

Bringing the Fight to Cancer.

2016 Annual Report



Quality Study

Adherence to Adjuvant Systemic Therapy Following Primary Surgery in Stage II Breast Cancer Patients: Baylor Scott & White Medical Center – Grapevine 2012-2014

Data Review by Edward Clifford, MD

Introduction

The American Cancer Society estimates that approximately one in eight women in the United States will develop invasive breast cancer during their lifetime with about 246,000 new cases of invasive breast cancer being diagnosed in 2016¹. In addition to high incidence rates, breast cancer is the second leading cause of cancer death in women. Death rates from breast cancer have decreased since 1989 resulting in more than 2.8 million breast cancer survivors in the United States². Improvements in survival rates are attributed to advances in detection and treatment³⁻⁵.

Early stage breast cancer (stages I or II) is the most common invasive breast cancer in the United States. Stage II breast cancers are larger than stage I cancers and/or have spread to nearby lymph nodes. Stage II is divided into two categories: stage IIA and stage IIB. Tumor size and penetration into the lymph nodes determines stage II categories. Survival rates for stage IIA may be slightly higher than for stage IIB. However, all women with stage II breast cancer are considered to have a good prognosis⁶.

Treatment for early stage breast cancer usually involves a combination of surgery, radiation

therapy, chemotherapy or hormone therapy. Primary surgery (lumpectomy or mastectomy) is typically the first step in treating early stage breast cancer. The need for and selection of various local and systemic therapies are based on several prognostic and predictive factors. Factors such as hormone receptor status Estrogen Receptor (ER), Progesterone Receptor (PR) and Human Epidermal Growth Factor Receptor 2 (HER2) help predict response to therapy. ER and PR tumor status should be determined for all samples of invasive breast cancer⁷. In addition to ER and PR, guidelines also recommend the determination of HER2 for all newly diagnosed invasive breast cancers. Following surgery, provider should consider adjuvant systemic therapy in the form of chemotherapy, radiation or hormone therapy based on individual risk and predicted sensitivity to treatment. The decision to use systemic adjuvant therapy requires collaboration between the health care team and patient in determining the balance between risk of recurrence and the benefits from therapy.

Several published results from the Early Breast Cancer Trialists Collaborative Group (EBCTCG) demonstrate the benefit of adjuvant systemic therapy in reducing cancer recurrence following primary surgery. In a meta-analysis, results show that adjuvant chemotherapy and tamoxifen demonstrated strong reductions in the odds of

cancer recurrence and death in all age groups for chemotherapy and endocrine therapy^{8,9}. In addition, a meta-analysis by the EBCTCG demonstrated a reduction in 10-year risk of recurrence in those who received whole breast irradiation versus those who did not following lumpectomy¹⁰. The results of EBCTCH meta-analysis¹¹ showed that radiation therapy and axillary node dissection following mastectomy reduced both recurrence and breast cancer mortality in women with one to three positive lymph nodes. Lastly, patients with invasive breast cancers that are hormone receptor positive should be considered for adjuvant endocrine therapy regardless of patient age, lymph node status or whether chemotherapy are to be administered¹².

The purpose of the following analysis is to evaluate treatment patterns based on hormone receptor status (ER/PR) and HER2 amplification following primary surgery in stage II breast cancer patients treated at Baylor Scott & White Medical Center – Grapevine from 2012-2014 in comparison to the national treatment guidelines from the National Comprehensive Cancer Network (NCCN).

Methods

Using the Baylor Scott & White Health North Texas Cancer Registry data, all stage II breast cancer

cases receiving primary surgery (lumpectomy or mastectomy) at Baylor Scott & White – Grapevine from 2012-2014 were compared to the evaluation and treatment guidelines published by the National Comprehensive Cancer Network (NCCN) for systematic treatment following surgery. To abstract stage II breast cancer patients, data was filtered by histology codes (85003, 85203 and 85223) and grouped by the cancer directed surgery code provided by the cancer registry. In addition to the analysis, the report contains demographic data of the sample, including surgery type, AJCC stage, age and race. In addition to descriptive data, the following 2016 NCCN guidelines act as the framework for the analysis:

1. Following lumpectomy, radiation therapy to follow chemotherapy when chemotherapy is indicated.
2. Following mastectomy, radiation therapy recommended.
3. ER Positive and/or PR Positive and HER2 Positive, adjuvant chemotherapy followed by endocrine therapy recommended.
4. ER Negative and PR Negative and HER2 Positive or HER2 Negative, adjuvant chemotherapy recommended.

Results

Breast Cancer Surgery

During the time period of calendar years 2012, 2013 and 2014, Baylor Scott & White – Grapevine diagnosed and/or treated 337 breast cancers. The population by AJCC Stage breakdown was Stage 0-15 percent, Stage I – 46 percent, Stage II – 22 percent, Stage III – 4 percent, Stage IV – 1 percent, and Unknown Stage – 12 percent. For the purpose of this study, Stage II breast cancer treatment will be reviewed.

From the population of 337 diagnosed and/or treated breast cancers, Baylor Scott & White – Grapevine encountered 65 Stage II breast cancers. Primary cancer directed surgeries of which 28 (43 percent) were lumpectomies and 37 (57 percent) were mastectomies. In those patients receiving primary surgery, 64.61 percent were 51 years of age or above and 93.84 percent were white. Divided by AJCC stage treated at Baylor Scott & White – Grapevine, 68.75 percent were IIA, 23.43 percent were IIB and 7.81 percent were II.

Treatment Following Primary Surgery

Of those receiving a lumpectomy:

- 20 (71.42 percent) were ER Positive and/or PR Negative tumors.
- Eight (28.57 percent) were ER Negative and PR Negative tumors.

All but three lumpectomy ER Positive and PR Positive/Negative patients received adjuvant systemic therapy with the majority receiving radiation and chemotherapy. One of the three refused all treatment. Seven of eight lumpectomy patients with ER Positive and PR Positive/Negative status received chemotherapy with six patients receiving radiation therapy. The two not receiving radiation therapy were “not recommended” due to age and comorbidities.

Of those receiving mastectomies:

- 28 (77.77 percent) were ER Positive and PR Positive/Negative tumors.
- Seven (19.44 percent) were ER Negative and PR Negative tumors.
- One was unknown ER/PR.

A total of 26 of the 28 mastectomy patients with ER Positive and PR Positive/Negative status were documented as receiving chemotherapy and/

or hormone therapy with one patient refusing treatment. Six of the seven mastectomy patients with ER Negative and/or PR Negative received chemotherapy with the seventh refusing treatment.

Per NCCN guidelines, radiation therapy is recommended following lumpectomy. Twenty-two of the 28 patients receiving a lumpectomy at Baylor Scott & White – Grapevine had documentation in the Cancer Registry of receiving radiation therapy or radiation was recommended following surgery (78.57 percent). Of the six with no documentation of radiation therapy, three were over the age of 70 (10.71 percent). Patients greater than 70 years of age are excluded in the NCCN guideline. One patient refused treatment (3.57 percent). There was no documentation of why the remaining two patients did not receive radiation therapy in the hospital medical record. In addition, 85 percent of lumpectomy patients with ER Positive and PR Positive/Negative status received hormone therapy; while one refused hormonal treatment although it was recommended (5 percent).

The guidelines also strongly recommend that mastectomy patients receive radiation therapy following surgery. The majority of mastectomy patients received hormone or chemotherapy with only 10 patients receiving radiation therapy. This finding may be due to the nature of the tumor or the lack of documentation noted in the Cancer Registry.

ER Positive and PR Positive/Negative with HER2 Positive Expression

Of all stage II breast cancer patients treated at Baylor Scott & White – Grapevine, seven patients presented with ER Positive and PR Positive/Negative status with HER2 Positive expression. All patients elected to proceed with mastectomy. All patients received chemotherapy and hormone therapy. The NCCN guidelines recommend that

patients with ER Positive and PR Negative tumors with HER2 Positive expression receive adjuvant chemotherapy followed by endocrine therapy. Of all patients with ER Positive and PR Positive/Negative status with HER2 Positive expression, all (100 percent) received chemotherapy. All (100 percent) received hormone therapy, which aligns with guidelines. In addition, five received Immunotherapy (71.4 percent).

ER Negative and PR Negative Status with Positive or Negative HER2 Expression

Of all stage II breast cancer patients treated at Baylor Scott & White – Grapevine, 15 patients presented with ER Negative and PR Negative tumor status with Positive or Negative HER2 expression. Eight patients received a lumpectomy and seven patients received a mastectomy. The majority of lumpectomy patients received radiation (75 percent) and chemotherapy (87.5 percent). One lumpectomy patient did not receive radiation due to age.

Six out of seven mastectomy patients received chemotherapy (85.7 percent) in addition to surgery. One mastectomy patient refused chemotherapy post-operatively. Given that hormone receptor status was negative for all patients, none received hormone therapy. According to NCCN guidelines, patients with ER Negative and PR Negative tumors and HER2 Positive or HER2 Negative expressions, adjuvant chemotherapy is recommended. All were recommended to receive chemotherapy, which aligns with guidelines.

Discussion

The first course of treatment for stage II breast cancer is primary surgery either lumpectomy or mastectomy. Women treated with lumpectomy are treated with radiation therapy following surgery while women who have a mastectomy are typically treated with radiation if the cancer spreads to

the lymph nodes. Systemic adjuvant therapy is recommended for women with stage II breast cancer. Systemic treatment can occur before or after surgery takes place. In some cases, systemic therapy will be started before surgery and continue following surgery.

Several studies published by the EBCTCG provide the framework for determining the decision to use systemic adjuvant therapy after surgical treatment. The decision to use systemic adjuvant therapy requires the consideration of various factors, including the risk for disease recurrence and the benefit from applying adjuvant therapy. Importantly, the decision making process requires the collaboration between the health care team and the patient.

This analysis demonstrates that Baylor Scott & White – Grapevine is in accordance with the examined NCCN guidelines for treatment following primary surgery in stage II breast cancer patients. A few cases did not meet recommended guidelines but this is likely due to the nature of the tumor and/or patient educated treatment decision.

References

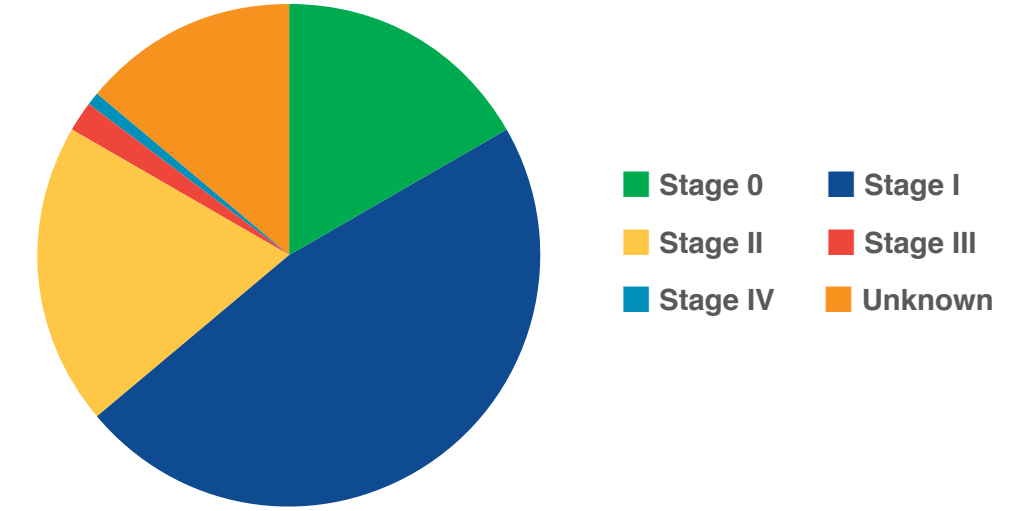
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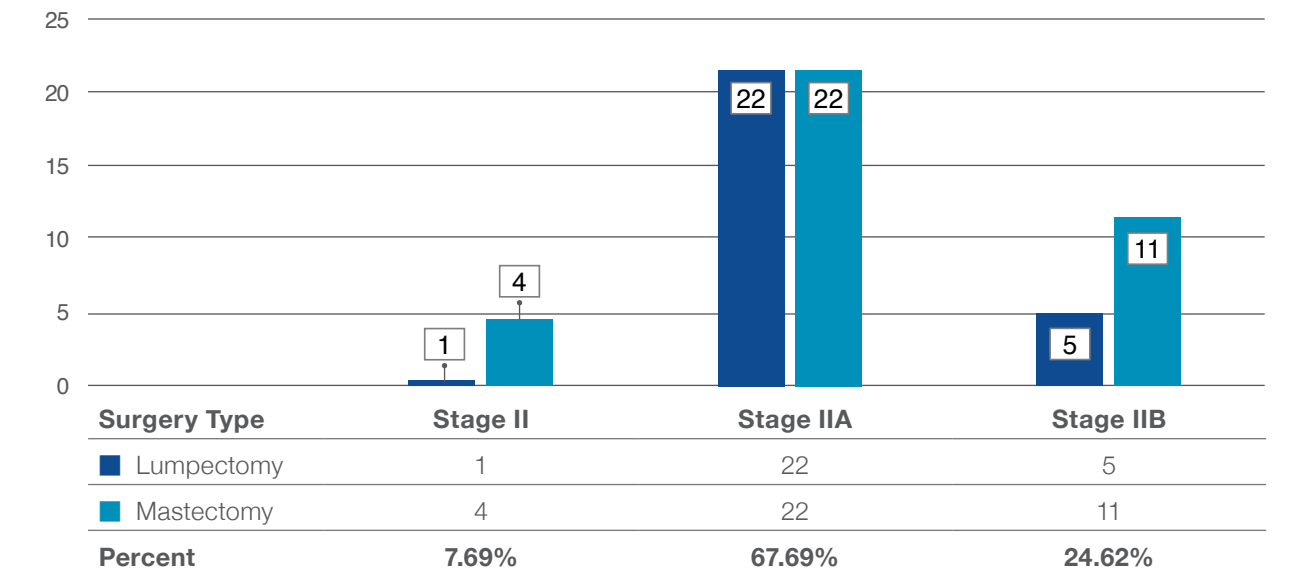
Surgery Type	Total
Lumpectomy	28
Mastectomy	37
Total	65

Age Group	Frequency	Percent
less than 30	2	3.0%
31-40	4	6.15%
41-50	16	24.61%
51-60	20	30.76%
61-70	17	26.15%
71 or greater	6	9.24%
Total	65	100%

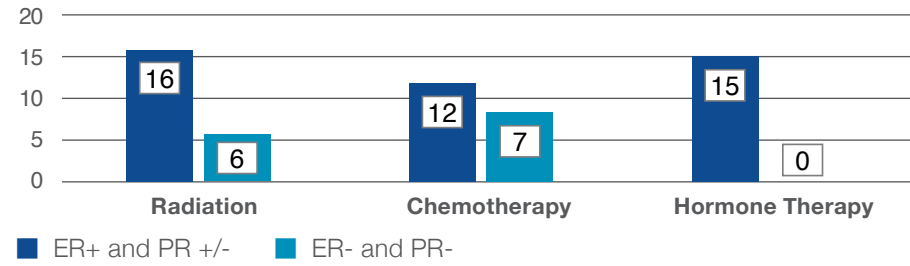
Race	Frequency	Percent
White	61	93.85%
Black	2	3.07%
Asian	1	1.54%
Other/Unknown	1	1.54%
Total	65	100%
71 or greater	6	9.24%
Total	65	100%



Breast Cancer Surgery Type by Stage
Baylor Scott & White Medical Center – Grapevine 2012-2014

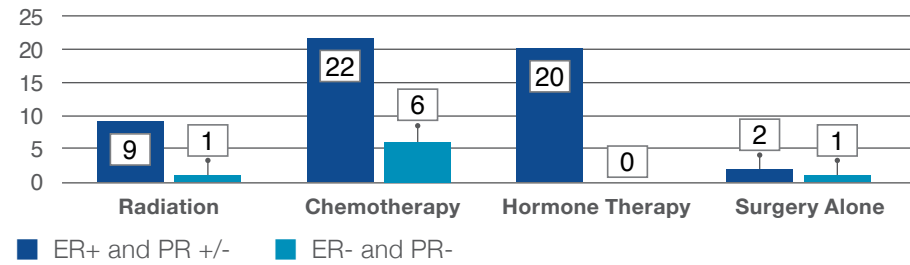


**Treatment Type Following Lumpectomy Based ER/PR Status
Baylor Scott & White Medical Center – Grapevine 2012-2014**



Status	Lumpectomy Pts	Percent
ER Positive and PR +/-	20	71.43%
ER -/PR -	8	28.57%
Total	28	100%

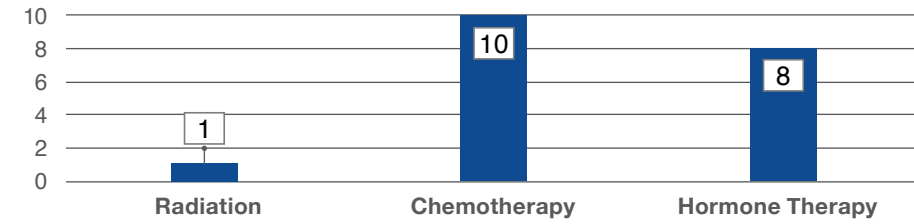
**Treatment Type Following Mastectomy Based on ER/PR Status
Baylor Scott & White Medical Center – Grapevine 2012-2014**



Status	Lumpectomy Pts	Percent
ER +/-PR+ or -	28	77.78%
ER-/PR-	7	19.45%
Unknown	1	2.77%

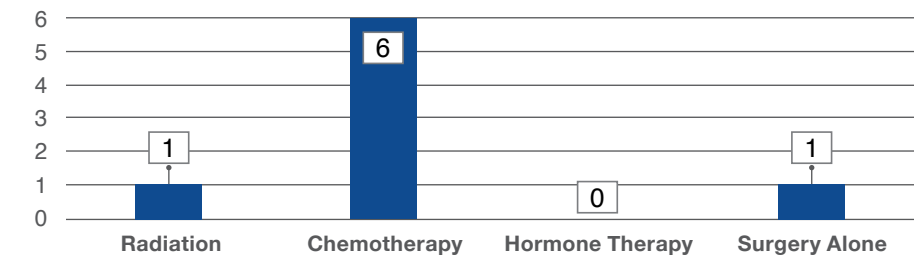
	Lumpectomy	Mastectomy	Total
ER+ and PR + or - and HER2 +	1	6	7
ER- and PR- and HER2 +/-	8	7	15
Total	9	13	22

**Frequency of Treatment Based on ER+ and PR +/- and HER2+
Baylor Scott & White Medical Center – Grapevine 2012-2014**



ER+ and PR +/- and HER2 +	Lumpectomy	Mastectomy	Total
Radiation/Chemo/Hormone	1	0	1
Radiation/Hormone	0	0	0
Chemo/Hormone	0	4	4
Chemo Only	0	6	6
Hormone Only	0	4	4

**Frequency of Treatment Based on ER- and PR- and HER2+/-
Baylor Scott & White Medical Center – Grapevine 2012-2014**



ER- and PR- and HER2 +/-	Lumpectomy	Mastectomy	Total
Radiation/Chemo	5	1	6
Chemo Only	2	5	7
Surgery Only	0	1	1



Cancer Screenings

Baylor Scott & White Medical Center – Grapevine 2016

SCREENING TYPE	NUMBER OF 2016 SCREENINGS	NUMBER AT RISK	CANCERS DIAGNOSED
Breast	8,537	698	29
Colon	657	87	100
Low-Dose CT Lung	15	1	0

Cancer Registry

	NCDB Target	CoC State of Texas Performance Rate	CoC Census Region (West) Performance Rate	All CoC Programs Performance Rate	Baylor Scott & White – Grapevine Performance Rate			
					2015 Forward	Diagnosis Year 2014 (CoC)	2013*	2014*
Breast Cancer								
BCS: Breast conservation surgery rate for women with AJCC clinical stage 0, I, or II breast cancer	NA	54.0%	57.0%	64.0%	56.0%	66.0%	67.0%	
NbX: Image or palpation-guided needle biopsy (core or FNA) is performed for the treatment of breast cancer (Quality Improvement Measure - Released Spring 2014)	80.0%	88.8%	87.5%	87.3%	100.0%	100.0%	96.0%	
HT: Adjuvant hormonal therapy: Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1cNoMo, or Stage II or III hormone receptor positive breast cancer (Accountability Measure - Released Fall 2008)	90.0%	90.5%	90.4%	93.2%	96.0%	97.0%	93.0%	
MASRT: Radiation therapy is considered or administered following any mastectomy within 1 year (365 days) of diagnosis for women with >= 4 positive lymph nodes (Accountability Measure)	90.0%	82.0%	83.3%	87.8%	100.0%	100.0%	100.0%	
BCRST: Post breast conserving surgery irradiation: Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 and receiving breast conserving surgery for breast cancer (Accountability Measure - Released Fall 2008)	90.0%	86.8%	88.6%	91.8%	93.0%	97.0%	97.0%	
MAC: Adjuvant chemotherapy: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cNoMo, or Stage II or III hormone receptor negative breast cancer (Accountability Measure - Released Fall 2008)	NA	92.9%	92.1%	93.5%	83.0%	100.0%	100.0%	
Colorectal Cancer								
ACT: Adjuvant chemotherapy: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis to patients under age 80 with AJCC III (lymph node positive) colon cancer (Accountability Measure - Released Fall 2008)	NA	90.0%	97.7%	93.0%	91.0%	100.0%	85.0%	
12 RLN: Surgical resection includes at least 12 lymph nodes: At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer (Quality Improvement - Released Fall 2008)	85.0%	90.5%	89.1%	87.8%	94.0%	100.0%	94.0%	
Rectal Cancer								
RECRCT: Pre-operative chemo and radiation are administered for clinical AJCC T3N0, T4N0, or Stage III; or Postoperative chemo and radiation are administered within 180 days of diagnosis for clinical AJCC T1-2N0 with pathologic AJCC T3N0, T4N0, or Stage III; or treatment is considered; for patients under the age of 80 receiving resection for rectal cancer (Quality Improvement - Released Spring 2015)	85.0%	86.1%	84.9%	84.6%	0.0%	89.0%	100.0%	

	NCDB Target	CoC State of Texas Performance Rate	CoC Census Region (West) Performance Rate	All CoC Programs Performance Rate	Baylor Scott & White – Grapevine Performance Rate			
					2015 Forward	Diagnosis Year 2014 (CoC)	2013*	2014*
Gastric								
G15RLN: At least 15 regional lymph nodes are removed and pathologically examined for resected gastric cancer (Quality Improvement - Released Fall 2014)	80.0%	87.3%	88.9%	89.4%	NA	NA	NA	
Non-Small Cell Lung								
10RLN: At least 10 regional lymph nodes are removed and pathologically examined for AJCC Stage 1A, 1B, IIA, and IIB resected NSCLC (Surveillance Measure - Released Fall 2014)	NA	39.4%	37.1%	38.9%	50.0%	33.0%	50.0%	
LNoSurg: Surgery is not first course of treatment for cN2, M0 cases (Quality Improvement)	85.0%	90.2%	91.2%	90.6%	0.0%	50.0%	NA	
LCT: Systemic chemotherapy is considered or administered within 4 months to the day pre-operatively or day of surgery to 6 months postoperatively or surgically resected cases with pathologic lymph node positive (pN1) and (pN2) NSCLC (Quality Improvement - Released Fall 2014)	85.0%	80.5%	84.7%	87.8%	50.0%	100.0%	100.0%	
Cervix								
CBRR: Use of brachytherapy in patients treated with primary radiation with curative intent in any stage of cervical cancer (Surveillance Measure - Released Spring 2015)	NA	74.2%	69.8%	72.1%	NA	NA	NA	
CERRT: Radiation therapy completed within 60 days of initiation of radiation among women diagnosed with any stage of cervical cancer (Surveillance Measure - Released Spring 2015)	NA	79.6%	78.6%	77.9%	NA	NA	NA	
CERCT: Chemotherapy administered to cervical cancer patients who received radiation for Stages IB2-IV cancer (Group 1) or with positive pelvic nodes, positive surgical margin, and/or positive parametrium (Group 2) (Surveillance Measure - Released Spring 2015)	NA	88.7%	86.7%	86.6%	NA	NA	NA	
Endometrium								
ENDLRC: Endoscopic, laparoscopic, or robotic performed for all endometrial cancer (excluding sarcoma and lymphoma), for all stages except Stage IV (Surveillance Measure- Released Fall 2015)	NA	54.9%	54.6%	60.6%	86.0%	88.0%	38.0%	
ENDCTR: Chemotherapy and/or radiation administered to patients with Stage IIIC or IV endometrial cancer (Surveillance Measure - Released Fall 2015)	NA	74.8%	72.6%	77.8%	NA	50.0%	100.0%	
Ovary								
OVSAL: Salpingo-oophorectomy with omentectomy, debulking/cytoreductive surgery, or pelvic extenteration in Stages I-IIIC ovarian cancer (Surveillance Measure - Released Fall 2015)	NA	63.9%	64.0%	71.2%	100.0%	100.0%	100.0%	
Bladder								
BL2RLN: At least 2 lymph nodes are removed in patients under 80 undergoing partial or radical cystectomy (Surveillance Measure - Released Spring 2016)	NA	87.3%	88.9%	89.4%	NA	NA	NA	

*Source: Data is pending results by the Rapid Quality Reporting Process via the National Cancer Data Base.

**The facility did not have data to measure these metrics.



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