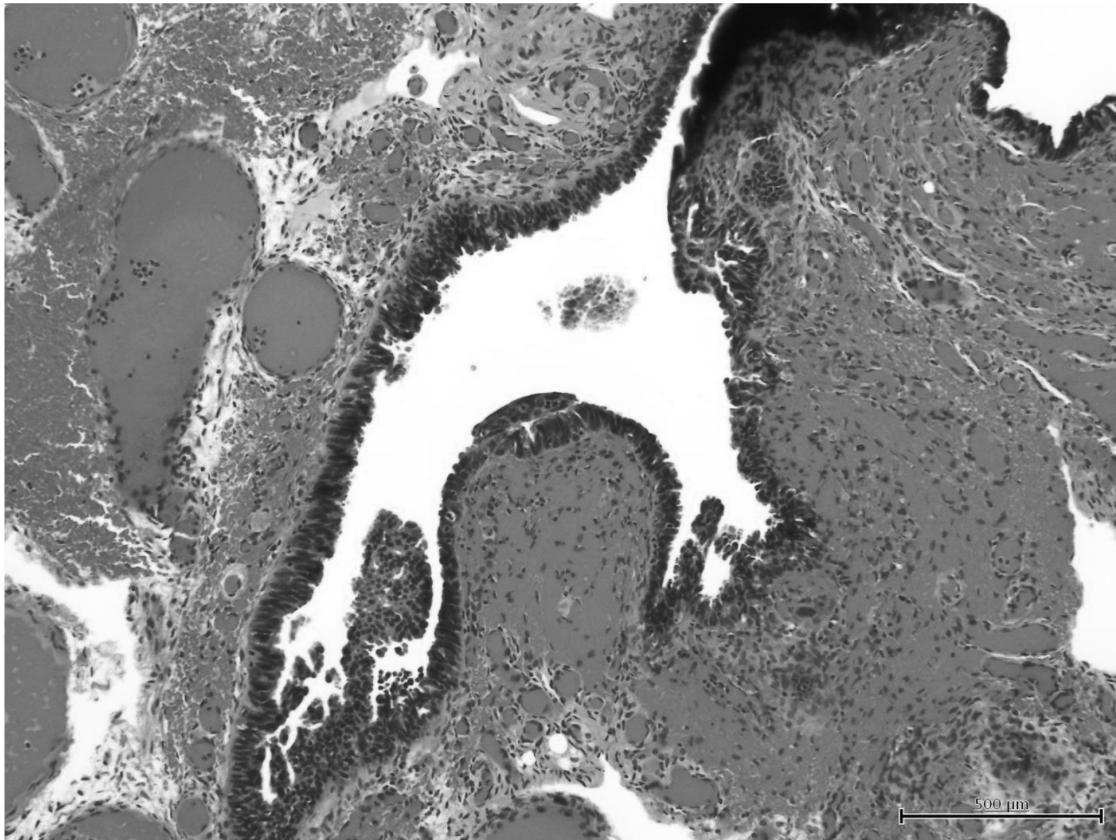


Figure 2
Serous tubal intraepithelial carcinoma (STIC) from a recent case at St. Peter's.

Finally, immunohistochemical stains such as p53 and Ki-67 can be performed to support a diagnosis of STIC (see Figure 3).

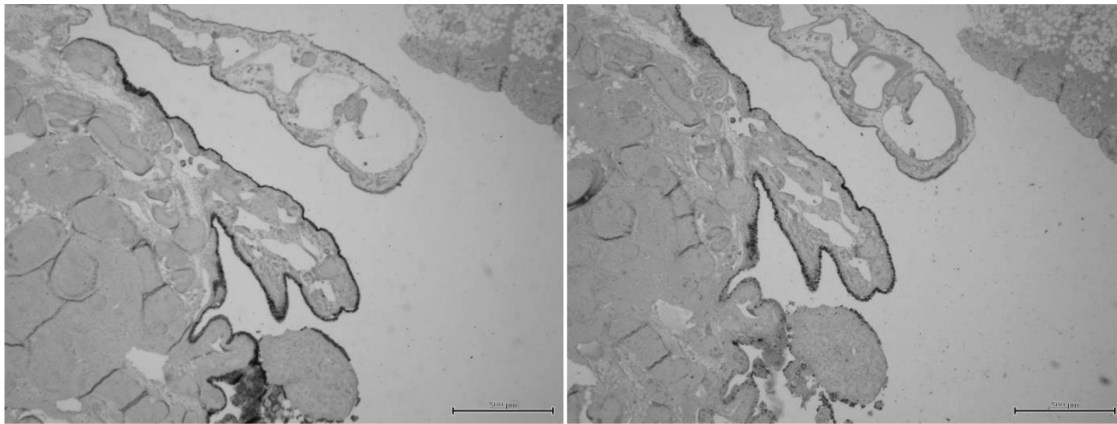


Figure 3

Strong p53 (left) and Ki-67 (right) staining in the neoplastic cells from the same case as Figure 2. Note lack of staining in non-neoplastic cells in upper right.

Although the rate of progression of TICs to invasive serous carcinoma is unknown, there is evidence that removal of early carcinomas is effective, and these women have an excellent prognosis. A team approach consisting of genetic counselors, surgeons, oncologists, and pathologists is essential in helping genetically predisposed women prevent ovarian cancer.

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Genetics

Hereditary Susceptibility to Ovarian Cancer



Erin E. Houghton, MS, CGC

ASSOCIATE DIRECTOR, FERRE INSTITUTE

While the majority of ovarian cancer is sporadic in nature, we know that approximately 10 percent of cases are due to a hereditary susceptibility. Clues to hereditary ovarian cancer include young age at diagnosis (under age 50), bilateral disease, family history of ovarian cancer, personal or family history of other related cancers (such as breast, colon or endometrial), and certain ethnicities (for example, the Ashkenazi Jewish population is at increased risk for hereditary breast/ovarian cancer). We know of several genes that, when mutated, cause an increased risk for ovarian cancer, among other cancers.

The vast majority of hereditary ovarian cancer is caused by hereditary breast/ovarian cancer syndrome (HBOC) due to mutations in the BRCA1 or BRCA2 genes. Approximately 75 percent of hereditary ovarian cancer is due to BRCA1 mutations, and less than 15 percent is due to BRCA2 mutations. BRCA1 and BRCA2 genes normally function as tumor suppressors in the body. Individuals with mutations are at an increased lifetime risk of breast and ovarian cancer, as well as other cancers including male breast, prostate, and pancreatic cancers, and melanoma. The lifetime risk for ovarian cancer is 34 to 44 percent for BRCA1 mutation carriers and 12 to 20 percent for BRCA2 mutation carriers.

Another seven percent of cases of hereditary ovarian cancer are caused by Lynch syndrome, formerly known as HNPCC (hereditary non-polyposis colorectal cancer). Most individuals with Lynch syndrome have a mutation in one of five known genes: MLH1, MSH2, MSH6, PMS2 and EPCAM. Women with Lynch syndrome have up to a 12 percent lifetime risk of developing ovarian cancer.

There are other, rarer cancer syndromes that are also associated with an increased risk for ovarian cancer. Li-Fraumeni syndrome (LFS), caused by mutations in the p53 gene, dramatically increases the risk for a variety of cancers including breast cancer, bone and soft tissue sarcomas, adrenocortical carcinoma and brain tumors. Women with p53 mutations also have an increased lifetime risk for ovarian cancer; the precise risk estimate is not yet well defined.

Peutz-Jeghers syndrome (PJS) is another rare cancer syndrome caused by mutations in the STK11 gene. This syndrome causes an 18 to 21 percent lifetime risk for ovarian cancers; a specific type of ovarian tumor called a sex cord tumor is most common.

Many genetic testing laboratories are now offering panel testing for patients who have a suspected hereditary risk for cancer. These panels often include other cancer risk genes for which there is less known clinical information, and for which there are no clinical guidelines at present. The genes BRIP1, RAD51C, and RAD51D are often included in these panels and are known to increase a woman's lifetime risk for ovarian cancer. As more individuals are tested, more information will be learned about the cancer risks associated with these genes which, in turn, will allow for the eventual development of appropriate clinical guidelines.

Women found to be at an increased risk for ovarian cancer due to a hereditary susceptibility may elect to increase surveillance, which would include transvaginal ultrasound, pelvic exam and the CA-125 blood test. However, the efficacy of such screening measures is not yet proven so many women elect (or are encouraged to consider) bilateral salpingo-oophorectomy after child-bearing is complete to dramatically reduce their lifetime risk for ovarian cancer.

It is now recommended that all women with ovarian cancer, regardless of age at diagnosis, be offered genetic testing for BRCA1 or BRCA2 mutations unless their personal or family history is more suggestive of another hereditary cancer syndrome. Women who have tested negative for BRCA1 and BRCA2 gene mutations may wish to meet with a genetic counselor to review their personal and family histories to determine if additional genetic testing is appropriate. Genetic counselors are important members of the health care team to help patients and their medical providers best assess the appropriate genetic testing strategy, in addition to reviewing current clinical recommendations and discussing potential risks to family members.

QI Study: 2014 Evaluation of First Course of Treatment for Epithelial Ovarian Cancer



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The National Comprehensive Cancer Network (NCCN) guidelines recommend a combination of surgery and chemotherapy as part of the first course of therapy for most patients with epithelial ovarian cancer (the most common form of cancer involving the ovaries). Radiotherapy is not a standard part of the first course of treatment for patients with epithelial ovarian cancer. The most common histologic types of epithelial ovarian cancer include high-grade serous carcinoma, endometrioid carcinoma, clear cell carcinoma, mucinous carcinoma, low-grade serous carcinoma and carcinosarcoma. Treatment recommendations depend on the clinical stage (IA-C through IV) and histologic grade at presentation.

NCCN recommends observation alone after surgery for stage IA or IB tumors with grade 1 or 2 histology, although adjuvant treatment with chemotherapy is also considered a reasonable option for grade 2 tumors. For all other stages, regardless of grade, optimal debulking followed by adjuvant chemotherapy is recommended or, when optimal debulking

is not feasible, chemotherapy followed by surgery (when appropriate).

All patients with ovarian cancer diagnosed at St. Peter's Hospital in 2012 were reviewed. There were 82 patients with data abstracted by the Tumor Registry. Three patients had non-epithelial ovarian cancer and were excluded from review, leaving 79 patients. Of these, 16 patients were stage I, 11 were stage II, 42 were stage III and 10 were stage IV.

Of the 16 stage I patients, only two had grade 1 tumors and both were treated with surgery alone without chemotherapy, as per NCCN guidelines. Four patients had grade 2 tumors, one of whom was treated with chemotherapy in addition to surgery. Two other grade 2 patients had surgery alone. Whether the fourth patient received chemotherapy was unknown. All other stage I patients received chemotherapy in addition to surgery, except for one patient with unknown grade who received no chemotherapy, and one patient with a grade 3 tumor for whom chemotherapy treatment was unknown.

Of the 11 patients with stage II disease, two were listed as having no chemotherapy and one had unknown chemotherapy status. These patients were investigated more fully. One patient lived at a distance and was referred to an oncologist at an outside institution who did administer chemotherapy. Another patient, listed as grade 2 serous carcinoma, was found to have a mixed serous and mucinous carcinoma of borderline malignant potential; chemotherapy would not be recommended for this tumor. (This patient will be excluded from further analyses.) The final patient, listed as unknown status, was noted to be of profound intellectual disability and required a feeding tube; this patient would not be medically appropriate for chemotherapy.

There were 42 patients with stage III disease. All but two patients had debulking surgery and chemotherapy. Both of those patients had abdominal carcinomatosis of unknown primary site, but were treated for presumed ovarian primaries. One of these patients was treated with chemotherapy alone, and the other patient declined all treatment after initial biopsy. These were coded correctly, and were treated according to usual standards, but fall outside the scope of the treatment guidelines.

Of the 10 stage IV patients, four received chemotherapy before surgery (neoadjuvant chemotherapy), one received chemotherapy alone, four either had surgery followed by chemotherapy, or a plan for chemotherapy, and one had unknown chemotherapy status.

First course of treatment by stage is summarized in Table 1.

First Course of Treatment by Stage

State	Surgery	Chemo	Per NCCN	Comments
I A/B gr 1	2/2	0/2	Yes	
I A/B gr 2	4/4	1/4*	Yes	*1 pt unknown
I A/B gr 3/4	5/5	4/5*	Yes (1 unknown)*	*1 pt unknown
I C	5/5	5/5	Yes	
II	10/10	9/10	Yes*	*1 exception for cause
III	40/42	41/42	Yes	2 exceptions for cause
IV	9/10	9/10*	Yes*	*1 pt unknown

(Table 1)

In summary, of 79 patients with epithelial ovarian cancer, 78 were found to be appropriate for evaluation of first course of treatment according to national guidelines; one patient was excluded because of a histology showing a tumor of borderline malignant potential. Of these, all patients received surgery and/or chemotherapy according to NCCN guidelines, with the exception of two patients with unknown chemotherapy status (another patient with unknown chemotherapy status had a stage IB, grade 2 tumor, for which NCCN guidelines allow surgery with or without chemotherapy). Three exceptions from standard guideline therapy were found to be for medically acceptable reasons.

Community Outreach and Education

Promoting Prevention and Awareness

The National Cancer Institute estimates that approximately 21,980 new cases of ovarian cancer will be diagnosed in 2014, and 14,270 women will die from the disease. Ovarian cancer, when detected early, has a 90 percent cure rate. However, most ovarian cancers are found at a later stage due to the fact that there are no symptoms until the disease has progressed to an advanced stage. Often times, symptoms of ovarian cancer can also be associated with normal abdominal or gastric upset, therefore many women ignore them. Studies have found the risk factors for developing ovarian cancer include:

- **Family history of ovarian cancer:** Women with a family history of ovarian cancer are at increased risk.
- **Genetic factors:** Women with an inherited predisposition to ovarian cancer, such as a BRCA1 or BRCA2 genetic mutation and/or a family history of Lynch syndrome, have a very high risk of developing ovarian cancer.
- **Nulliparity:** Women who have not produced any offspring are usually at higher risk.
- **Postmenopausal hormone therapy:** Women who have used hormonal therapy to combat symptoms of menopause are at higher risk.
- **Fertility drugs:** Women who have used fertility drugs to become pregnant are at higher risk.

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COMMUNITY OUTREACH NURSE
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- **Perineal talc exposure:** Perineal application of talc is associated with a small increased risk of ovarian cancer.
- **Obesity:** Being obese increases the risk of ovarian cancer.

Because the main risk factors for ovarian cancer are family history and genetics, the community outreach nurse (CON) at St. Peter's Cancer Care Center works diligently to educate the community on the importance of maintaining family and personal health histories, and encourages women to have regular gynecological checkups. The CON also works to raise awareness of symptoms of ovarian cancer, and to increase strategies to incorporate healthy lifestyles that decrease obesity.

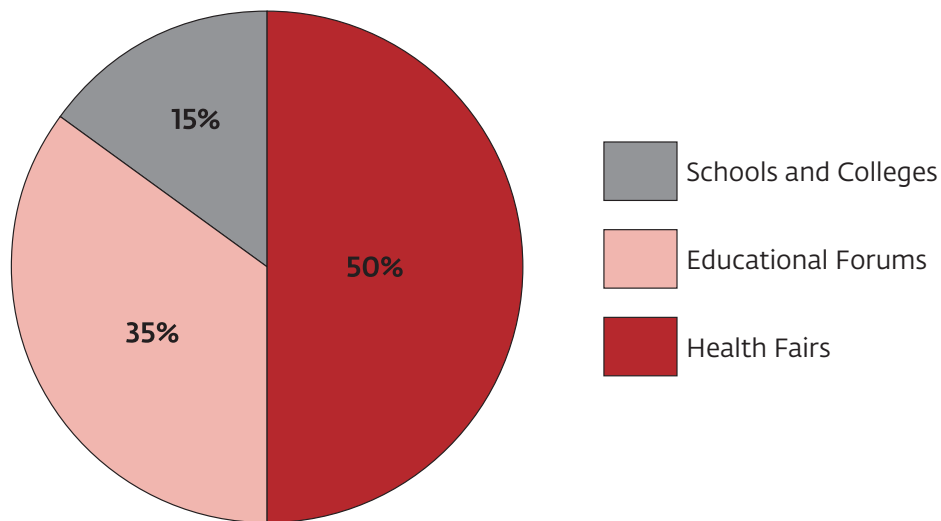
The CON educates the general public about personal and genetic risk factors for ovarian cancer, as well as hidden symptoms. He/she also promotes healthy lifestyles, and teaches the benefits of regular surveillance. Outreach is done at various educational forums, health fairs, schools and colleges, and events at St. Peter's Cancer Care Center and other facilities and venues within the Capital District.

The CON also works collaboratively with other community organizations such as the American Cancer Society, Caring Together and Trujoy. These organizations help by providing resources and support to local facilities, patients and families, as well as outreach and education within the community.

Useful resources that support ovarian cancer patients and their families are listed below:

- American Cancer Society Hope Club, www.cancer.org, 1-800-227-2345, 518-220-6960
- Caring Together, www.caringtogetherny.org, (518) 783-7600, P.O. Box 12383, Albany, NY 12212
- Ovarian Cancer National Alliance, www.ovariancancer.org, 1101 14th Street NW, Suite 850, Washington, DC 20005, 1-866-399-6262
- TruJoy, Inc., www.trujoy.org, trujoyinc@gmail.com, 37 Meadowlark Drive, Cohoes, NY 12047
- NYS Department of Health, www.health.ny.gov, Strategic Plan for Overweight and Obesity Prevention

Education and Prevention



Statistical Analysis for St. Peter's Hospital

Ovarian Cancer



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QUALITY IMPROVEMENT MANAGER
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Report Parameters

This report presents an overview of the St. Peter's Hospital (SPH) experience in diagnosing and treating ovarian cancer, and examines how this experience compares with other hospitals, both state and nationwide. The primary data source for this report is the data base of cancer cases encountered and documented at SPH, which is maintained by St. Peter's Cancer Data Management Department in its Cancer Registry. Cancer registrars in this department collect data on all identified cases of cancer that are diagnosed and/or treated at the institution. Data is compiled according to the Facility Oncology Registry Data Standards (FORDS) established by the program's accrediting body, the American College of Surgeons Commission on Cancer (ACoS-CoC).

FORDS establishes criteria for designating cases as either analytic or non-analytic. Analytic cases have a significant proportion of their diagnosis and/or treatment performed at the reporting institution. Only analytic cases were counted in compiling case volumes for this report. Depending on the context of comparison, data may encompass various time periods. Date ranges throughout this report are clearly identified.

Data submitted to the Commission on Cancer (CoC) by accredited programs across the country are aggregated into National Cancer Data Base (NCDB) Benchmark Reports. These site-specific reports encompass data from years 2000 through 2012. For this report, aggregates of data between 2002 and 2012 were used to obtain a meaningful local sample size.

For the 11-year period evaluated, an average of 1,530 hospitals across the US reported a total of 174,356 cases of ovarian cancer. During that same period, an average of 73 hospitals within New York state reported 10,566 cases, while St. Peter's reported 705 cases. Proportional (relative percent) rather than numerical data have been used in much of this report to allow comparison between these disparately sized data cohorts.

Ovarian Cancer at St. Peter's

St. Peter's Cancer Registry began tracking cancer cases in 1985. Cases between 2003 (current reference year) and 2013 (the last complete year of data collected) are currently being followed. St. Peter's Cancer Care Center diagnosed and/or treated 767 ovarian cases between 2003 and 2013. The volume of analytic cases is broken down by stage, as shown in Table 1.

There are some histological grades of cancer that are not necessary to stage by the American Joint Committee on Cancer (AJCC) guidelines. These grades are denoted by N/A throughout the report. The largest proportion of cases present as Stage III disease, followed by Stage I disease. Of the 78 unknown cases, 10 of those cases are categorized as Class of Case 00, which indicates the patient had an initial diagnosis at SPH, but either did not receive treatment or received treatment at another facility. This reduces the actual number of unknown cases to 68 or 8.9 percent.

Table 1

Stage at Diagnosis	I	II	III	IV	N/A*	Unknown
Volume of Analytic Cases	152	69	340	119	9	78
Percent by Stage	19.8%	9.0%	44.3%	15.5%	1.2%	10.2%

*N/A represents cancers by histology that are not necessary to stage by AJCC guidelines.

SPH Ovarian Cancer Incidence

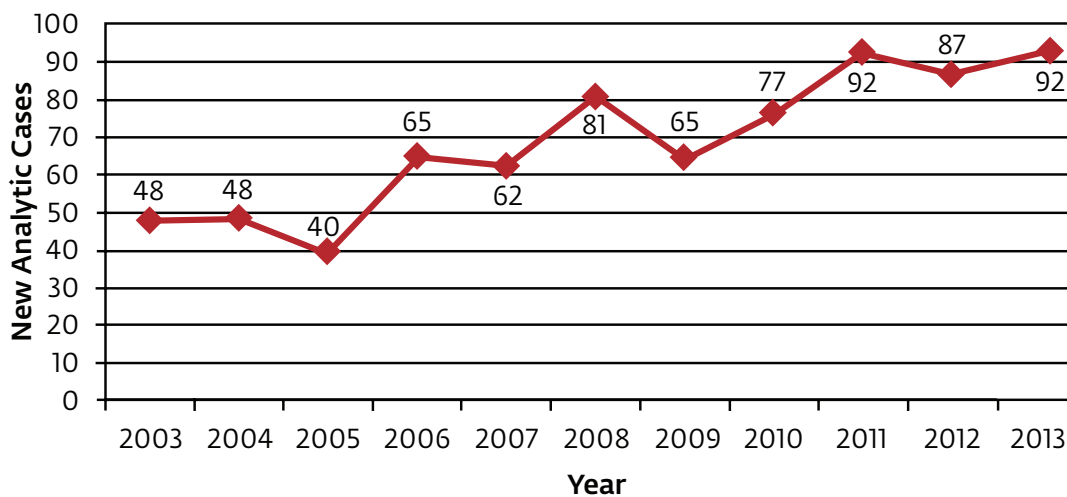


Figure 1

During the most recent 11-year period, including the most recent complete year of data (2013), new analytic cases of ovarian cancer have grown by an average of nine percent. There was a slight decrease between 2008 and 2009, but otherwise, growth was generally steady. The incidence data for the 11-year historical period is depicted in Figure 1.

Incidence by Year of Diagnosis

According to the NCDB, between 2002 and 2012, newly diagnosed cases of ovarian cancer had an overall increasing trend for all three cohorts. There was a slight decrease for SPH in 2005, followed by a steady rise in cases. There were marked increases in 2006, 2008 and 2011 (Table 2).

Table 2

Diagnosis Year	Ovarian Cancer by Diagnosis Year		
	SPH %	NY %	US %
2002	6.4	8.7	8.6
2003	6.7	8.6	8.6
2004	6.8	8.8	8.4
2005	5.8	8.3	8.9
2006	9.5	8.3	8.9
2007	9.4	9.3	9.3
2008	10.8	9.6	9.5
2009	9.4	9.5	9.5
2010	9.8	9.5	9.4
2011	13.5	9.7	9.5
2012	12.1	9.6	9.3

Demographic Factors

Incidence by Age at Diagnosis

The slight majority of SPH patients are diagnosed with ovarian cancer between the ages of 50-59, with a slightly higher incidence of diagnosis in the 60-69 group for NYS and the US. The smallest percentages are in the younger than 20, 90+ and 20-29 age ranges for all three cohorts (Table 3).

Table 3

Age at Diagnosis	Ovarian Cancer by Age		
	SPH %	NY %	US %
<20	0.7	1.4	1.1
20-29	1.6	1.8	1.8
30-39	4.0	4.1	4.1
40-49	12.5	14.5	13.2
50-59	26.5	23.6	23.1
60-69	25.8	23.8	23.7
70-79	18.9	17.9	20.0
80-89	9.1	11.0	11.5
90+	1.0	1.8	1.6

Overall Survival for Ovarian Cancer

Figure 2 shows the relative survival for cases of ovarian cancer diagnosed at SPH between 2005 and 2009. The overall five-year survival rate for ovarian cancer at SPH is 41.7 percent. Survival data at SPH is dependent on follow-up data obtained from letters mailed to patients and physicians, and various other sources of vital status indicators.

Overall Relative Survival

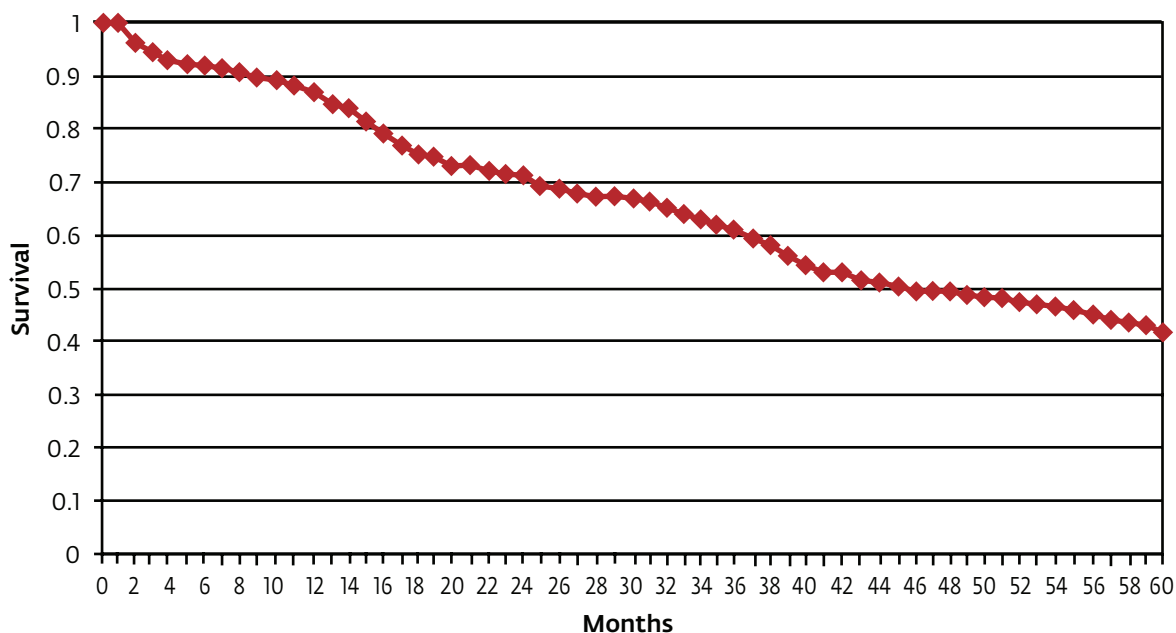


Figure 2

Incidence by Race

As a proportion of overall cases, the Caucasian population is most heavily affected by ovarian cancer. Caucasians in the St. Peter's population represent a higher proportion of total patient numbers than is reported in both the state and the nation. The African American population presenting with ovarian cancer to SPH is 2.4 percent, however, at the state and national levels, the burden of ovarian cancer on the African American population is 10.7 percent and 8.1 percent, respectively. The Hispanic population presents to St. Peter's with 0.7 percent, however, the incidence of

ovarian cancer at the state and national levels is 7.5 and 5.7 percent, respectively. Other and Unknown populations are depicted in Table 4.

Table 4

Race	Ovarian Cancer by Race		
	SPH %	NY %	US %
Caucasian	90.1	74.6	81.4
African American	2.4	10.7	8.1
Hispanic	0.7	7.5	5.7
Other/Unknown	6.8	7.2	4.8

Insurance Coverage

Incidence by Insurance Coverage

The largest proportion of patients have private insurance/managed care in all three cohorts. Medicare is the second largest group at 38.3 percent, 38.8 percent, and 40.6 percent for SPH, NYS, and the US, respectively.

The largest percentage of patients who are uninsured is in the US cohort, which is 4.4 percent. Medicaid has the highest percentage in NYS at 8.1 percent, with 5.7 percent in the US, and 4.1 percent at SPH (Table 6).

Table 6

Insurance	Ovarian Cancer by Insurance Type		
	SPH %	NY %	US %
Not Insured	1.8	2.2	4.4
Private Insurance/ Managed Care	55.0	49.1	45.7
Medicaid	4.1	8.1	5.7
Medicare	38.3	38.8	40.6
Other Gov't Insurance	0.1	0.3	1.1
Unknown	0.6	1.6	2.5

Disease-Related Factors

Morphology

Morphology refers to the histological classification of the cancer tissue, and a description of the course of development that a tumor is likely to take: benign or malignant behavior. The designation is based on a microscopic diagnosis of morphology by a pathologist. Not otherwise specified (NOS), is a categorization which is used in accordance with the College of American Pathologists (CAP) current protocols.

Table 7

Histology	Ovarian Cancer by Histology		
	SPH %	NY %	US %
Carcinoma, NOS	2.3	5.9	5.3
Adenocarcinoma, NOS	7.7	11.4	12.1
Clear Cell Adenocarcinoma, NOS	5.8	5.3	4.8
Endometrioid Carcinoma	12.8	8.9	9.7
Serous Cystadenocarcinoma, NOS	30.6	20.2	18.2
Papillary Serous Cystadenocarcinoma	14.0	18.4	19.1
Serous Surface Papillary Carcinoma	3.1	6.5	6.2
Mucinous Adenocarcinoma	3.7	3.3	3.6
Other Specified Types	20.1	20.1	21.2

According to the NCDB, the two predominant histologies of ovarian cancer are serous cystadenocarcinoma for SPH and NYS, and papillary serous cystadenocarcinoma for the US. Carcinoma, NOS is the least common form for SPH, while mucinous adenocarcinoma is the least common for NYS and the US (Table 7).

Stage at Diagnosis

Cancer stage at diagnosis is a strong predictor of disease outcomes. Proper clinical staging of cancer allows the physicians to determine appropriate treatment options. The Cancer Registry monitors the use of stage in treatment planning, and records physician-assigned clinical and pathologic staging in the registry data base. Certified tumor registrars are able to assign clinical stage based on the available information in the medical record if a clinical stage is not assigned by a physician. In cases where clinical information related to stage is absent or unavailable, a stage designation of “unknown” is assigned.

Incidence by Stage

The data below (Table 8) demonstrates relative frequency of ovarian cancers by stage at time of diagnosis for reporting years 2002-2012 from NCDB data.

Table 8

Stage at Diagnosis	Ovarian Cancer by Stage		
	SPH %	NY %	US %
I	17.3	21.4	21.1
II	7.1	8.0	7.9
III	40.4	33.6	37.5
IV	10.5	26.1	22.6
NA	0.6	0.6	0.5
UNK	24.1	10.4	10.5

A review of stage data reveals that a larger percent of unknown stage is reported at SPH than in the comparable state and national cohorts. The largest percentage of patients present with Stage III disease across all three geographic groups. Stage I is the second largest group for SPH; however Stage IV is the second largest group for NYS and the US. The smallest groups of patients present with Stage II disease across all three cohorts.

Incidence by First Course of Surgery

The most frequently performed first course treatment for ovarian cancer is surgery plus chemotherapy in all three cohorts. This is followed by surgery only in all three cohorts. "Chemo only" is the least frequent course of treatment at SPH, whereas "Other Specified Therapies" is the least frequent course of treatment for NYS and US.

Table 9

First Course Treatment	Ovarian Cancers by First Course Surgery		
	SPH %	NY %	US %
Surgery Only	32.5	21.0	23.0
Surgery and Chemo	55.7	54.0	55.0
Chemo Only	3.3	9.4	9.1
Other Specified Therapies	5.1	5.5	3.6
No 1st Course Treatment	3.4	10.4	9.2

Summary

To summarize the observations and conclusions of this data analysis:

- St. Peter's reported 705 cases of ovarian cancer between 2002 and 2012.
- Since 2003, new analytic cases of ovarian cancer have shown a general increasing trend of 9.0 percent.
- More than 45 percent of patients diagnosed with ovarian cancer are between the ages of 50 and 69, in all three cohorts. Few patients are diagnosed at a very young or very elderly age.
- The overall five-year survival rate for ovarian cancer was 41.7 percent for patients diagnosed at St. Peter's Hospital between 2005 and 2009.
- The largest percentage of patients across all three cohorts has private insurance/ managed care, followed by medicare. The uninsured population is less than five percent across all three cohorts.
- The most common histologies found in ovarian cancers in all three cohorts are serous cystadenocarcinoma and papillary serous cystadenocarcinoma.
- A review of stage data reveals that a much larger percent of unknown stage is reported at SPH than in the comparable state or national cohorts. The largest percentage of patients present with Stage III disease across all three geographic groups.
- The most frequently performed first course treatment for ovarian cancer is surgery plus chemotherapy in all three cohorts.





St Peter's Hospital

Cancer Care Center

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