



HAPPY LABOR DAY

WHAT'S NEW:

The following newsletters and reports are currently available from the FCDS website:

- **2004 FCDS DATA ACQUISITION MANUAL (Under the downloads)**
FCDS will not be providing hard copies to any facility or contractor.
- **FCDS REGISTER VOL. 24**
- **6/24/2004: FCDS CHANGES FOR HOSPITALS SUBMITTING FULL CANCER ABSTRACTS FOR NAACCR V10.1**
(Does not pertain to Pathology Data or Radiation Therapy ID Data)

On the Web:

- **CS SCHEMA "ERRATA" FOR THE PRINTED MANUAL, PART 2**
<http://www.cancerstaging.org/cstage/csreplacement.pdf>
- **COLLABORATIVE STAGING MANUAL AND CODING INSTRUCTIONS**
<http://seer.cancer.gov/tools/collabstaging/>

FLORIDA CANCER DATA SYSTEM

SEPTEMBER 2004 MONTHLY MEMO



Ovarian Cancer

National Cancer Institute website:

<http://cancer.gov/cancertopics/pdq/treatment/ovarianepithelial/healthprofessional/allpages>

Cellular Classification

The following is a list of ovarian epithelial cancer histologic classifications.

- Serous cystomas:
 - Serous benign cystadenomas
 - Serous cystadenomas with proliferating activity of the epithelial cells and nuclear abnormalities, but with no infiltrative destructive growth (low potential or borderline malignancy)
 - Serous cystadenocarcinomas
- Mucinous cystomas:
 - Mucinous benign cystadenomas
 - Mucinous cystadenomas with proliferating activity of the epithelial cells and nuclear abnormalities, but with no infiltrative destructive growth (low potential or borderline malignancy)

- Mucinous cystadenocarcinomas.

- Endometrioid tumors (similar to adenocarcinomas in the endometrium):

- Endometrioid benign cysts
- Endometrioid tumors with proliferating activity of the epithelial cells and nuclear abnormalities, but with no infiltrative destructive growth (low malignant potential or borderline malignancy)
- Endometrioid adenocarcinomas

- Clear cell (mesonephroid) tumors:

- Benign clear cell tumors
- Clear cell tumors with proliferating activity of the epithelial cells and nuclear abnormalities, but with no infiltrative destructive growth (low malignant potential or borderline malignancy)

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NCDB EDITS ARE ADAPTED TO BETTER FIT WITH STATE REQUIREMENTS

CoC Flash, July 2004: <http://www.facs.org/cancer/cocflash/july04.pdf>

Edit requirements for data submitted to NCDB for the Fall 2004 Call for Data slated to begin October 4, 2004, have been slightly modified to better coordinate with the data collection requirements of some state central registries. As originally posted, the NCDB edits required that Collaborative Stage fields be blank for all cases diagnosed prior to 2004. Because some states are requiring those items to be completed for cases currently being abstracted, regardless of the diagnosis date, NCDB will not apply the edits requiring blanks for pre-2004 cases. The purpose of this action is to accommodate soft-

ware providers that might otherwise need to create competing forms of submission files for the NCDB and some states, in order to smooth the submission process for registries regardless of their software services. The revised information, for registrars and software providers who wish to begin testing their data for the next submission, is posted on the NCDB Web page at <http://www.facs.org/cancer/ncdb/index.html>. The updated files are identified on the Web page by the date indicator "7/29/04."



September 10, 2004

TO: All Facility Registrars and Abstractors Submitting Full Cancer Abstracts

FROM: Jill MacKinnon

RE: September 30th Reporting Deadline

September 30th is right around the corner and this date marks several important revisions to the FCDS data processing. I have summarized the revisions below:

Case Reporting: September 30th is the reporting deadline for your 2003 cases. The Department of Health must be notified of any facility that is delinquent in submitting their 2003 cases. Secondly, this is implementation date for NAACCR v10.1. After the deadline, records submitted in the current NAACCR v10 will no longer be accepted. The implications of v10.1 are that any case submitted on or after October 1st must be submitted in the new format and must have **all collaborative staging fields completed, regardless of the diagnosis date.**

Pending Records: The v10.1 conversion in October will also affect cases in the pending file which are awaiting correction or documentation for force. These records must be corrected by September 30th. If they are not, the records must be resubmitted in v10.1 with all the collaborative staging fields complete. Please send all the corrections and force documentation to your Field Coordinator immediately.

Batch Upload Revisions: In addition to implementation of national standards, FCDS will implement 'real time edits' for all batch up-loads. That is, immediately upon uploading a batch, your records will undergo the full series of inter and intra-item edits checks. Once all records in the batch have been edited, a message will be returned to you instructing you to download the discrepancy journal. If all records successfully pass the edits, the batch will be accepted and the discrepancy journal will reflect this. If **any** record fails an edit, the **entire batch** will be rejected. The discrepancy journal will reflect which record(s) failed and a description of the error(s). The facility must correct the record on their system and resubmit the batch. This process must continue until all records successfully pass the edit process.

The only records that will be accepted in spite of an error are those records that have an 'over-rideable' discrepancy. That is, a record that does not satisfy national edit criteria but will have the opportunity to be 'forced' into the system with appropriate documentation from the facility. These records will remain in the FCDS pending file until the appropriate documentation is received and accepted. The discrepancy journal will reflect which records failed and based on the error, what documentation is necessary.

Should you have any questions please contact your Field Coordinator.

Thank you.

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malignancy).

■ Clear cell cystadenocarcinomas

- Unclassified tumors that cannot be allotted to one of the above groups
- No histology
- Other malignant tumors (malignant tumors other than those of the common epithelial types are not to be included with the categories listed above)

(Refer to the PDQ summary on Ovarian Low Malignant Potential Tumor Treatment on the National Cancer Institute website at <http://cancer.gov/templates/doc.aspx?viewid=d0360d63-9af5-4fb1-bb06-9d8b805d7130&version=1> for more information.)

Stage Information

In the absence of extra-abdominal metastatic disease, definitive staging of ovarian cancer requires laparotomy. The role of surgery in patients with stage IV disease and extra-abdominal disease remains to be established. If disease appears to be limited to the ovaries or pelvis, it is essential at laparotomy to examine and biopsy the diaphragm, both paracolic gutters, the pelvic peritoneum, para-aortic and pelvic nodes, and infracolic omentum, and to obtain peritoneal washings.[1]

In addition, invasion of the bladder and bowel needs to be taken into consideration, and a preoperative intravenous pyelogram and barium enema may be useful to evaluate the urinary tract and large bowel.

The serum CA 125 level is valuable in the follow-up and restaging of patients who have elevated CA 125 levels at the time of diagnosis.[2-4] While an elevated CA 125 level indicates a high probability of epithelial ovarian cancer, a negative CA 125 level cannot be used to exclude the presence of residual disease.[5] CA 125 levels can also be elevated in other malignancies and benign gynecologic problems such as endometriosis, and CA 125 levels should be used with a histologic diagnosis of epithelial ovarian cancer.[6,7]

The Federation Internationale de Gynecologie et d'Obstetrique (FIGO) and the American Joint Committee on Cancer (AJCC) have designated staging.[8,9]

Stage I

Stage I ovarian cancer is limited to the ovaries.

- Stage IA: Tumor limited to 1 ovary; capsule intact, no tumor on ovarian surface. No malignant cells in ascites or peritoneal washings.*
- Stage IB: Tumor limited to both ovaries; capsules intact, no

tumor on ovarian surface. No malignant cells in ascites or peritoneal washings.*

- Stage IC: Tumor limited to 1 or both ovaries with any of the following: capsule ruptured, tumor on ovarian surface, malignant cells in ascites or peritoneal washings.[8]

* [Note: malignant ascites is not classified. The presence of ascites does not affect staging unless malignant cells are present.]

Stage II

Stage II ovarian cancer is tumor involving 1 or both ovaries with pelvic extension and/or implants.

- Stage IIA: Extension and/or implants on the uterus and/or fallopian tubes. No malignant cells in ascites or peritoneal washings.
- Stage IIB: Extension to and/or implants on other pelvic tissues. No malignant cells in ascites or peritoneal washings.
- Stage IIC: Pelvic extension and/or implants (stage IIA or IIB) with malignant cells in ascites or peritoneal washings.

Different criteria for allotting cases to stages IC and IIC have an impact on diagnosis. In order to evaluate this impact, it would be of value to know if rupture of the capsule was (1) spontaneous or (2) caused by the surgeon, and if the source of malignant cells detected was (1) peritoneal washings or (2) ascites.

Stage III

Stage III ovarian cancer is tumor involving 1 or both ovaries with microscopically confirmed peritoneal implants outside the pelvis. Superficial liver metastasis equals stage III. Tumor is limited to the true pelvis but with histologically verified malignant extension to small bowel or omentum.

- Stage IIIA: Microscopic peritoneal metastasis beyond pelvis (no macroscopic tumor).
- Stage IIIB: Macroscopic peritoneal metastasis beyond pelvis 2 cm or less in greatest dimension.
- Stage IIIC: Peritoneal metastasis beyond pelvis more than 2 cm in greatest dimension and/or regional lymph node metastasis.

Stage IV

Stage IV ovarian cancer is tumor involving 1 or both ovaries with distant metastasis. If pleural effusion is present, there must be positive cytologic test results to designate a case to stage IV. Parenchymal liver metastasis equals stage IV.

References

1. Hoskins WJ: Surgical staging and cytoreductive surgery of epithelial ovarian cancer. *Cancer* 71 (4 Suppl): 1534-40, 1993. [PUBMED Abstract]

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2. Mogensen O: Prognostic value of CA 125 in advanced ovarian cancer. *Gynecol Oncol* 44 (3): 207-12, 1992. [PUBMED Abstract]
3. Högberg T, Kågedal B: Long-term follow-up of ovarian cancer with monthly determinations of serum CA 125. *Gynecol Oncol* 46 (2): 191-8, 1992. [PUBMED Abstract]
4. Rustin GJ, Nelstrop AE, Tuxen MK, et al.: Defining progression of ovarian carcinoma during follow-up according to CA 125: a North Thames Ovary Group Study. *Ann Oncol* 7 (4): 361-4, 1996. [PUBMED Abstract]
5. Makar AP, Kristensen GB, Børmer OP, et al.: CA 125 measured before second-look laparotomy is an independent prognostic factor for survival in patients with epithelial ovarian cancer. *Gynecol Oncol* 45 (3): 323-8, 1992. [PUBMED Abstract]
6. Berek JS, Knapp RC, Malkasian GD, et al.: CA 125 serum levels correlated with second-look operations among ovarian cancer patients. *Obstet Gynecol* 67 (5): 685-9, 1986. [PUBMED Abstract]
7. Atack DB, Nisker JA, Allen HH, et al.: CA 125 surveillance and second-look laparotomy in ovarian carcinoma. *Am J Obstet Gynecol* 154 (2): 287-9, 1986. [PUBMED Abstract]
8. Shepherd JH: Revised FIGO staging for gynaecological cancer. *Br J Obstet Gynaecol* 96 (8): 889-92, 1989. [PUBMED Abstract]
9. Ovary. In: American Joint Committee on Cancer.: *AJCC Cancer Staging Manual*. 6th ed. New York, NY: Springer, 2002, pp 275-284.

Treatment Option Overview

Stage I Ovarian Epithelial Cancer

Standard treatment options:

1. If the tumor is well or moderately well differentiated, total abdominal hysterectomy and bilateral salpingo-oophorectomy with omentectomy is adequate for patients with stage IA and IB disease. The undersurface of the diaphragm should be visualized and biopsied; pelvic and abdominal

peritoneal biopsies and pelvic and para-aortic lymph node biopsies are required and peritoneal washings should be obtained routinely.[1] In selected patients who desire childbearing and who have grade I tumors, unilateral salpingo-oophorectomy may not be associated with high risk of recurrence.[2]

2. If the tumor is grade III, densely adherent, or stage IC, the chance of relapse and subsequent death from ovarian cancer is substantial (up to 20%), although the importance of tumor rupture if it is the only adverse characteristic is not clear.[3-5] Several treatment approaches that have been taken in such patients are listed below

- Intraperitoneal P-32 or radiation therapy.[1,6,7]
- Systemic chemotherapy.[1,6,8-10]
- Total abdominal and pelvic radiation therapy.[11,12]
- Careful observation without immediate treatment in selected patients (watchful waiting).

References

1. Young RC, Brady MF, Walton LA, et al.: Localized ovarian cancer in the elderly. The Gynecologic Oncology Group experience. *Cancer* 71 (2 Suppl): 601-5, 1993. [PUBMED Abstract]
2. Zanetta G, Chiari S, Rota S, et al.: Conservative surgery for stage I ovarian carcinoma in women of childbearing age. *Br J Obstet Gynaecol* 104 (9): 1030-5, 1997. [PUBMED Abstract]
3. Dembo AJ, Davy M, Stenwig AE, et al.: Prognostic factors in patients with stage I epithelial ovarian cancer. *Obstet Gynecol* 75 (2): 263-73, 1990. [PUBMED Abstract]
4. Ahmed FY, Wiltshaw E, A'Hern RP, et al.: Natural history and prognosis of untreated stage I epithelial ovarian carcinoma. *J Clin Oncol* 14 (11): 2968-75, 1996. [PUBMED Abstract]
5. Monga M, Carmichael JA, Shelley WE, et al.: Surgery without adjuvant chemotherapy for early epithelial ovarian carcinoma after comprehensive surgical staging.

- Gynecol Oncol 43 (3): 195-7, 1991. [PUBMED Abstract]
6. Vergote IB, Vergote-De Vos LN, Abeler VM, et al.: Randomized trial comparing cisplatin with radioactive phosphorus or whole-abdomen irradiation as adjuvant treatment of ovarian cancer. *Cancer* 69 (3): 741-9, 1992. [PUBMED Abstract]
7. Piver MS, Lele SB, Bakshi S, et al.: Five and ten year estimated survival and disease-free rates after intraperitoneal chromic phosphate; stage I ovarian adenocarcinoma. *Am J Clin Oncol* 11 (5): 515-9, 1988. [PUBMED Abstract]
8. Bolis G, Colombo N, Pecorelli S, et al.: Adjuvant treatment for early epithelial ovarian cancer: results of two randomised clinical trials comparing cisplatin to no further treatment or chromic phosphate (32P). G.I.C.O.G.: Gruppo Interregionale Collaborativo in Ginecologia Oncologica. *Ann Oncol* 6 (9): 887-93, 1995. [PUBMED Abstract]
9. Piver MS, Malfetano J, Baker TR, et al.: Five-year survival for stage IC or stage I grade 3 epithelial ovarian cancer treated with cisplatin-based chemotherapy. *Gynecol Oncol* 46 (3): 357-60, 1992. [PUBMED Abstract]
10. McGuire WP: Early ovarian cancer: treat now, later or never? *Ann Oncol* 6 (9): 865-6, 1995. [PUBMED Abstract]
11. Martinez A, Schray MF, Howes AE, et al.: Postoperative radiation therapy for epithelial ovarian cancer: the curative role based on a 24-year experience. *J Clin Oncol* 3 (7): 901-11, 1985. [PUBMED Abstract]
12. Dembo AJ: Epithelial ovarian cancer: the role of radiotherapy. *Int J Radiat Oncol Biol Phys* 22 (5): 835-45, 1992. [PUBMED Abstract]

Stage II Ovarian Epithelial Cancer

Standard treatment options:

Surgery should include total abdominal hysterectomy and bilateral salpingo-oophorectomy with omentectomy and tumor debulking to remove all or most of the tumor. If there is no clinically apparent disease outside of the pelvis

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and systemic therapy is contemplated, additional staging procedures, while possibly influencing choice of therapy, may not influence survival.[1] If there is no clinical residual disease, the undersurface of the diaphragm should be visualized and biopsied and the abdominal peritoneum sampled; selective pelvic and para-aortic node sampling is required. The options for further treatment include:

1. If minimal postsurgical residual disease (<1 cm) remains, systemic chemotherapy:[2]
 - TP: paclitaxel (Taxol) + cisplatin or carboplatin.[3-8]
 - CP: cyclophosphamide + cisplatin.[9]
 - CC: cyclophosphamide + carboplatin.[10]
 - Total abdominal and pelvic radiation therapy (only if there is no macroscopic upper abdominal disease, and minimal residual pelvic disease is <0.5 cm).[11,12]
 - Intraperitoneal P-32 radiation therapy is less frequently used (only if residual tumor is <1 mm).[2] This option is associated with a significant number of late bowel complications. [13]
2. If macroscopic postsurgical residual disease (>2 cm) remains in the pelvis, combination chemotherapy should be used. The following regimens are commonly used:
 - TP.[3-8]
 - CP.[9]
 - CC.[10]

References

1. Potter ME, Partridge EE, Hatch KD, et al.: Primary surgical therapy of ovarian cancer: how much and when. *Gynecol Oncol* 40 (3): 195-200, 1991. [PUBMED Abstract]
2. Young RC, Walton LA, Ellenberg SS, et al.: Adjuvant therapy in stage I and stage II epithelial ovarian cancer. Results of two prospective randomized trials. *N Engl J Med* 322 (15): 1021-7, 1990. [PUBMED Abstract]
3. McGuire WP, Rowinsky EK,

Rosenshein NB, et al.: Taxol: a unique antineoplastic agent with significant activity in advanced ovarian epithelial neoplasms. *Ann Intern Med* 111 (4): 273-9, 1989. [PUBMED Abstract]

4. Einzig AI, Wiernik PH, Sasloff J, et al.: Phase II study and long-term follow-up of patients treated with taxol for advanced ovarian adenocarcinoma. *J Clin Oncol* 10 (11): 1748-53, 1992. [PUBMED Abstract]
5. Thigpen T, Blessing J, Ball H, et al.: Phase II trial of taxol as second-line therapy for ovarian carcinoma: a Gynecologic Oncology Group study. [Abstract] *Proceedings of the American Society of Clinical Oncology* 9: A-604, 156, 1990.
6. Kohn EC, Sarosy G, Bicher A, et al.: Dose-intense taxol: high response rate in patients with platinum-resistant recurrent ovarian cancer. *J Natl Cancer Inst* 86 (1): 18-24, 1994. [PUBMED Abstract]
7. Trimble EL, Adams JD, Vena D, et al.: Paclitaxel for platinum-refractory ovarian cancer: results from the first 1,000 patients registered to National Cancer Institute Treatment Referral Center 9103. *J Clin Oncol* 11 (12): 2405-10, 1993. [PUBMED Abstract]
8. Trimble EL, Arbuck SG, McGuire WP: Options for primary chemotherapy of epithelial ovarian cancer: taxanes. *Gynecol Oncol* 55 (3 Pt 2): S114-21, 1994. [PUBMED Abstract]
9. Decker DG, Fleming TR, Malkasian GD Jr, et al.: Cyclophosphamide plus cis-platinum in combination: treatment program for stage III or IV ovarian carcinoma. *Obstet Gynecol* 60 (4): 481-7, 1982. [PUBMED Abstract]
10. Trask C, Silverstone A, Ash CM, et al.: A randomized trial of carboplatin versus iproplatin in untreated advanced ovarian cancer. *J Clin Oncol* 9 (7): 1131-7, 1991. [PUBMED Abstract]
11. Martinez A, Schray MF, Howes AE, et al.: Postoperative radiation therapy for epithelial ovarian cancer: the curative role based on a 24-year experience. *J Clin Oncol* 3 (7): 901-11, 1985. [PUBMED Abstract]
12. Dembo AJ: Epithelial ovarian cancer: the role of radiotherapy. *Int J Radiat Oncol Biol Phys* 22 (5): 835-45,

1992. [PUBMED Abstract]

13. Vergote IB, Vergote-De Vos LN, Abeler VM, et al.: Randomized trial comparing cisplatin with radioactive phosphorus or whole-abdomen irradiation as adjuvant treatment of ovarian cancer. *Cancer* 69 (3): 741-9, 1992. [PUBMED Abstract]
14. Young RC: Initial therapy for early ovarian carcinoma. *Cancer* 60 (8 Suppl): 2042-9, 1987. [PUBMED Abstract]

Stage III and IV Ovarian Epithelial Cancer

Note: Some citations in the text of this section are followed by a level of evidence. The PDQ editorial boards use a formal ranking system to help the reader judge the strength of evidence linked to the reported results of a therapeutic strategy. (For more information refer to the PDQ summary on Levels of Evidence located on the NCI website at <http://cancer.gov/templates/doc.aspx?viewid=2b9ac8c6-7202-4728-9dd0-77ca57170044&version=1> .)

Standard treatment options:

Surgery

Surgery has been used as a therapeutic modality and also to adequately stage the disease. Surgery should include total abdominal hysterectomy and bilateral salpingo-oophorectomy with omentectomy and debulking of as much gross tumor as can safely be performed. While primary cytoreductive surgery may not correct biologic characteristics of the tumor, there is considerable evidence that the volume of disease left at the completion of the primary surgical procedure is related to patient survival.[1] A literature review showed that patients with optimal cytoreduction had median survival of 39 months compared with survival of only 17 months in patients with suboptimal residual disease.[1] However, results of a retrospective analysis of 349 patients with postoperative residual masses less than or equal to 1 cm suggested that patients who present at the outset with large-volume disease and achieve small-volume disease by surgical debulking have poorer outcomes than similar

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EDUCATION AND TRAINING

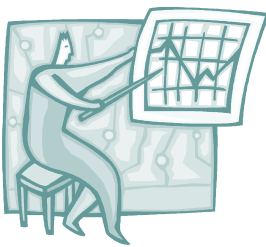


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2005 CTR EXAM CONTENT

<http://www.ctrexam.org/>

The content of the 2005 CTR Examinations will be drawn in part from the publications of several national standard-setting organizations, including:

- **International Classification of Diseases for Oncology 3rd Edition (ICD-O-3);**
- **Facility Oncology Registry Data Standards "FORDS: Revised for 2004";**
- **AJCC Cancer Staging Manual 6th Edition;**
- **CoC Cancer Program Standards 2004**
- **Collaborative Staging Manual and Coding Instructions, version 1.0.**



The Collaborative Staging (CS) will test on the following data fields and sites.

CS DATA FIELDS:	SPECIFIC CS FIELD SITES:
1. CS Extension 2. CS Lymph nodes 3. CS Metastasis at Diagnosis	1. Breast 2. Lung 3. Colon Rectal Bladder 4. Kidney 5. Melanoma 6. Ovary 7. Corpus Uteri (Endometrium) 8. Pancreas 9. Thyroid

Please note that Summary Stage 2000 is no longer tested. Plus, the exam content excludes any clarifications posted in the SEER SINQ and Commission on Cancer's Inquiry and Response system.

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patients who present with small-volume disease.[2] It is nevertheless likely that there is gradual improvement in survival with decreasing residual tumor volume. Although the association may not be causal, retrospective analyses, including a meta-analysis of patients receiving platinum-based chemotherapy, have found cytoreduction to be an independent prognostic variable for survival.[3,4]

The value of interval cytoreductive surgery has also been the subject of phase III trials. In the first study, performed by the European Organisation for Research and Treatment of Cancer, patients subjected to debulking after 4 cycles of cyclophosphamide and cisplatin (with additional cycles given later) had an improved survival over patients who completed 6 cycles of this chemotherapy without surgery.[5] [Level of evidence: 1iiB] A similar trial by the Gynecologic Oncology Group (GOG-162 [6]), but using paclitaxel plus cisplatin as the chemotherapy, did not demonstrate any advantage from interval cytoreductive surgery. Wider use of maximal surgical effort at the time of diagnosis by US gynecologic oncologists may be a factor accounting for these divergent results. Although many patients with stage IV disease undergo cytoreductive surgery, whether this improves survival has not been established. [7]

Surgery also has a role in reassessment to determine the extent of residual disease, if any, following the initial (induction) chemotherapy. Historically, second-look laparotomies were routinely performed after completion of chemotherapy for those stage III patients who have a computed tomographic scan not suggestive of residual active disease, who are clinically without evidence of disease, and whose CA 125 is normal. There are no data from randomized trials to show that therapeutic decisions based on results of this procedure alter outcomes for the patient. In a large nonrandomized trial, there was no survival advantage in patients who received a second-look operation as compared to those who did not [8] and the only randomized trial, albeit statistically underpowered, was negative.[9]

Approximately one third of patients found to have macroscopic tumor at second-look surgery achieve complete cytoreduction resulting in microscopic residual disease, approximately one third achieve partial debulking resulting in optimal residual disease, and the remainder are left with bulky tumors. The value of secondary tumor reduction at the time of second-look laparotomy is controversial. Some have reported improved survival in patients who achieve optimal secondary debulking, [10-12] while others report survival benefit for those left with microscopic disease only.[13] Whether the survival benefit of complete secondary cytoreduction is a function of the surgical debulking or a reflection of the characteristics of the tumor that permits complete cytoreduction is not known.[14-16] Since there are no controlled clinical trials that demonstrate a survival advantage for the second-look operation, it is often performed either as part of a clinical trial or when a prescribed second-line therapy is being tested. Finally, reassessment surgery has been linked to the introduction of IP catheters, in order to test the

pharmacologically derived concept of IP consolidation with drugs delivered directly into the peritoneal cavity. A number of IP regimens have been tested, and phase III trials have provided support for the validity of this concept.[17]

Intraperitoneal regimens

A pharmacologic advantage for this route possibly resulting in an improved outcome pertains only to the minimal or no residual disease setting. Therefore, the extent of residual disease after the initial surgery or at reassessment has been used to guide the development of these treatment strategies. The use of IP radioactive phosphate after negative second-look surgery does not appear to increase overall or disease-free survival rates. [18] Early reports suggested a role for IP chemotherapy [19-21] by demonstrating surgically defined complete response rates and prolonged survival [22] in approximately 25% to 35% of patients with small-volume residual persistent disease after a variety of IP regimens.[21,23] Outcome was particularly favorable in patients defined as platinum-sensitive, a feature indicative of a greater overall responsiveness to other treatments as well. A randomized trial will be necessary to determine whether IP chemotherapy given as consolidation has a survival advantage over alternative second-line therapies. Platinum compounds alone or in combination have received the most attention but nonplatinum drugs have also been studied. For example, the Southwest Oncology Group adopted continuous infusion of floxuridine over mitoxantrone as consolidation for minimal residual disease, in view of the results of a phase II randomized trial.[17]

The use of IP cisplatin as part of the initial up-front approach in stage III optimally-debulked ovarian cancer is supported by the results of 3 randomized clinical trials. These studies tested the role of IP drugs (IP cisplatin in all 3 studies, and IP paclitaxel in the last study) versus the standard IV regimen. In all 3 studies superior progression-free survival was documented favoring the IP arm, and in the 2 fully reported to date, the overall survival was also significantly better in the IP arm.[17] [Level of evidence: 1iiB] However, IP therapy has not been routinely adopted, in part because of issues relating to greater toxicity and inconvenience.[24] Moreover, since 2001 the GOG and International Collaborators have embarked in trials that do not distinguish optimally debulked (<1 cm residuum) versus suboptimally debulked (residuum >1 cm) patients for entry into studies, and do not encourage reassessment after completion of induction regimens.

Chemotherapy options

First-line chemotherapy has been built on 2 premises supported by retrospective analyses and consecutive clinical trials by cooperative groups:

1. Platinum compounds, up to an "optimal dose-intensity," represent the core of the treatment (e.g., platinum-based chemotherapy). An initial analysis noted a relationship between survival and dose-intensity of cisplatin.[25]

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However, clinical trials escalating the drug to 100 mg/m² every 3 weeks did not support an advantage over 50 mg/m² every 3 weeks, and adopted 75 mg/m² as the standard.[26,27] Similarly for carboplatin, a large retrospective study suggested improved outcome up to a target area under the curve (AUC) of 5, and then a plateau in effectiveness in spite of increasing drug exposure.[28] Subsequently, a randomized trial comparing carboplatin dosed according to a target AUC of 6 versus a target AUC of 12 yielded similar results.[29]

2. Cisplatin and carboplatin yield equivalent results. Several clinical trials supporting the introduction of carboplatin into the clinic demonstrated it yielded similar results in ovarian cancer as cisplatin. Trials of either platinum in combination with cyclophosphamide [30,31] [Level of evidence: 1iiB] or with paclitaxel [8,32] [Level of evidence: 1iiB] have also shown similar outcomes.

Therefore, current efforts are focusing on how a number of drugs with activity against ovarian cancer may be optimally combined with the platinum drugs, either in combination or in sequence.

References

1. Hoskins WJ: Surgical staging and cytoreductive surgery of epithelial ovarian cancer. *Cancer* 71 (4 Suppl): 1534-40, 1993. [PUBMED Abstract]
2. Hoskins WJ, Bundy BN, Thigpen JT, et al.: The influence of cytoreductive surgery on recurrence-free interval and survival in small-volume stage III epithelial ovarian cancer: a Gynecologic Oncology Group study. *Gynecol Oncol* 47 (2): 159-66, 1992. [PUBMED Abstract]
3. Hoskins WJ, McGuire WP, Brady MF, et al.: The effect of diameter of largest residual disease on survival after primary cytoreductive surgery in patients with suboptimal residual epithelial ovarian carcinoma. *Am J Obstet Gynecol* 170 (4): 974-9; discussion 979-80, 1994. [PUBMED Abstract]
4. Bristow RE, Tomacruz RS, Armstrong DK, et al.: Survival effect of maximal cytoreductive surgery for advanced ovarian carcinoma during the platinum era: a meta-analysis. *J Clin Oncol* 20 (5): 1248-59, 2002. [PUBMED Abstract]
5. van der Burg ME, van Lent M, Buyse M, et al.: The effect of debulking surgery after induction chemotherapy on the prognosis in advanced epithelial ovarian cancer. *Gynecological Cancer Cooperative Group of the European Organization for Research and Treatment of Cancer. N Engl J Med* 332 (10): 629-34, 1995. [PUBMED Abstract]
6. Spriggs DR, Gynecologic Oncology Group: Phase III Randomized Study of 24 Hour Versus 96 Hour Infusion of Paclitaxel With Cisplatin in Patients With Suboptimal Stage III or IV Ovarian Epithelial Cancer or Primary Peritoneal Cancer (Summary Last Modified 10/2000), GOG-162, Clinical trial, Closed. [PDQ Clinical Trial]
7. Goodman HM, Harlow BL, Sheets EE, et al.: The role of cytoreductive surgery in the management of stage IV epithelial ovarian carcinoma. *Gynecol Oncol* 46 (3): 367-71, 1992. [PUBMED Abstract]
8. Ozols RF, Bundy BN, Fowler J, et al.: Randomized phase III study of cisplatin (CIS)/paclitaxel (PAC) versus carboplatin (CARBO)/PAC in optimal stage III epithelial ovarian cancer (OC): a Gynecologic Oncology Group trial (GOG 158). [Abstract] *Proceedings of the American Society of Clinical Oncology* 18: A-1373, 356a, 1999.
9. Nicoletto MO, Tumolo S, Talamini R, et al.: Surgical second look in ovarian cancer: a randomized study in patients with laparoscopic complete remission--a Northeastern Oncology Cooperative Group-Ovarian Cancer Cooperative Group Study. *J Clin Oncol* 15 (3): 994-9, 1997. [PUBMED Abstract]
10. Bertelsen K: Tumor reduction surgery and long-term survival in advanced ovarian cancer: a DACOVA study. *Gynecol Oncol* 38 (2): 203-9, 1990. [PUBMED Abstract]
11. Podczaski E, Manetta A, Kaminski P, et al.: Survival of patients with ovarian epithelial carcinomas after second-look laparotomy. *Gynecol Oncol* 36 (1): 43-7, 1990. [PUBMED Abstract]
12. Eisenkop SM, Friedman RL, Wang HJ: Complete cytoreductive surgery is feasible and maximizes survival in patients with advanced epithelial ovarian cancer: a prospective study. *Gynecol Oncol* 69 (2): 103-8, 1998. [PUBMED Abstract]
13. Hoskins WJ, Rubin SC, Dulaney E, et al.: Influence of secondary cytoreduction at the time of second-look laparotomy on the survival of patients with epithelial ovarian carcinoma. *Gynecol Oncol* 34 (3): 365-71, 1989. [PUBMED Abstract]
14. Williams L: The role of secondary cytoreductive surgery in epithelial ovarian malignancies. *Oncology (Huntingt)* 6 (8): 25-32; discussion 37-9, 1992. [PUBMED Abstract]
15. Potter ME: Secondary cytoreduction in ovarian cancer: pro or con? *Gynecol Oncol* 51 (1): 131-5, 1993. [PUBMED Abstract]
16. Carson LF, Rubin SC: Secondary cytoreduction--thoughts on the "pro" side. *Gynecol Oncol* 51 (1): 127-30, 1993. [PUBMED Abstract]
17. Alberts DS, Markman M, Armstrong D, et al.: Intraperitoneal therapy for stage III ovarian cancer: a therapy whose time has come! *J Clin Oncol* 20 (19): 3944-6, 2002. [PUBMED Abstract]
18. Vergote IB, Winderen M, De Vos LN, et al.: Intraperitoneal radioactive phosphorus therapy in ovarian carcinoma. Analysis of 313 patients treated primarily or at second-look laparotomy. *Cancer* 71 (7): 2250-60, 1993. [PUBMED Abstract]
19. Markman M, Hakes T, Reichman B, et al.: Intraperitoneal cisplatin and cytarabine in the treatment of refractory or recurrent ovarian carcinoma. *J Clin Oncol* 9 (2): 204-10, 1991. [PUBMED Abstract]
20. Piver MS, Recio FO, Baker TR, et al.: Evaluation of survival after second-line intraperitoneal cisplatin-based chemotherapy for advanced ovarian cancer. *Cancer* 73 (6):

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INFORMATION & NEWS

THE 2004 FCDS DATA ACQUISITION MANUAL

The 2004 FCDS Data Acquisition Manual is available for download from the FCDS website, <http://fcds.med.miami.edu> under the downloads link.

FCDS will not be providing hard copies to any facility or contractor.

NATIONAL HEALTH INFORMATION AND TECHNOLOGY WEEK

National Health Information and Technology Week, November 7-13, sponsored by AHIMA. The annual event was started 15 years ago to recognize the work of HIM professionals who maintain and protect the health information of individuals nationwide. The theme of this year's celebration is "Health Information: Powered by Professionals," and we have prepared a kit to help you plan your week. To access the planning kit online, visit: <http://www.ahima.org/hitweek>.

CS SCHEMA "ERRATA" PRINTED MANUAL, PART 2

CS Schema "Errata" for the Printed Manual, part 2, is now available online. Please visit <http://www.cancerstaging.org/cstage/csreplacement.pdf>.

COLLABORATIVE STAGING MANUAL AND CODING INSTRUCTIONS

[_http://seer.cancer.gov/tools/collabstaging/](http://seer.cancer.gov/tools/collabstaging/)

The Collaborative Staging Manual and Coding Instructions is published jointly by the SEER Program, the National Program of Cancer Registries of the Centers for Disease Control and Prevention, and the American College of Surgeons Commission on Cancer. The Collaborative Staging System is a carefully selected set of data items that describe how far a cancer has spread at the time of diagnosis. It provides the codes and coding instructions for the Collaborative Staging System fields for cases diagnosed January 1, 2004 and forward. These fields are now required by all central registries in the US and Canada and all hospitals that report to them.

The Collaborative Staging Manual and Coding Instructions publication is available electronically and can be downloaded from American Joint Committee on Cancer Web site. Or, you may order a printed copy of this book from the SEER website at <http://seer.cancer.gov/cgi-bin/pubs/order1.pl?CODING,BOOK,CONV,MONO,CSR,,ABOUT>.



FCDS Q & A

SEER INQUIRY SYSTEM:
[HTTP://SEER.CANCER.GOV/SEERINQUIRY/](http://seer.cancer.gov/seer inquiry/)



1. Question

Surgery of Primary Site--Ovary: What code is used to represent this field when a patient has a history of a previous organ removal and has additional surgery/organ removal for a present cancer (e.g., History of a 1984 hysterectomy and in 2003 has ovarian primary treated with BSO)?

Answer

For cases diagnosed 1/1/2003 and after: Code the Surgery of Primary Site field to 52 [Bilateral salpingo-oophorectomy WITH hysterectomy].

References

SEER Program Code Man, 3rd Ed ;pgs 14

2. Question

Multiple Primaries--Ovary: Are mucinous cystic tumors of low malignant potential diagnosed in the left ovary in 12/2000 and in the right ovary in 7/2001 considered reportable as two primaries?

Answer

Borderline tumors are not reportable to SEER in 2001. If you are collecting them in your registry, use the following procedure: Exception 1 in the SEER Program Code Manual responds to the issue of processing ovarian tumors. Simultaneously occurring ovarian tumors with a single histology are coded as one primary. In the case you cite, the right ovary primary occurred 7 months after the left ovary primary. This is not simultaneous, so it would be counted as a second primary.

3. Question

Reportability--Ovary: Are borderline ovarian tumors diagnosed in 2001 and later with implants, or "focal microinvasion," or "focus of intraepithelial carcinoma" reportable to SEER?

Answer

Borderline ovarian tumors are not reportable, behavior is /1. If the principal tumor is borderline and there are tumor deposits on other pelvic surfaces, the case remains borderline and non-reportable by SEER rules UNLESS the pathologist makes a definite statement that the tumor deposits are malignant. For borderline ovarian tumors, the following are NOT statements of definite malignancy: "microinvasive," "focus of intraepithelial carcinoma."

4. Question

Primary Site--Ovary/Peritoneum: When ovaries are not found on a resection or if the ovaries removed are negative for malignancy, but the clinician refers to the adenocarcinoma in the pelvis as being an "ovarian" primary, should the primary site be coded as ovary, pelvic peritoneum or unknown?

Answer

Code the Primary Site for both examples to peritoneum [C48.2]. When the physician refers to a case as "ovarian" even though the ovaries are negative or when the histology is an ovarian histology, such as papillary serous ca, the primary site should be coded to the peritoneum. Code the Primary Site to where it appears the disease is arising.

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1693-8, 1994. [PUBMED Abstract]

21. Howell SB, Kirmani S, McClay EF, et al.: Intraperitoneal cisplatin-based chemotherapy for ovarian carcinoma. *Semin Oncol* 18 (1 Suppl 3): 5-10, 1991. [PUBMED Abstract]

22. Markman M, Reichman B, Hakes T, et al.: Impact on survival of surgically defined favorable responses to salvage intraperitoneal chemotherapy in small-volume residual ovarian cancer. *J Clin Oncol* 10 (9): 1479-84, 1992. [PUBMED Abstract]

23. Markman M: Intraperitoneal chemotherapy. *Semin Oncol* 18 (3): 248-54, 1991. [PUBMED Abstract]

24. Atkins CD: Intraperitoneal chemotherapy for stage III ovarian cancer. *J Clin Oncol* 21 (5): 957; author reply 957-8, 2003. [PUBMED Abstract]

25. Levin L, Simon R, Hryniuk W: Importance of multiagent chemotherapy regimens in ovarian carcinoma: dose intensity analysis. *J Natl Cancer Inst* 85 (21): 1732-42, 1993. [PUBMED Abstract]

26. McGuire WP, Hoskins WJ, Brady MF, et al.: Assessment of dose-intensive therapy in suboptimally debulked ovarian cancer: a Gynecologic Oncology Group study. *J Clin Oncol* 13 (7): 1589-99, 1995. [PUBMED Abstract]

27. Kaye SB, Paul J, Cassidy J, et al.: Mature results of a randomized trial of two doses of cisplatin for the treatment of ovarian cancer. *Scottish Gynecology Cancer Trials Group. J Clin Oncol* 14 (7): 2113-9, 1996. [PUBMED Abstract]

28. Jodrell DI, Egorin MJ, Canetta RM, et al.: Relationships between carboplatin exposure and tumor response and toxicity in patients with ovarian cancer. *J Clin Oncol* 10 (4): 520-8, 1992. [PUBMED Abstract]

29. Gore M, Mainwaring P, A'Hern R, et al.: Randomized trial of dose-intensity with single-agent carboplatin in patients with epithelial ovarian cancer. *London Gynaecological Oncology Group. J Clin Oncol* 16 (7): 2426-34, 1998. [PUBMED Abstract]

30. Alberts DS, Green S, Hannigan EV, et al.: Improved therapeutic index of carboplatin plus cyclophosphamide versus cisplatin plus cyclophosphamide: final report by the Southwest Oncology Group of a phase III randomized trial in stages III and IV ovarian cancer. *J Clin Oncol* 10 (5): 706-17, 1992. [PUBMED Abstract]

31. Swenerton K, Jeffrey J, Stuart G, et al.: Cisplatin-cyclophosphamide versus carboplatin-cyclophosphamide in advanced ovarian cancer: a randomized phase III study of the National Cancer Institute of Canada Clinical Trials Group. *J Clin Oncol* 10 (5): 718-26, 1992. [PUBMED Abstract]



DEADLINES AND REMINDERS



AMBULATORY CARE CENTERS CANCER REPORTING PROGRAM

On August 11, 2004, FCDS completed the matching of the 2002 outpatient discharges reported by Florida Ambulatory Patient Care Centers' Finance-Billing/Medical Records Department to the Agency for Health Care Administration (AHCA). All records with principal or secondary diagnoses of cancer were linked to the FCDS database. Only records reported to AHCA but not matched to a FCDS record will appear on the lists titled "AHCA Ambi Unmatched Cancer Records Request."

On August 13, 2004, FCDS mailed the "AHCA Ambi Unmatched Cancer Records Request" lists for 2002 to the Florida Ambulatory Patient Care Centers. The 2002 listings included patient encounters between January 1, 2002 and December 31, 2002. The centers received notification for cases that were never reported from any other source to FCDS.

Any facility with fewer than 35 cancer cases identified on the "AHCA Ambi Unmatched Cancer Records Request" list need only submit copies of patient records to FCDS for each of the cases on the list. A

Batch Transmittal Form must be included with any chart copies submitted. The following reports (if available) from each patient record must be submitted by September 30, 2004: Face sheet, Summary, History & Physical, Operative Reports, Consultation Reports, Pathology Reports, Radiology Reports, Laboratory Reports and all other pertinent reports.

Any facility with greater than 35 cancer cases on the "AHCA Ambi Unmatched Cancer Records Request" list must determine whether or not each of the identified case records must be reported to the FCDS by referring to the FCDS reporting criteria outlined in Section I of the *FCDS Data Acquisition Manual*. If the case meets the FCDS reporting criteria, a full case abstract must be submitted to FCDS by September 30, 2004. All data submitted to FCDS must be via the encrypted Internet transmission, FCDS IDEA. For further information, visit the FCDS website at <http://fcds.med.miami.edu>. If the case does not meet the FCDS reporting criteria, the appropriate Disposition Code must be documented on the "AHCA Ambi Unmatched Cancer Records Request" list and returned to FCDS by September 30, 2004.

FCDS CONVERTING TO NAACCR VERSION 10.1 October 1-15, 2004

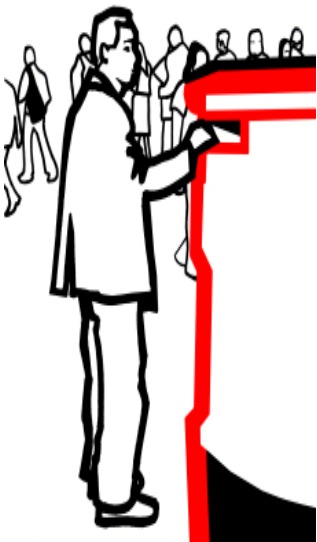
FCDS will be converting the state registry database to the NAACCR version 10.1 record layout from October 1, 2004 until October 15, 2004. Data will continue to be accepted through FCDS IDEA during this period.

Due to the conversion, please be aware of the following dates. The dates will affect your workload. Cases received by FCDS on or before September 30, 2004: All abstracts for diagnosis prior to 2004 may continue to be submitted according to the current reporting guidelines and record layout (NAACCR version 10). Cases received by FCDS October 1, 2004 and after: All abstracts regardless of diagnosis date must be submitted according to the new reporting guidelines and new NAACCR version 10.1 record layout (This includes the new data items).

REMINDER:

Effective with NAACCR version 10.1, all Collaborative Staging fields must be completed on ALL cases regardless of date of diagnosis. This includes "historical cases."

FCDS MAILING INFORMATION



For those facilities and physician office that need to mail the patient(s) medical record, please use our general mailing information listed below:

In order to protect and properly handle all packages, particularly those containing confidential patient information, we ask that US Postal Service mail including Express mail, Priority mail, and Certified mail be sent to FCDS via the PO Box address below:

FCDS/ University of Miami School of Medicine
PO BOX 016960 (D4-11)
Miami, FL 33101

FCDS STREET ADDRESS SHOULD ONLY BE USED FOR COURIER PACKAGES

(Federal Express, UPS, Airborne Express).

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FLORIDA CANCER DATA SYSTEM

**Path Reporting
and
Radiation Therapy
Reporting**

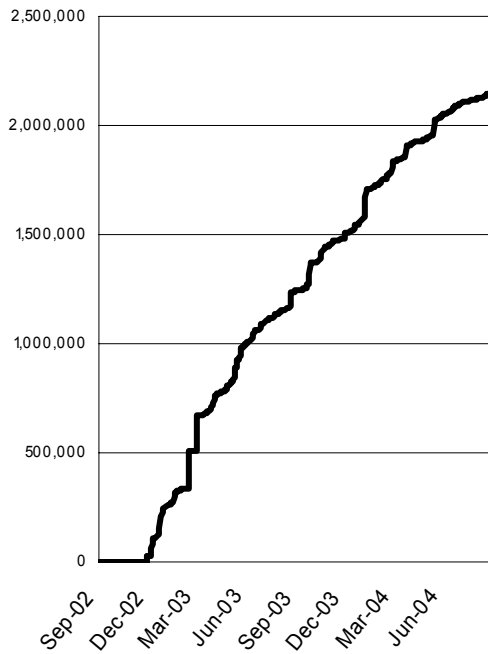
PROJECT DIRECTOR:
Lora Fleming, MD, PhD

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Jill Mackinnon, CTR

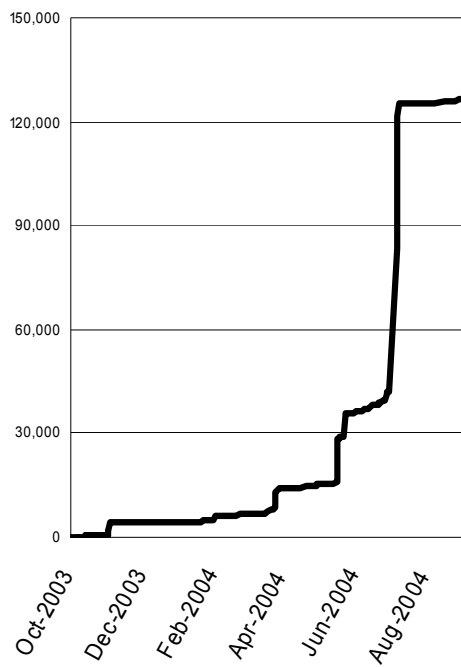
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Radiation



A Joint Project of the Sylvester Comprehensive Cancer Center and the Florida Department of Health

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