

The Miriam Hospital

A Lifespan Partner

Cancer Program

Annual Report 2011

THE MIRIAM HOSPITAL

The Comprehensive Cancer Center

Rhode Island Hospital • The Miriam Hospital • Newport Hospital

2011 Administrative Report of the Cancer Control Committee

Cancer Control Committee Membership - 2011

Edward Wittels, MD, Chair Division Director, Hematology/Oncology – TMH

Arnold Herman, MD
Surgeon –TMH
COC Cancer Liaison Physician & Co-Chairman
American College of Surgeons
Commission on Cancer Liaison
407 East Ave, Pawtucket, RI 02860

Cheryl Albright
American Cancer Society

Pamela Bakalarski, MPA, CCRP Manager, Medical Oncology Clinical Research – RI Hospital (RIH) & TMH

> Megan Begnoche, RN, MSN, AOCN Clinical Nurse Specialist

Eve Block, MD Palliative Care/Pain Management

Sheila Earle, BA, CTR Oncology Data Management

Mary Flynn, PhD, RD, LDN Nutrition Services – TMH

Kathleen Higginbotham, LICSW Clinical Social Worker

Mary Hillstrom, MD Radiology – TMH

Donald Joyce, MD Gabriela Masko, MD North Main Radiation Oncology

Cancer Control Committee Membership - 2011

William J. Kirkpatrick, MSW Director of Clinical Social Work, Interpreter Services and Spiritual Care

Susan Korber, MS, RN, OCN, NE-BC Director of Cancer Services and Ambulatory Care - TMH

> Georgette Mahoney, RPH Manager, Pharmacy - TMH

Carrie Marcil, PT Rehabilitation Services – TMH

Jayne Ritz, RN, BSN, OCN Nurse Manager 4B

Murray Resnick, MD Pathology – RIH & TMH

William Sikov, MD Hematology/Oncology – TMH

Marsha Stephenson, RN, BSN, CHPN Home and Hospice Care of Rhode Island 1085 North Main Street – Providence, RI 02904

> Rochelle Strenger, MD Hematology/Oncology –TMH

Ellen Therrien, RN Hematology/Oncology Nurse Navigator – TMH

> Christina Vieira, BA, CTR Oncology Data Management

Matthew Vrees, MD Colorectal Surgery - TMH

Diana Wantoch, RN, MBA, CPHQ Director, Quality Management – TMH

Marsha Weiss, RN, MS Director, Community Outreach

2011 Administrative Report of the Cancer Control Committee

The Cancer Control Committee oversees all of the various services relating to cancer care at The Miriam Hospital (TMH). Physicians representing Medical Oncology, Radiation Oncology, Surgery, Thoracic Surgery, Urology, Colorectal Surgery, Pathology, Radiology, and Palliative Care/Hospice serve on this committee as well as representatives from Nursing, Rehabilitation Services, Social Work, Spiritual Care, Interpreter Services, Pharmacy, Oncology Data Management, Oncology Clinical Research, Nutrition Services, Community Outreach, Quality Management, Health Information Services and the American Cancer Society.

The Miriam Hospital Cancer Program first achieved approval from the American College of Surgeons' Commission on Cancer in 1992. In our most recent survey from April 2010 all eight standards were met and in the spring of 2011 we were officially notified that TMH received the Outstanding Achievement Award for our survey an honor achieved by only 90 hospitals nationwide. The next survey is scheduled for the fall of 2012 and will be a combined survey with the National Accreditation Program for Breast Cancer Centers.

The goals and achievements of the Cancer Program for 2011 were as follows:

Programmatic:

The Miriam Hospital Cancer Program is actively pursuing a Survivorship Program for all cancer patients. The Miriam Hospital is partnering with Rhode Island Hospital in this initiative. The committee has developed a pilot program for breast and colon; the intent is to expand this to all malignancies in the upcoming months.

Clinical:

The clinical goal for 2011 was to expand the Navigator concept to all of our patients. At the beginning of the year we had a Navigator for our breast cancer patients. Thanks to a generous donation from the Decof family we have been able to hire two part time navigators for GI Oncology and GU Oncology; the hope is to continue to expand this program to cover all of the major malignancies.

The clinical study this year was conducted by Dr. William Sikov. This study explored the diagnosis and treatment of small (<1cm), lymph node negative, her2 positive and triple negative breast cancers in The Miriam population and expanded this study to include the four regional hospitals in Rhode Island. This study is included in this report.

Quality:

The quality goal for this year was to participate in the Rapid Quality Reporting System with The Commission on Cancer. The goal is to evaluate The Miriam Hospital rates of appropriate treatment using standard guidelines for breast and colorectal cancer. The Miriam Hospital has enrolled in this program and is following reports to watch for any discrepancies in treatment.

Research:

We continue to try to make research protocols available to our patients and encourage their enrollments. The clinical research office is directed by Dr. Howard Safran who aggressively pursues studies including national protocols, investigator initiated protocols, and pharmaceutical protocols. It is the committee's intent to increase our clinical trial accrual rates to 8% of our analytic caseload.

Community Outreach:

The goal for 2011 has been to expand and reorganize support groups at The Miriam Hospital. Currently there is a support group for Men's Health, facilitated by a dedicated Oncology Social Worker, additionally; in partnership with Jewish Family Services a breast support group has been initiated. "Drop in" support groups are scheduled once a week in The Fain Clinic. Additionally, the social work department and medical oncology are coordinating monthly sessions with patients and their families where they can have lunch with a physician and discuss topics relevant to their disease.

CANCER CLINICAL RESEARCH 2011

The Miriam Hospital Lifespan Oncology Clinical Research (LOCR) Office accrued 78 patients during the calendar year 2011. There has been a 35% increase in the amount of Pharmaceuticals trial accruals since CY10 and a 39% increase of overall accruals since 2010 for LOCR alone. There were also 4 patients in 2011 referred for protocol treatment elsewhere.

The Mega GU Suite opened in 2011 as a result of the overall importance of treating patients in a dedicated environment. Dr. Mega has been involved in a new Pharmaceutical Prostate trial entitled "A Phase 1 Dose-Escalation Study of PSMA ADC in Subjects with Progressive, castration-resistant Metastatic Prostate Cancer". Also opened in 2011 was another GU study entitled: "A Randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of pazopanib as adjuvant therapy for subjects with localized or locally advanced Renal cell carcinoma following nephrectomy". Overall, the number of studies involving GU accounted for 23% of overall accruals.

Of note, a study was instituted involving a Chemotherapy Teaching Assessment Study, which asked study volunteers about their level of understanding concerning their treatment. This study accounted for 32% of overall accruals at TMH.

.The Abraxane trial for Breast Cancer continues to accrue under the supervision of Dr. William Sikov, with 4 accruals to Abraxane studies in 2011, and 11 breast accruals at TMH overall.

Various other studies through the Radiation Therapy Oncology Group (RTOG) have been utilized in 2010, including those for Esophageal and Pancreatic Cancer.

In addition, several new trials related to Pancreas, Gastrointestinal, Esophagus and Lung cancer have been opened during 2011, with multiple Principal Investigators including:

- LS-P-Hedgehog: A Phase 1b/2 Study Evaluating IPI-926 in Combination with Gemcitabine in Patients with Metastatic Pancreatic Cancer (PROTOCOL IPI-926-03);
 PI: Howard Safran, MD
- LS-P-Aurora A: A Phase I Dose Escalation Study of MLN8237, an Aurora A Kinase Inhibitor, in Adult Patients with Nonhematological Malignancies, Followed by a Phase 2 of MLN8237 in Lung, Breast, Head and Neck, or Gastroesophageal Malignancies; PI: Kimberly Perez, MD
- RTOG 1010: A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma;

PI: Howard Safran, MD

- CALGB 30801: A Randomized Phase III Double Blind Trial Evaluating Selective Cox-2 Inhibition in Cox-2 Expressing Advanced Non-Small Cell Lung Cancer;
 PI; Humera Khurshid, MD
- BrUOG 243: Phase II Study of Cabazitaxel for Metastatic Gastroesophageal Adenocarcinomas That Have Relapsed After At Least One Line Of Chemotherapy; PI: Howard Safran, MD

CALGB 80803: Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer;

PI: Howard Safran, MD

• RTOG 1102: A Phase I Study of Induction Ganitumab and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer;

PI: Howard Safran, MD

In addition, new investigators have become involved in various BrUOG studies including Angela Taber, MD for **BrUOG Non-small cell Lung Cancer (NSCL) 233** and Jorge Castillo, MD for **BrUOG Non-Hodgkin's Lymphoma (NHL) 227**. Additional studies are underway for 2012.

Oncology Data Management Department 2010

The Oncology Data Management Department maintains a computerized data system for collecting, managing and analyzing information on patients that are diagnosed and/or treated at the Miriam Hospital. This database has proven to be a valuable component of the hospital's Commission on Cancer Approval Program since 1992. Information on cancer site, stage, histology, treatment, survival, and epidemiological characteristics is maintained in accordance with Commission on Cancer quality standards and conforms to all HIPAA confidentiality standards.

Susan Korber, RN, MSN, OCN, NE-BC is responsible for the overall coordination and management of the Oncology Data Management Department. Sheila Earle, BA, CTR, Christina Vieira, BA, CTR, Carol Ovios, RN, CTR, and Merrill Rodenbaugh perform the daily coordination and management of the clinical information. The information contained in the database is provided to our researchers, administrators, and clinicians to assist in research, grant application, administrative planning, and clinical outcome measurement activities. In addition, the cancer registrars coordinate the many prospective tumor board conferences held at The Miriam Hospital.

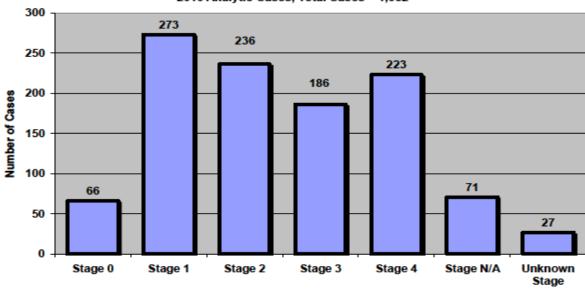
The Department reports new cases of cancer on a monthly basis to the Rhode Island Cancer Registry, as mandated by the rules and regulations of the Department of Health, State of Rhode Island. The registry also participates in the annual Call for Data of the National Cancer Data Base (NCDB). The NCDB is a nationwide oncology database which collects data items required by the Commission on Cancer Approvals Program. This data allows comparative analysis with other hospitals of similar size and organization, enabling hospitals to evaluate the quality of care of cancer patients.

A total of 1,211 cases have been collected in the TMH Oncology Database for year 2010 with numbers trending upwards to 19,653 in the total oncology database since 1992. During the year 2010, 1,082 analytic and 128 non-analytic cases were accessioned.

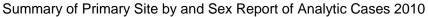
A lifetime follow-up rate of at least 90% is maintained by the Data Management staff on all analytic patients. Early diagnosis, treatment, intervention, and long-term follow-up surveillance for continuity of care are important factors in long-term cancer survival.

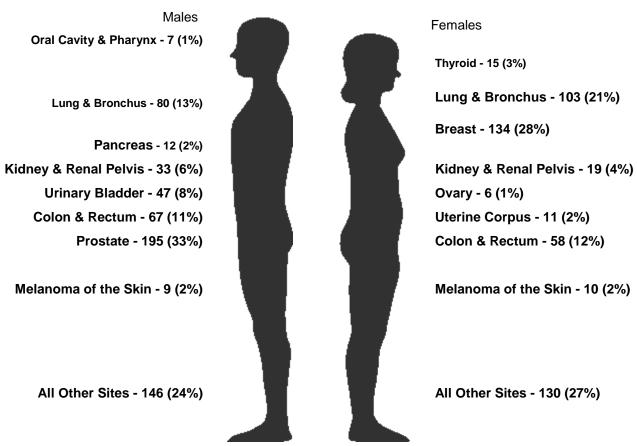
The Oncology Database serves as a resource for the Medical Staff and researchers to apply registry data towards the management of care for all cancer patients. The registry filled 20 requests for data for studies in 2010. The registry staff is available to assist members of the Medical Staff in gathering statistics for any endeavor utilizing cancer data and can be reached by calling (401)793-2224 or 2052.

The Miriam Hospital AJCC Stage of Disease at Diagnosis 2010 Analytic Cases, Total Cases = 1,082









Images reprinted by the permission of the American Cancer Society, Inc. from www.cancer.org. All rights reserved.

The Miriam Hospital 2010 Primary Site Distribution

		<u>Sex</u>			<u>Stag</u>	<u>e Distribu</u>	ution - Ar	nalytic Cases	s Only	
PRIMARY SITE	Total (%)	М	F	Stg 0	Stg I	Stg II	Stg III	Stg IV	Stg N/A	Unk
ORAL CAVITY & PHARYNX	8 (0.7%)	6	2	0	1	0	2	4	0	1
Tongue	5 (0.5%)	3	2	0	1	0	1	3	0	0
Floor of Mouth	1 (0.1%)	1	0	0	0	0	0	1	0	0
Gum & Other Mouth	2 (0.2%)	2	0	0	0	0	1	0	0	1
DIGESTIVE SYSTEM	212 (19.6%)	120	92	8	32	36	68	54	2	12
Esophagus	9 (0.8%)	9	0	0	1	1	5	0	0	2
Stomach	18 (1.7%)	10	8	1	4	1	4	5	0	3
Small Intestine	9 (0.8%)	5	4	0	0	1	3	5	0	0
Colon Excluding Rectum	81 (7.5%)	41	40	3	15	13	31	17	0	2
Cecum	21	8	13	0	4	6	6	5	0	0
Appendix	2	1	1	0	0	0	1	1	0	0
Ascending Colon	17	8	9	0	5	3	7	2	0	0
Hepatic Flexure	5	1	4	0	1	0	2	2	0	0
Transverse Colon	5	3	2	0	0	1	4	0	0	0
Splenic Flexure	3	3	0	0	1	0	2	0	0	0
Descending Colon	3	1	2	0	1	0	1	0	0	1
Sigmoid Colon	21	14	7	3	3	2	8	4	0	1
Large Intestine, NOS	4	2	2	0	0	1	0	3	0	0
Rectum & Rectosigmoid	44 (4.1%)	26	18	0	9	9	19	4	0	3
Rectosigmoid Junction	13	8	5	0	4	2	7	0	0	0
Rectum	31	18	13	0	5	7	12	4	0	3
Anus, Anal Canal & Anorectum	12 (1.1%)	7	5	4	0	4	3	0	0	1
Liver & Intrahepatic Bile Duct	9 (0.8%)	6	3	0	0	2	1	5	1	0
Liver	7	6	1	0	0	2	1	3	1	0
Intrahepatic Bile Duct	2	0	2	0	0	0	0	2	0	0
Gallbladder	4 (0.4%)	1	3	0	1	1	0	2	0	0
Other Biliary	2 (0.2%)	2	0	0	1	0	0	1	0	0
Pancreas	23 (2.1%)	12	11	0	1	4	2	15	0	1
Other Digestive Organs	1 (0.1%)	1	0	0	0	0	0	0	1	0
RESPIRATORY SYSTEM	191 (17.7%)	88	103	1	39	17	34	93	1	6
Larynx	9 (0.8%)	8	1	1	2	0	2	4	0	0
Lung & Bronchus	182 (16.8%)	80	102	0	37	17	32	89	1	6
SOFT TISSUE	7 (0.6%)	3	4	0	5	1	0	1	0	0
SKIN EXC BASAL&SQUAMOUS	17 (1.6%)	8	9	5	4	4	1	2	0	1
Melanoma Skin	16 (1.5%)	7	9	5	4	4	0	2	0	1
Other Non-Epithelial Skin	1 (0.1%)	1	0	0	0	0	1	0	0	0
BREAST	136 (12.6%)	2	134	24	67	28	14	2	0	1
FEMALE GENITAL SYSTEM	22 (2.0%)	0	22	0	12	2	3	5	0	0
Cervix Uteri	3 (0.3%)	0	3	0	2	0	0	1	0	0
	- (/-)	-	-	-	_	-	-	-	-	-

Corpus & Uterus, NOS 11 (1.0%) 0 11 0 7 1 2 1 0 0

Ovary	6 (0.6%)	0	6	0	2	1	0	3	0	0
Other Female Genital Organs	2 (0.2%)	0	2	0	1	0	1	0	0	0
MALE GENITAL SYSTEM	205 (18.9%)	205	0	0	25	123	36	20	0	1
Prostate	195 (18.0%)	195	0	0	17	123	35	19	0	1
Testis	8 (0.7%)	8	0	0	7	0	1	0	0	0
Penis	2 (0.2%)	2	0	0	1	0	0	1	0	0
URINARY SYSTEM	117 (10.8%)	81	36	28	56	9	7	13	1	3
Urinary Bladder	63 (5.8%)	47	16	26	20	8	0	7	0	2
Kidney & Renal Pelvis	52 (4.8%)	33	19	1	36	1	7	5	1	1
Ureter	2 (0.2%)	1	1	1	0	0	0	1	0	0
BRAIN & OTHER NERVOUS SYSTEM	12 (1.1%)	3	9	0	0	0	0	0	12	0
Brain	1 (0.1%)	0	1	0	0	0	0	0	1	0
Other Nervous System	11 (1.0%)	3	8	0	0	0	0	0	11	0
ENDOCRINE SYSTEM	25 (2.3%)	10	15	0	18	1	3	2	1	0
Thyroid	24 (2.2%)	9	15	0	18	1	3	2	0	0
Other Endocrine incl Thymus	1 (0.1%)	1	0	0	0	0	0	0	1	0
LYMPHOMA	72 (6.7%)	38	34	0	14	14	18	24	0	2
Hodgkin Lymphoma	12 (1.1%)	6	6	0	0	4	4	3	0	1
Non-Hodgkin Lymphoma	60 (5.5%)	32	28	0	14	10	14	21	0	1
NHL - Nodal	47	27	20	0	7	9	14	17	0	0
NHL - Extranodal	13	5	8	0	7	1	0	4	0	1
MYELOMA	7 (0.6%)	3	4	0	0	0	0	0	7	0
LEUKEMIA	28 (2.6%)	15	13	0	0	0	0	0	28	0
Lymphocytic Leukemia	10 (0.9%)	3	7	0	0	0	0	0	10	0
Acute Lymphocytic Leukemia	2	1	1	0	0	0	0	0	2	0
Chronic Lymphocytic Leukemia	7	1	6	0	0	0	0	0	7	0
Other Lymphocytic	1	1	0	0	0	0	0	0	1	0
Leukemia Myeloid & Monocytic Leukemia	17 (1.6%)	12	5	0	0	0	0	0	17	0
Acute Myeloid Leukemia	14	9	5	0	0	0	0	0	14	0
Chronic Myeloid Leukemia	2	2	0	0	0	0	0	0	2	0
Other Myeloid/Monocytic Leukemia	1	1	0	0	0	0	0	0	1	0
Other Leukemia	1 (0.1%)	0	1	0	0	0	0	0	1	0
MESOTHELIOMA	4 (0.4%)	2	2	0	0	1	0	3	0	0
KAPOSI SARCOMA	2 (0.2%)	1	1	0	0	0	0	0	2	0
MISCELLANEOUS	17 (1.6%)	11	6	0	0	0	0	0	17	0
Total Analytic Cases	1,082	596	486	66	273	236	186	223	71	27

Clinical Social Work Activity in the Cancer Center in 2011

Clinical Social Work in The Miriam Hospital Cancer Center is a vital component within the larger interdisciplinary treatment team that cares for patients and families at all stages of disease. One aspect of the role of the clinical social worker is to provide direct service. This aspect takes many forms and can include crisis intervention, short-term counseling, health education as well as referral to services and resources in the larger community.

The Oncology Clinical Social Worker provides on-going emotional support to patients and families as they move through the treatment process. This begins as early as when the initial diagnosis is presented, moves through the teaching visit (where an in-depth psychosocial assessment is performed) and continues through treatment and beyond. The social worker is present for milestone medical visits, disease progression conversations and the social worker is present for end of life discussions. One important facet of the clinical social worker's role is to attend specifically to the emotional needs of patients' children.

Many indirect activities were also accomplished by the clinical social worker in 2011. During the past year the social worker received permission from the NCCN to pilot the Distress Thermometer, a scale that measures the emotional distress of patients over the course of their treatment. The Cancer Center will be able to provide this service in five languages and the pilot program will commence in 2012. The Men's Cancer Wellness Group as well as the Partners' Group were officially launched in 2011. These groups were specifically designed to address the emotional needs of the GU population. The clinical social worker also cochaired the Cancer Survivors Day committee.

The clinical social worker is a member of the Association of Oncology Social Workers (AOSW), the Social Work Oncology Group (SWOG), and participates in Avenues of Healing, the Women's Wellness Workshop, facilitates Look Good, Feel Better and is the liaison for The Miriam Hospital Woman's Association wig program and The Flanagan Foundation. A clinical social worker facilitates the Hematology/Oncology Fellows process group. The clinical social worker serves on several committees including the Survivorship Committee, the Pain and Palliative Care Committee and the Schwartz Rounds Executive Committee.

The Miriam Hospital Cancer Program 2011 Annual Report

<u>Diagnosis and Treatment of Small (<1 cm), Lymph Node-Negative HER2+ and Triple- Negative Breast Cancers</u>

William M. Sikov, MD

Introduction

Increases in the percentage of women undergoing regular screening mammography raises the number of premalignant lesions and noninvasive breast cancers found, reduces the median size of the invasive cancers diagnosed, and results in an increase in the number of small (<1 cm, T1a and T1b), node-negative cancers detected. Most of these early cancers are hormone receptor (estrogen and/or progesterone)-positive and human epidermal growth factor receptor 2 (HER2)-negative, typically less aggressive cancers with a low (<5-10%) likelihood of distant recurrence even in the absence of systemic adjuvant therapy. However, a significant minority of smaller tumors are high grade, and either HER2-positive or triple-negative (expressing neither of the hormone receptors or HER2). Retrospective analyses presented and published over the last few years have demonstrated that patients with these more aggressive T1a/b N0 cancers may be at increased risk of developing local recurrences and distant metastases, and thus may warrant at least consideration of systemic adjuvant therapy (1-3). This treatment could include cytotoxic chemotherapy, trastuzumab in HER2+ patients, and/or anti-hormonal therapies for the approximately 50% of HER2+ tumors that co-express hormone receptors. We undertook a review of patients diagnosed with either HER2+ or triplenegative (TNBC) T1a/b N0 breast cancers at the Miriam Hospital (TMH) over the past decade to see if there have been any changes in treatment recommended and received, and to see if this has impacted patient outcomes. We also sought to put our hospital's experience within the larger context of this group of patients treated at any of 4 hospitals in the region (in addition to TMH, Memorial Hospital of Rhode Island, Rhode Island Hospital, and Women and Infants Hospital).

Materials and Methods

With the assistance of the tumor registrars at the participating institutions, we identified patients with T1a (invasive component 1-5 mm in greatest dimension) or T1b (6-10 mm) N0 cancers diagnosed between 2000 and 2010. Pathology reports were reviewed to focus on the subset of patients who were either HER2+ or triple-negative. We excluded patients for whom information as to their hormone receptor and HER2 status were not available. Patients were considered HER2+ if their cancer was either reported as 3+ by immunohistochemical (IHC) staining or had a fluorescent-in-situ-hybridization (FISH) ratio (HER2/chromosome 17) of >2.2. Patients were considered hormone receptor-

negative (HR-) if their tumor stained negative (<1%) for both estrogen and progesterone receptors. Patients were considered node-negative if they had no focus of cancer \geq 0.2 mm in greatest dimension in any examined axillary lymph node.

Once patients were identified, data entered into the tumor registry and data from their outpatient (clinic) record were reviewed to determine treatment recommended and received, recurrence-free and overall survival. The latter endpoints were censored as of last date of contact. Results were analyzed by subtype (HER2+ or TNBC), tumor size (T1a vs. T1b), date of diagnosis, and hospital of record. Patients were classified by the hospital at which they received their definitive surgery (local excision or mastectomy), even if their diagnostic biopsy was performed at another site.

Results

- I. Demographics: A total of 1415 cases of T1a/b N0 breast cancer diagnosed and treated at one of the 4 hospitals between 2000 and 2012 were reviewed. Of these patients for whom sufficient information as to hormone receptor and HER2 status was available, 161 (11.4%) were confirmed to be either HER2+ (104) or TNBC (57). Of these, 34 (20 HER2+, of which 12 were hormone receptor-positive (HR+) and 8 HR-, and 14 TNBC) were treated at TMH (Table 1). The TMH patients had a median age of 56 (range 36-81). 8 were classified as T1a, 26 as T1b, and 19 (56%) were grade 3. Most (88%) of the tumors were invasive ductal carcinomas (IDC). These results are not dissimilar from those reported for the overall study population.
- II. Treatment recommended and received (Table 2): 27 (79%) of the patients underwent lumpectomy, 7 (21%) mastectomy, with 26 (77%) undergoing sentinel node sampling only compared to 8 (24%) who underwent a full axillary lymph node dissection. 12 (44%) of the lumpectomy patients received post-op radiation. Overall, slightly more than half of the patients (17, 53%) received adjuvant chemotherapy, 6 (30%) of the HER2+ patients received chemotherapy plus trastuzumab and 3 (15%) chemotherapy without trastuzumab. Of 12 patients with HR+/HER2+ cancers, 10 (83%) received adjuvant endocrine therapy, while 2 of the 8 patients (25%) who were HR- and HER2+ were started on endocrine therapy (presumably as secondary prevention therapy). Patients treated at TMH were not significantly more or less likely to receive adjuvant therapy than patients treated at other hospitals (see Table 1).
- III. Outcomes: Median follow-up for the TMH cohort is 48.5 months (range 2-118). Of the 34 patients treated at TMH, only one a 72 year-old woman with a T1b (9 mm) HR+/HER2+ IDC who did not receive chemotherapy, trastuzumab or endocrine therapy developed distant metastases, 54 months from her diagnosis, and subsequently died of metastatic disease less than 3 months later. Another patient a 51 year-old woman with a 9 mm, HR-/HER2+ IDC who received adjuvant AC without trastuzumab developed a contralateral breast

cancer more than 5 years from her initial diagnosis. A third patient – an 80 year old woman with a 6 mm TNBC who received no adjuvant therapy – died of unrelated causes a little more than 2 years after her breast cancer diagnosis. For the overall study, in terms of treatment recommendations, multivariate analysis demonstrates that younger age, stage T1b (vs. T1a), high tumor grade and being both HR- and HER2+ were significantly predictive of the likelihood of the oncologist recommending (and the patient subsequently receiving) chemotherapy. The presence of LVI was marginally significant. Chemotherapy was also more often prescribed after 2006; this trend was significant for HER2+ patients (P=0.047), but not for TNBC (P=0.78). There was less anthracycline-based chemotherapy administered to HER2+ patients after approval of adjuvant trastuzumab in November 2006 (p<0.01) but no change in the TNBC group (p=0.40). However, after 2006 there was significantly more taxane use (p<0.001) for the entire population.

Since there were so few events in the TMH cohort, the following results and analysis are derived from the overall (4 hospital) patient group. Among the 161 patients, with a median follow-up of 46 months, there have been only 4 instances of distant recurrence, 3 locoregional recurrences, 2 diagnosed contralateral breast cancers and 4 non-cancer-related deaths. There has been only 1 relapse in the T1a group, no relapses in TN patients who received chemotherapy, no relapses in HER2+ patients who received trastuzumab and no relapses in HER2+/HR+ patients who received endocrine therapy. The Kaplan-Meier estimate of recurrence at 5 years for the overall study population is 6.0%, 2.6% for T1a and 7.9% for T1b, 7.7% for patients who did not receive chemotherapy compared to 4.0% for patients who did. The 95% confidence intervals for these comparisons overlap, and thus they are not statistically significant.

Within the overall patient population, trends suggest that older age and administration of chemotherapy may be associated with a reduced risk of relapse, while the presence of lymphovascular invasion (LVI) may increase the risk of relapse, but none of these reach statistical significance. However, if the analysis is limited to the patients with T1b tumors, older age (p=0.02) and receipt of chemotherapy (p=0.022) do correlate with improved recurrence-free survival while LVI (p=0.012) predicts for a higher risk of relapse.

Discussion

Following publication of the first large retrospective analysis of prognosis in patients with T1a/N0 cancers (2), results of several other analyses have been presented (4-9). While there appears to be a consensus that patients with small HER2+ and triple-negative breast cancers have a worse prognosis than those with small HR+/HER2- cancers, differences in outcomes do not always reach statistical significance. In most studies age (<50 vs. ≥50), tumor grade (3 vs. 1-2), hormone receptor status (HR- vs. HR+) and HER2 status (HER2+ vs. HER2-) are associated with a poorer prognosis, but there are disagreements as to the impact of tumor size (T1b vs.T1a) and LVI (present vs. absent) on recurrence-

free survival. The prognostic impact of other variables, such as proliferative index (mitotic index or Ki67), are commented on in only a few of these analyses. What percentage of and which patients received systemic adjuvant therapy, and what impact that treatment had on recurrence-free or overall survival is also reported in only a few of the retrospective series. The available data appears to be strongest favoring administration of chemotherapy and trastuzumab in HR-/HER2+ patients, even those with T1a tumors (10-11), but some groups of authors also argue in favor of treating at least the T1b triple-negative cancers with adjuvant chemotherapy.

Given the likelihood that the number of patients diagnosed with small (<1 cm) invasive breast cancers will increase with efforts to expand the availability of screening mammography, it becomes all the more important to identify markers of risk of local and distant recurrence so that effective treatment can be offered to higher risk patients while avoiding the cost and morbidity of such treatment in those at minimal risk of relapse. While there appears to be some justification for administering systemic adjuvant therapy to patients with T1b HER2+ and TNBC, there may be a subset of patients with T1a disease who also warrant treatment, such as the HR-/HER2+ patients or those with definite LVI despite their small tumor size. Of even greater importance may be identifying patients with higher grade, small cancers who can safely be followed off treatment, and the identification of effective, less toxic and, ideally, briefer and less costly regimens for patients diagnosed with smaller, high grade cancers.

Both HER2+ and TNBC cancers are comprised of subtypes with different biologic behavior; for example, it is clear that patients with HR+/HER2+ cancers have a better prognosis than patients with HR-/HER2+ cancers, but whether this is due to differences in biology or the beneficial effects of adjuvant endocrine therapy on the former group is not known. The role of combining endocrine therapy with HER2-targeted therapy, in the absence of chemotherapy, in such patients may warrant study, especially in patients with small HR+/HER2+ cancers. Among TNBC, while cancers with basal-like characteristics are most common, a number of other subtypes have been identified, including what are being called claudin-low tumors, that may have different prognoses and responses to treatment than the basal-like cancers. And what to do about aggressive small tumors detected in patients who carry a BRCA1 or BRCA2 mutation? Retrospective analyses suggest that these patients have a better prognosis than patients with sporadic cancers of similar stage - do they need aggressive treatment?

The current analysis is scheduled to be presented as a poster at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2012. While there may be interest in publishing the data presented here, efforts are underway to combine our analysis with those performed on these patient groups at other centers, to see if more robust correlations, and thus more definitive conclusions and recommendations, can be reached.

- 1. Gonzalez-Angulo AM, Litton JK, Broglio KR, et al: **High risk of recurrence for patients with breast cancer who have human epidermal growth factor receptor 2-positive, node-negative tumors 1 cm or smaller.** J Clin Oncol 27:5700-6, 2009
- 2. Hanrahan EO, Gonzalez-Angulo AM, Giordano SH, et al. **Overall survival and cause-specific mortality of patients with stage T1a,bN0M0 breast carcinoma.** J Clin Oncol 25;4952-4960, 2007.
- 3. Amar S, McCullough AE, Tan W, et al. **Prognosis and outcome of small (≤1 cm), node-negative breast cancer on the basis of hormonal and HER-2 status**. Oncologist 15;1043-1049, 2010
- 4. Amir E, Seruga B, Ocana A, Carlsson L, Bedard P. **Pooled Analysis of Outcomes of T1a/bN0, HER2-Amplified Breast Cancer.** Cancer Research 2011;71(24 Suppl.): P2-12-07.
- 5. Peron J, Vano Y, Frenel J-S, et al. **Systemic Adjuvant Treatment of T1a and T1b N0M0 HER2+ Breast Carcinomas; an AERIO/UNICANCER Study.** Cancer Research 2011;71(24 Suppl.): P2-18-03.
- 6. Ho AY, Gupta G, Perez CA, King TA, et al. Favorable Prognosis in Patients with T1a,b Node-Negative Triple Negative Breast Cancers Treated with Multimodality Therapy. Cancer Research 2011;71(24 Suppl.): P5-14-13.
 7. Shao T, Boolbol SK, Boachie-Adjei K, Klein P. Clinical Significance of
- HER2+ and Triple-Negative Status in Patients with Tumor Size ≤ 1 cm and Node Negative Breast Cancer. Cancer Research 2011;71(24 Suppl.): P4-09-03.
- 8. Chew HK, Brown M. Cause-specific and all-cause mortality of HER2-positive, node-negative, T1a and T1b breast cancers. J Clin Oncol 28;15S, abstr 583, 2010.
- 9. Cancello G, Maisonneuve P, Rotmensz N, et al. **Prognosis in women with small (T1mic,T1a,T1b) node-negative operable breast cancer by immunohistochemically selected subtypes**. J Clin Oncol 28;15S, abstr 546, 2010.
- 10. McArthur HL, Mahoney KM, Morris PG, et al: **Adjuvant trastuzumab with chemotherapy is effective in women with small, node-negative, HER2-positive breast cancer**. Cancer 117:5461-8, 2011
- 11. Rodrigues MJ, Wassermann J, Albiges L, et al: **Trastuzumab treatment in t1ab, node-negative, human epidermal growth factor receptor 2-overexpressing breast carcinomas**. J Clin Oncol 28:e541-2, 2010

Acknowledgements: The multihospital project was coordinated by Dr. Yazan Migdady, a resident in the internal medicine program based at Memorial Hospital of RI and Dr. Adam Olszewski, a staff hematologist-oncologist at Memorial Hospital of RI, and with the assistance of Dr. Bachir Sakr, a medical oncologist at Women and Infants Hospital and the tumor registrars at Miriam Hospital, Rhode Island Hospital, Memorial Hospital of RI and Women and Infants Hospital.

Table 1: Demographics and Treatment: TMH vs. Overall

Variable		At Miriam Hospital (n=34)	All patients (n=161)	Triple- negative (n=57)	Her2- positive (n=104)	p-value (for difference between TN/Her2+)
Age	Median Range	56 36-81	57 28-88	63 33-86	55.5 28-88	0.0141
Menopausal status	Premenopausal Postmenopaus al Unrecorded	8 (23.5%)	42 (26%) 113 (70%) 6 (4%)	11 (19%) 44 (79%) 2 (2%)	31 (30%) 69 (66%) 4 (4%)	0.189
Stage	T1a T1b	8 (24%) 26 (76%)	54 (34%) 107 (66%)	19 (33%) 38 (67%)	35 (34%) 69 (66%)	1.0
Size	Mean	6.5 mm	6.3 mm	6.4 mm	6.3 mm	0.71
ER/PR positive		TN: 14 (41%) H2+ER-: 8 (24%) H2+ER+: 12(35%)	-	-	57 (55%)	-
Grade	1 2 3 Not established	2 (5.9%) 13 (38%) 19 (56%)	6 (4%) 62 (40%) 88 (56%) 5	3 (6%) 20 (36%) 32 (58%) 2	3 (3%) 42 (42%) 56 (55%) 3	0.635
Histology	Ductal Lobular Mixed Apocrine Mucinous Medullary	30 (88%) Others: 4 (12%)	146 (91%) 2 3 7 2	49 (86%) 1 1 4 1	97 (93%) 1 2 3 1	0.158 (ductal vs. others)
Lymphovascular invasion	Present Absent	Absent in 100%	10 (6%) 151 (94%)	1 (2%) 56 (98%)	9 (9%) 95 (91%)	0.099
0	I 1	07 (700/)	400 (000/)	F0 (000()	70 (700/)	1 0 000
Surgery type	Lumpectomy Mastectomy	27 (79%) 7 (21%)	129 (80%) 32 (20%)	53 (93%) 4 (7%)	76 (73%) 28 (27%)	0.002
Prophylactic bilatera		00 (==0()	9 (6%)	1 (2%)	8 (8%)	0.161
Axilla evaluation	SNB ALND Not pursued	26 (77%) 8 (24%)	125 (77%) 20 (12%) 16 (10%	45 (78%) 4 (7%) 8 (14%)	80 (77%) 16 (15%) 8 (8%)	0.142
Adjuvant radiation			122 (76%)	48 (84%)	74 (71%)	0.083
Adjuvant hormonal t			48 (30%)	3 (5%)	45 (43%)	<0.001
Adjuvant chemother			75 (47%)	25 (44%)	50 (48%)	0.624
BRCA mutation	Present Absent No record	0 1 (3%) 33 (97%)	3 (2%) 13 (8%) 145 (90%)	2 (3.5%) 4 (7%) 51 (89%)	1 (1%) 9 (9%) 94 (90%)	0.532
Relapsed		1 (2.9%)	7 (4.3%)	2 (3.5%)	5 (4.8%)	0.522
Dead		2 (5.9%)	8 (5%)	4 (7%)	4 (3.8%)	0.455
Follow-up duration (months)	Median Range Interquartile range	48.5 2-118 21-103	46 2-136 25-78	37 2-130 22-61	52 8-136 27.5-82.5	0.044

Table 2a: Chemotherapy recommendations

Miriam only:

	Triple- negative	Her2- positive	Total	T1a	T1b	total
Chemotherapy not recommended	5	10	15	6	9	15
	35.7%	50%	44 %	75%	35%	44%
Chemotherapy recommended	9	10	19	2	17	19
	64.3%	50%	56 %	25%	65%	56%
Total	14	20	34	8	26	34

All hospitals:

·	Triple- negative	HER2+	Total	T1a	T1b	total
Chemotherapy not recommended	29	46	75	37	38	75
	50.88%	44.23%	46.58 %	69%	36%	47%
Chemotherapy recommended	28	58	86	17	69	86
	49.12%	55.77%	53.42 %	31%	64%	53%
Total	57	104	161	54	107	161

Table 2b: Chemotherapy regimens administered

TMH - Chemotherapy Regimens used

Triple Negative patients (n=14)

None	5	35.7%
CMF	3	21.4%
AC	1	7.1%
TC	2	14.3%
AC-T	3	21.4%

HER2+ patients (n=20)

		- /
None	11	55%
CMF	1	5%
AC	2	10%
AC-H	2	10%
AC-TH	1	5%
ТС-Н	1	5%
Т-Н	2	10%

Patient Care Study: 2011

Assessment of the Effectiveness of Chemotherapy Teaching

As part of The Miriam Hospital's ongoing efforts to improve patient care we measure patient satisfaction using the Press Ganey Outpatient Oncology Satisfaction Survey. Patients are randomly surveyed throughout the year and results are available online biannually to promote analysis and opportunity to change practice improve care. Several of the questions asked refer to patient education in management of chemotherapy side effects, education for management of fatigue and loss of appetite and keeping the patient and family informed about what to expect during active therapy. These results consistently appear in bold italics: they are among our facility's top ten priorities for improvement based on our Internal Priority Index. Our program used this information to validate the need for more information and help initiate this study to evaluate chemotherapy teaching sessions and promote enhanced patient education and care.

1.1 Primary Objective:

To evaluate whether chemotherapy teaching sessions improves patient's knowledge, preparedness and anxiety in relation to chemotherapy

1.2 Secondary Objective:

- 1.2.1 To compare changes in patient's knowledge, preparedness and anxiety in relation to chemotherapy teaching sessions between participating Brown University Oncology Research Group Hospitals
- 1.2.2 To evaluate the influence of age, race, native language, education level, type of cancer and chemotherapy regimen on the effectiveness on the oncology teaching session.

2.0 BACKGROUND:

The administration of chemotherapy for patients with cancer is associated with substantial emotional distress. Common fears include potential side effects, lack of knowledge on what will happen, how treatment will affect body image and integrity, and how chemotherapy will change lifestyle and social interactions.¹⁻⁴

To help patients be prepared for their chemotherapy, The American Society of Clinical Oncology has recommended formal teaching sessions for patients explaining the planned chemotherapy to increase patient's knowledge and decrease anxiety. There is evidence that with an understanding of potential side effects and management strategies, patients will be more comfortable with their

chemotherapy including reduction of stress and anxiety.⁶⁻¹⁷ This could lead to better compliance to therapy translating to improved outcomes and better quality of life.

Chemotherapy teaching sessions, coordinated in the outpatient setting by nursing personnel, are meant to educate patients about the chemotherapy they will be receiving. Education topics include an understanding of side effects, treatment schedule, medications to treat side effects and how to contact the oncology team if adverse events develop. Some of these issues are addressed in the American Society of Clinical Oncology's Quality Oncology Practice Initiative (QOPI). This study will perform an analysis of the teaching process that is provided prior to chemotherapy administration.

This study will provide data for each participating hospital to individually assess their teaching process. Multivariate analysis can be performed to evaluate whether age, sex, native, language, race highest level of education, cancer type, chemotherapy regimen, institution where chemotherapy will be administered, and type of personnel performing the teaching visit, influences the effectiveness of the teaching visit.

In addition, results can be compared across different hospitals such as The Miriam Hospital (community based academic hospital), The Rhode Island Hospital (tertiary care and principal teaching hospital) and The Veterans Hospitals, Memorial Hospital, and Women and Infants Hospital. This analysis may lead to improvements in each hospital's chemotherapy teaching practices and lead to advances in patient's cognitive and emotional preparedness.

The questionnaire utilized for this study has been developed by investigators of the Brown University Oncology Group to assess and evaluate the changes in knowledge and feelings experienced by patients undergoing chemotherapy.

3.0 ELIGIBILITY:

- 3.1 Patients > 18 years of age who will be receiving chemotherapy (including targeted anticancer therapy) at a Brown University Oncology Research Group Affiliated Hospital for a period of 1-year after study activation.
- 3.2 Patients who will be undergoing a chemotherapy teaching session at an institution affiliated with the Brown University Oncology Research Group.
- 3.3 No prior chemotherapy or targeted anticancer treatment.
- 3.4 Signed informed consent.

4.0 STUDY DESIGN:

The process for this trial will be as follows: When a treating physician explains to a patient that they will be receiving chemotherapy and having a teaching visit, patients will be offered the opportunity to participate in this study. After informed consent for this study is obtained, patients will be given questionnaire #1 that includes rating their knowledge of the side effects of treatment, their understanding of the treatment schedule, what do in the event of complication, how to reach the medical team and an assessment of the level of anxiety. The questionnaire will be repeated prior to administration of the first chemotherapy treatment to assess the effectiveness of the teaching session. In addition, questionnaire #3 will be administered approximately 3-4 weeks after their first chemotherapy in recognition that teaching is a continuous process and other professionals such as the chemotherapy nurse will have additional teaching opportunities. At all time points, the questionnaire may not be administered by the teaching nurse it must be someone different.

Information that will be obtained on all patients prior include the following:

- Age
- Sex
- Fluent in what languages
- Race
- Highest Level of Education
- Cancer Type
- Chemotherapy Regimen
- Is this the first chemotherapy regimen
- Institution where chemotherapy will be administered
- Personnel performing teaching visit

5.0 Statistical Analysis:

Statistical analysis for the effectiveness of teaching will be scored, graded and analyzed with higher scores indicating better chemotherapy teaching.

The primary objective in the analysis is to assess improvement in the Teaching Score as defined as increases of points from baseline to completion time points. Chi-squared tests and logistic regression models will be used to test the null hypothesis that the proportion of patients categorized as "improved" will be the same between different institutions within the Brown University Oncology Research Group, versus the alternative hypothesis that the proportion of patients categorized as "improved" is higher in one institution. Statistical methods can be applied for instances of missing data collection points.

Multivariate analysis will be performed to evaluate the effect of age, sex, native, language, race highest level of education, cancer type, chemotherapy regimen, institution where chemotherapy will be administered and personnel performing teaching visit influences the effectiveness of the teaching visit.

6.0 Results to Date: 28 patients enrolled so far

7.0 REFERENCES

- 1. Weeks JC, Cook EF, O'Day SJ, et al: Relationship between cancer patients' predictions of prognosis and their treatment preferences. JAMA 279: 1709–1714, 1998.
- 2. Charles C, Gafni A, Whelan T: Shared decision making in the medical encounter: What does it mean? (Or it takes at least two to tango). Soc Sci Med 44: 681–692, 1997
- 3. Segelov E, Tattersall MH, Coates AS: Redressing the balance: The ethics of not entering an eligible patient on a randomised clinical trial. Ann Oncol 3: 103–105, 1992
- 4. Emanuel EJ, Emanuel LL: Four models of the physician-patient relationship. JAMA 267: 2221–2226, 1992
- 5. www.asco.org
- 6. Sutherland HJ, Llewellyn-Thomas HA, Lockwood GA, et al: Cancer patients: Their desire for information and participation in treatment decisions. J R Soc Med 82: 260–263, 1989
- 7. Braddock CH 3rd, Edwards KA, Hasenberg NM, et al: Informed decision making in outpatient practice: Time to get back to basics. JAMA 282: 2313–2320, 1999
- 8. Fogarty LA, Curbow BA, Wingard JR, et al: Can 40 seconds of compassion reduce patient anxiety? J Clin Oncol 17: 371–379, 1999
- 9. Korsch BM, Gozzi EK, Francis V: Gaps in doctor-patient communication: 1. Doctor-patient interaction and patient satisfaction. Pediatrics 42: 855–871, 1968
- 10. Roter DL: Patient participation in the patient provider interaction: The effects of patient question asking on the quality of interaction, satisfaction, and compliance. Health Educ Monogr 5: 281–315, 1977
- 11. Hosmer D, Lemeshow S: Applied Logistic Regression (ed 2). New York NY, John Wiley and Sons, 2000
- 12. Ubel PA, Loewenstein G: The role of decision analysis in informed consent: Choosing between intuition and systematicity. Soc Sci Med 44: 647–656, 1997
- 13. O'Connor AM: Validation of a decisional conflict scale. Med Dec Making 15: 25–30, 1995[Abstract/Free Full Text]
- 14. O'Connor AM: Effects of framing and level of probability on patients' preferences for cancer chemotherapy. J Clin Epidemiol 42: 119–126, 1989[CrossRef][Medline]
- 15. Ferris FD, Bruera E, Cherny N, et al. (2009) Palliative cancer care a decade later: Accomplishments, the need, next steps—From the American Society of Clinical Oncology. J Clin Oncol 27:3052–3058.
- 16. Keating NL, Landrum MB, Rogers SO Jr., et al. (2010) Physician factors associated with discussions about end-of-life care. Cancer 116:998–1006

- <u>17.</u> Stubenrauch JM (2010) Study: Few physicians discussing end-of-life options with advanced-stage patients. Oncology Times 32:26, 28, 29.
- 18. Glasziou PP, Simes RJ, Gelber RD. Quality Adjusted Survival Analysis. Stat Med 1990;9:1256-76.
- 19. Donaldson GW, Moinpour CM. Learning to live with missing quality of life data in advanced-stage disease trials. J Clin Oncol 2005;23:1-5.

Patient Care Improvements 2011

Quality Improvement: Development of the Survivorship Program to include multiple disciplines from both Comprehensive Cancer Center sites in a collaborative effort to offer survivorship information to all patients. This improvement reflects the work of the Survivorship Team: approximately thirty caregivers meet monthly to assess needs, seek education, explore opportunities and benchmark existing programs in an effort to develop a sustainable program that is seamless across our multi-hospital system. The team was formed in November 2010 and has noted these accomplishments in 2011:

- An internal database was developed for the use of the Journey Forward website as a template for breast and colorectal patient's treatment plan and summary. In 2011, 65 patients were given a treatment plan and summary at The Miriam Hospital. Physicians, Nurse Navigators and Nurse Practitioners have been responsible for initiating the templates at time of diagnosis, completing the plan and summary, discussing with the patient and forwarding the information to the Primary Care Provider.
- The team organized a local Cancer Survivors Day, held September 18, 2011. Approximately one hundred survivors and multiple family members attended the event held at the Roger Williams Park Casino. An extensive array of informational booths, entertainment, refreshments and an hourlong speakers program with six physicians was a tremendous success. The public forum was an opportunity for questions and answers with many patients and families staying to speak individually with physicians in an informal, casual atmosphere.
- The concept of support groups and information sessions has been explored and enhanced. A partnership has been developed with the local Gloria Gemma Breast Cancer Foundation to sponsor breast cancer support groups. Counselors from Jewish Family Services have facilitated the sessions. An opportunity to focus on young women with breast cancer as a separate group is being explored. The biannual Cancer Survivors Lecture Series has continued and will be reevaluated for a potential annual presentation only. Daily drop in groups will be trialed one day per week in early 2012.
- Education of all cancer patients with a focus on survivorship issues will be the focus of a new Lunch and Learn with the Doctor series in early 2012. This format will offer a monthly onsite session with a physician and will correspond to the annual focus on cancer diseases.
- Initiation of use and evaluation of patient's distress using the NCCN Distress Thermometer was begun in late 2011. Initial evaluation will be done at the time of the teaching visit with scheduled reassessment done at specified times throughout the patients course of therapy. Referral to social work or psychiatry is made based on the patients response to the Distress Thermometer scale.

Quality Improvement: Transition of the Man to Man program to the Men's Cancer Wellness Group and Partners' Group.

This transition has allowed the customization of the traditional men's program to allow all men, particularly men with genitourinary and colorectal cancers, to participate in this program. Monthly sessions are held which feature specific topics of interest to men and are presented by clinical experts in the field. Topics have included side effects of cancer therapy (including incontinence and impotence), sexuality, infertility, financial issues and nutrition. The Partners' Group is facilitated by a quality of life expert who allows partners to explore together ways to cope with the impact of cancer on a loved one.

Quality Improvement: Incorporation of Palliative Care discipline into weekly Thoracic Multidisciplinary Clinic, this represents enhancement of the clinical goal achieved by the Cancer Control Committee in 2010.

In partnership with the Palliative Care Consult Service of The Miriam Hospital and Home and Hospice Care of Rhode Island, a palliative care physician is now part of the multidisciplinary team in the weekly Thoracic MDC. Each new patient seen in the MDC is evaluated by the medical oncologist for stage of disease, potential for therapy and intent of therapy and care. The oncologist introduces the concept of quality of life and potential transition to palliative care at the time of either the initial or second visit to the clinic. The palliative care physician is introduced as a member of the team who may be called upon then or at a later time to help coordinate care. Patient acceptance of this program has been positive with the goal of earlier transition to palliative or hospice care when appropriate.

Quality Improvement: Expansion of Navigator Program to address patient care needs of all active disease patients.

The Miriam Hospital has participated in the Avon Navigator Program for six years and this has provided partial funding of a full time Breast Health Navigator. In late 2011 two additional navigators were hired to enhance the navigation concept and provide support to all patients at risk for failure to complete therapy. The intent is to screen all patients for these referral triggers: non English speaking, no insurance, multiple comorbidities or diagnosed major psychiatric disorders. These initial triggers will be used as definite referral criteria. In addition, the navigators will work with collaborative physicians and care teams to identify patients with multiple planned therapies (chemotherapy, surgery, radiation) and increased need for financial, physical or emotional support during treatment.

Quality Improvement: Multidisciplinary design, funding and construction completion of the Oncology Conference Room.

Multiple tumor boards are held weekly at The Comprehensive Cancer Center hospitals and are either onsite at The Miriam Hospital or teleconferenced. Location for these tumor boards has been problematic in management of equipment, size of the conference room available and use of the space conflicting with other organizational priorities. A need was identified for an oncology specific space that would be consistently available and could house the needed technical equipment, including preloaded computer equipment and the microscope. As part of the capital improvement of the Cancer Center an area was designated as Oncology Conference Room space. Multiple disciplines including medicine, surgery, diagnostic imaging and pathology were consulted for audiovisual and space needs. A donor was identified for funding of the project. The completed space opened in late 2011 and is identified by all participants as an improvement in the ability of clinicians to promote multidisciplinary planning of care.

THE MIRIAM HOSPITAL CANCER CONTROL COMMITTEE COMMUNITY OUTREACH 2011 Annual Report

ANTI-TOBA	CCO RESOURCE BOOTHS	
3//22/2011	Health Fair- Jencks Middle School, Pawtucket	800
3/23/2011	Health Fair – Ponagansett Middle School	300
3/24/2011	Health Fair – Goff Middle School, Pawtucket	600
3/29/2011	Health Fair - Slater Middle School, Pawtucket	<u>800</u>
TOTAL		2500
	PREVENTION PROGRAMS	
2/7/2011	Cooley/Pais High School	225
2/11/2011	Bishop McVinney High School	75
3/3/2011	Bridge School/CHISPA	8
3/14/2011	Esek Hopkins Middle School	210
3/22/2011	Martin Luther King Elementary School	_60
12/7/2011	Bridge School	TBD
TOTAL		578
CANCER EI	DUCATION	
Breast Can		
3/7/2011	Foster Grandparents	63
4/19/2011	Crossroads (Spanish)	20
4/27/2011	Elmwood Senior Center (Spanish)	56
5/19/2011	Celebrate Pink – Warwick Mall	120
9/24/2011	Women's Wellness Workshop	341
10/15/2011	Avenues of Healing	153
10/19/2011	Tiffany & Company	<u>12</u>
TOTAL		7 65
PROSTATE		
4/19/2011	Cathedral of Life Christian Assembly Church	19
5/26/2011	Cathedral of Life Christian Assembly Church	20
6/29/2011	Elmwood Senior Center (Spanish)	<u>53</u>
TOTAL		92
MISCELLAN	JEOUS	
4/13/2011	Worksite Wellness/Cancer Program/Dr. Herman	
7/10/2011	Hasbro, Inc	54
6/17/2011	Speaker – Cancer Summit – Partnership to Reduce	01
5,, 20	Cancer in RI	200
9/18/2011	Cancer Survivors Day	90
TOTAL	•	344
TOTAL CAN	ICER EDUCATION	1221

CANCER SCREENINGS

PROSTATE	CANCER	8
SKIN CANC 7/31/2011	EER Roger Wheeler Beach	258
	AN (Skin Damage Assessment Screenings) Tyco Fire Suppression Products	50
8/21/2011	Pawsox Event	103
TOTAL CAN	NCER SCREENINGS	419
FREE WOM	IEN'S CANCER SCREENING IN-REACH PROGRAM 2011	
Lette	rs sent as of 11/30/201:	300
Appo	intments Made:	95



American Cancer Society 2011 report to Miriam Hospital Supporting COC Standards

CoC Standards: CoC Standard 6.1 - Supportive Services

American Cancer Society 2011 Report

437 newly diagnosed patients have been reached in the outpatient infusion center with cancer information, programs, services, and resources. The oncology teaching nurses include a one page overview of ACS programs and services in the resource section of each patient's binder. In addition, each female patient receives a Look Good Feel Better flyer and TLC catalog. Male patients experiencing hair loss will receive a Look Good Feel Better brochure for men. Teaching nurse and social workers will make referrals to ACS for inpatient unit when needed. All patients visited by ACS rep are given a magnet with ACS contact information. Patients speak with a cancer information specialist or oncology nurse 24/7. In addition, ACS representative offers appropriate referrals to both local and national programs.

10 newly diagnosed patients received transportation services from the Society.

31 newly diagnosed women attended the LGFB sessions. Breast navigator, teaching nurses, and social worker assist ACS staff in coordinating Look Good Feel Better sessions at Miriam.

ACS supported over 200 patients with various items such as prosthesis, bras, wigs, scarves, and hats.

2 Reach to Recovery visits were provided to newly diagnosed breast cancer patients.

Online courses are offered to all patients and family members to learn about nutrition, new treatment options, finances, etc. I Can Cope's online educational resource is for patients and family members to read or listen to videos and link to other resources related to the journey of the cancer patient and their loved one.www.cancer.org/onlineclasses.

TLC Catalog – A catalog of the American Cancer Society, to help women cope during and after cancer treatments by providing wigs and other hair loss products (plus how-to information) as well as mastectomy products.

A brochure of the Miriam survivorship lecture series is given to all patients attending the "Look Good Feel Better" sessions throughout the state. This brochure is also posted and given at other facilities throughout the state.