

COMPASSION • RESEARCH • TECHNOLOGY

BUILDING BRIDGES OF HOPE

WATSON CLINIC^{LLP}
Cancer & Research Center

 MOFFITT ONCOLOGY NETWORK MEMBER

2018 ANNUAL REPORT



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Since we first opened our doors in 2003, the Watson Clinic Cancer & Research Center has committed itself to building bridges for patients in need.

A bridge between the uncertainty and fear evoked by a cancer diagnosis, and the promise of a healthier tomorrow. A welcoming compassion that bridges the divide between hopelessness and empowerment.

A bridge can only be effective if it possesses a strong support system. From the very beginning of our operation 15 years ago, we’ve worked to elevate the level of cancer survivorship in our community and beyond by assembling a team of world-class specialists, employing the latest technologies and shepherding the most progressive research efforts.

Our multidisciplinary team includes experts in fields like oncology-hematology, radiation oncology, surgical oncology, and gynecologic and urologic oncology. They work in collaboration to formulate the most effective plans of action for each patient. Patients are provided additional support from Watson Clinic’s extended family of over 200 board-certified specialists in disciplines as diverse as gastroenterology, plastic & reconstructive surgery and primary care. Social

workers, nurse navigators and other support staff further compliment the care process by ensuring a smooth transition of care between specialists.

We’ve enjoyed generous recognition from some of the country’s leading cancer care advocacy organizations. We earned a full accreditation from the American College of Surgeons Commission on Cancer, and we were named Florida’s sole recipient of their Outstanding Achievement Award in both 2013 and 2016. We also hold the distinction of being the only local member of the Moffitt Oncology Network, an association that provides our patients with the caliber of resources normally available in only the largest metropolitan areas.

This acclaim pales in comparison to the satisfaction we receive from our patients. The opportunity to play a role in their recovery – to provide comfort in the face of their adversity and celebration in their moments of triumph – remains our greatest honor and privilege.

All of us come to the table with an ambition to eradicate cancer in our lifetime. Our patients are our bridge between these good intentions and the inspiration and resolve to see them through.



A MESSAGE FROM

Shalini Mulaparthi, MD

CANCER
COMMITTEE CHAIR

I'm pleased to present the following detailed report of our outstanding oncology program at the Watson Clinic Cancer & Research Center (CRC).

We continue our quarterly Commission on Cancer meetings and are pleased to affirm our involvement with American Cancer Society. In addition, we also carry on our proud tradition of offering our community various screening tests for early detection. As a designated screening center, we are committed to practicing safe, effective diagnostic care for individuals at the highest risk for various cancer types.

We are accredited by the American College of Radiology in computed tomography in the chest module, and we undergo a rigorous assessment of the organization's lung cancer screening protocol and infrastructure. We also have procedures in place for follow-up patient care, such as counseling and smoking cessation programs.

Our physicians and staff are dedicated to advancing the art of comprehensive and compassionate patient care. We have weekly multi-disciplinary tumor board and breast cancer conferences to discuss and collaborate on complicated cases.

This year we have fully embraced the genetic component of cancer care, including FoundationOne testing, next generation sequencing, and liquid biopsies.

Precision medicine is a key to reducing cancer mortality and we are proud to say that CRC is Polk County's leader in utilizing this approach.

The impact of immunotherapy in the field of oncology continues to evolve, changing the face of cancer care and advancing our understanding of the complex relationship between the immune system and cancers. Immunotherapies are more widely integrated into our practice, and its coordination between the multidisciplinary and multispecialty care teams are being implemented on a regular basis.

Our staff has also participated in several educational activities this year – including the empathy program – and we continue our weekly Conquering Chemotherapy educational classes for patients and caregivers. We have dedicated nurse navigators who coordinate care between physicians and patients. Our social services staff provides exceptional guidance in helping reduce patient distress.

CRC continues to provide groundbreaking clinical trials to the community, including five phase III treatment trials, which are currently being offered to improve overall survival.

As another year draws to a close, I'm thankful to be associated with one of the nation's most highly respected cancer centers, right here in Lakeland.



A MESSAGE FROM

Galina Vugman, MD

CANCER LIAISON
PHYSICIAN

It continues to be my privilege to serve as the Cancer Liaison Physician at the Watson Clinic Cancer & Research Center.

Caring for patients and families afflicted by cancer is a tremendous privilege that none of us take lightly. We understand that truly effective care can only be achieved through a carefully coordinated multi-disciplinary effort that calls upon our foremost experts in screening, treatment and research.

We continue to take a progressive approach in the areas of screening and prevention. These disciplines are constantly evolving. This past year, for example, as an increase in incidence of colorectal cancer in younger adults has been recognized, the American Cancer Society guidelines have recommended that screening for persons at average risk begin at the age of 45 years.

The use of checkpoint inhibitor immunotherapy has been a major advance in the treatment of a wide range of malignancies. Uses for immune checkpoint

inhibitors, which help unleash the body's immune response to cancer, continue to show efficacy in more cancer types.

These advances would not be possible without investment in cancer research. By staying up to date on new oncology breakthroughs, and pursuing innovative clinical trials, I am optimistic that we can help bring these promising treatments to more patients in our community.

"To confront cancer is to encounter a parallel species, one perhaps more adapted to survival than even we are," wrote acclaimed oncologist Siddhartha Mukherjee in his book *The Emperor of All Maladies*. A cancer diagnosis is a journey that reveals reserves of determination and empowerment that we never knew we had. All of us at CRC are proud to serve as our patients' main advocate and guide on their road to survivorship, and we continue to find our own reserves of inspiration and empowerment from each and every one of them.

Outreach & Community Events

The Watson Clinic Foundation, Watson Clinic LLP and the Watson Clinic Cancer & Research Center continue to collaborate in order to foster a more

informed and empowered community. These efforts include involvement in a series of outreach programs, sponsorships and special events.

- The Arts in Medicine program elevates the spirits and enhances the quality of life for cancer patients and their caregivers through the therapeutic practice of visual art, musical performances and other creative activities.
- Posters were distributed throughout multiple Clinic locations to raise awareness of colon, breast, prostate, lung and pancreatic cancer.
- An educational booth was set up at a Detroit Tigers Spring Training game to engage ballpark attendees in important discussions regarding the value of a healthier lifestyle.
- A series of free skin cancer screenings elevated awareness on the importance of early detection and prevention throughout Polk and Hillsborough counties.
- Monthly Smoking Cessation programs empower smokers to quit.
- A Speaker's Bureau program provides local businesses and organizations with medical professionals who educate on a variety of health-related topics.
- A community education program – Healthy in Pink - was developed that focuses on breast cancer.
- The annual Breast Cancer Awareness luncheon, hosted by Watson Clinic LLP, Watson Clinic Cancer & Research Center and Moffitt Cancer Center, delivered informative presentations on the latest research breakthroughs and inspiring personal stories of survival.
- Over the next year, breast cancer education and awareness opportunities will be offered to young men and women through retreats at four Polk County colleges.

The Watson Clinic Foundation was awarded \$5,000 by the Florida Breast Cancer Foundation to launch "Lakeland's PinkSync," a program designed to provide breast cancer awareness, education and prevention to college-aged students via the creation of four retreats at each of the local colleges in Lakeland. The goals of the program includes providing resources to young adults about breast cancer detection, adopting healthy habits for breast cancer prevention, cultivating a nurturing environment for young adults suffering with breast cancer, and creating a social network for college-aged students who have been impacted by a breast cancer diagnosis. The program will run through the 2018-2019 academic year, and is spearheaded by Dr. Neeharika Makani and Neha Shah.

Collectively, we have also been unwavering in our support of local cancer awareness and advocacy organizations. The Foundation provided sponsorships to the Breast Cancer Foundation of Central Florida, the Deliver the Dream children's retreat, and the American Cancer Society's Cattle Baron Ball. Meanwhile, Watson Clinic and the Cancer & Research Center were proud sponsors of a number of meaningful events as well, including the Making Strides Against Breast Cancer and Relay for Life events.



Center for Research

The Watson Clinic Cancer & Research Center Oncology team is dedicated to improving patient outcomes and the cancer care experience of their patients. The Clinical Oncology Research Legacy has been ongoing since mid 1980's. Our team of multispecialty physicians regularly explores clinical trials that focus on the treatment of breast, colon, lung, leukemia, lymphoma, melanoma, pancreatic and prostate cancers. Our physicians have research and training experience from a variety of specialties, including medical oncology, hematology, gynecologic oncology, radiation oncology and surgical oncology.

Due to the complexity of cancer research trials, we continue to collaborate with the various professionals throughout the practice. The Watson Clinic LLP collaborative team includes interventional radiologists, urologists, neurologists, otolaryngologists, pulmonologists and thoracic surgeons.

Providing clinical trials as an option for our cancer patients is a vital step in advancing personalized cancer treatment for our community. The scientific knowledge gleaned from the clinical trials helps us to build evidence to support future research efforts. Thanks to the progress made through clinical trials, many people treated for cancer are living longer and enjoying a better quality of life. Our Principal

Investigators are currently enrolling patients in numerous trials. These trials are studying new diagnostic testing to help screen and detect cancer, new treatment drug regimens to treat cancer, and supportive trials that manage the side effects of treatment.

We work hard to streamline the process of screening potential patients in our practice. Our coordinator team daily reviews new patient consults and any patient that has a new recurrence of their cancer. If the patient meets the trial inclusion and exclusion criteria, the physician discusses the trial opportunity with the patient. The coordinator then reviews the trial requirements and procedures with the patient. A full informed consent is completed and trial registration is performed. The patient is managed closely throughout the course of the trial to maintain protocol integrity and assist with any adverse side effects experienced by the patients. The patient and family develop a relationship with each of their coordinators to assist them with navigation of their care and adherence to protocol requirements.

The Watson Clinic Cancer & Research Center Oncology team plays a major role in advancing clinical cancer care in our community through their active participation in clinical trials.

Timely Referral to Hospice Care for Oncology Patients: A Retrospective Review

PRINCIPAL INVESTIGATOR: NEEHARIKA SRIVASTAVA MAKANI, MD

STUDENT RESEARCHERS: ANDREW K. MULVILLE AND NANCY N. WIDICK

Hospice care is medical care provided to terminally ill patients with a life expectancy of six months or less. Hospice services include symptom control, pain management, palliative care and other supportive services such as providing for home equipment or oxygen; however, it does not provide for life-prolonging therapies such as chemotherapy. Although oncologic benchmarks suggest patients should be enrolled in hospice three months prior to death, studies show that most hospice referrals are being made too late. These shorter stays in hospice result in increased cost of care especially at the end of life with most patients dying on aggressive treatments in the hospital. Thus, identifying barriers to hospice placement is critical to improving the referral process and enhancing

the quality of end-of-life care. This retrospective study collected data on 418 oncologic patients who passed in 2015 and categorized patients based on hospice status at the time of death. Our study found that the demographics between hospice and non-hospice patients were not significantly different. Hospice patients spent a median of 10 days in hospice and 71 percent (n=161) of patients were in hospice 30 days or less. Additionally, 56 percent of patients were in hospice 10 days or less. Increased education for patients and healthcare providers along with better utilization of palliative care services and incorporating a nurse navigator to help with transitioning patients to hospice would improve earlier referral to hospice care and enhance patients' quality of life.

This paper has been accepted and is pending publication in the American Journal of Hospice and Palliative Medicine in 2019



Cancer Conferences

WATSON CLINIC CANCER & RESEARCH CENTER – 2016 AND 2017

Cancer conferences not only serve as a forum for prospective review of cancer cases involving a multidisciplinary team in the patient care process, but also offers education for the physicians and care team. Our multidisciplinary team includes physicians in the departments of medical oncology-hematology, radiation oncology, surgical oncology, pathology, diagnostic radiology, and other specialties, as well as allied health professionals from research, nursing, social services, cancer registry and administration. They attend cancer conferences three times a week for collaborative discussions of diagnosis, stage, prognostic factors, and national treatment guidelines pertaining to the cases presented and cancer related educational activities.

CANCER CONFERENCES YEAR END 2017

Total # of Cancer Conferences:

94

Total # of Cancer Related Educational Activities:

22

Total # of Cases Presented:

781 — 85% of Analytic Caseload

Total # of Cases Presented Prospectively:

774 — 99% of Cases Presented

CANCER CONFERENCES JAN. 1, 2018 – SEPT. 30, 2018

Total # of Cancer Conferences:

72

Total # of Cancer Related Educational Activities:

18

Total # of Cases Presented:

631 — 73% of Analytic Caseload

Total # of Cases Presented Prospectively:

631 — 99% of Cases Presented



Cancer Committee Members 2018

PHYSICIAN MEMBERS

Dr. Elisabeth Dupont, Breast Surgery
Dr. Edward Garcia, Pathology
Dr. Howard Gorell, Radiology
Dr. Thomas Moskal, Surgical Oncology
Dr. Shalini Mulaparthy, Medical Oncology-Hematology, Cancer Committee Chair
Dr. Sandra Sha, Radiation Oncology
Dr. Galina Vugman, Medical Oncology-Hematology, Cancer Liaison Physician

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Dr. Richard Cardosi, Gynecologic Oncology
Dr. Tim Dickason, Pathology
Dr. Randy Heysek, Radiation Oncology
Dr. Scott Kelley, General Surgery
Dr. David Lowry, Radiology
Dr. Neeharika Makani, Oncology-Hematology
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Watson Clinic Cancer & Research Center Team

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Oral Chemotherapy Study at Watson Clinic

NANCY WIDICK AND GALINA VUGMAN, MD

INTRODUCTION

Oral chemotherapy is a convenient and less invasive method of administering treatment to patients and has shown to be very effective in decreasing the mortality rate of cancer patients. According to an article by Joyce Pagan, almost 50 percent of the 300 medications in clinical trials phase two and three are oral medications. Approximately 25 to 30 percent of all new anti-cancer treatment options are oral therapies (Pagan, 2017). The increased use of oral therapies has presented new challenges in the treatment of patients.

Utilization management creates financial and administrative barriers that can limit or defer a patient's access to prescribed treatments. Utilization management includes strategies such as step therapy, prior authorization requirements, and specialty tiers, which are used to control how much insurance companies are spending on drugs. A drug in a specialty tier often results in coinsurance payments being 30 to 50 percent of the drug's cost, causing a financial barrier for the

patient (Heath, 2017). Patients who cannot afford the treatment or are uninsured work with social workers to apply for financial assistance or grants to help cover the out of pocket cost. Utilization management strategies, in addition to numerous other barriers, result in long delays in time from when a physician first prescribes the drug to when the patient begins taking the drug. The American Society of Clinical Oncology (ASCO) states that utilization management strategies can impede a patient's access to high-value, clinically appropriate treatment when they are implemented without appropriate patient safeguards (Heath, 2017).

The objective of this study was to identify the barriers that Watson Clinic patients face when starting oral chemotherapy, and how these barriers compare nationwide. Assessing these barriers provides an insight in developing new ways to improve the timeliness in which a patient can receive and begin their prescribed oral therapy. Collaboration between patients, caregivers, physicians, pharmacies and healthcare companies is crucial in this process to ensure access to quality healthcare.





METHODOLOGY

The Watson Clinic Cancer & Research Center Clinical Informatics department provided a list of patients prescribed oral chemotherapy from January 1, 2016 to December 31, 2017. A retrospective medical record review was performed in order to identify the potential barriers in receiving oral chemotherapy. Data from the physician notes, social worker notes, telephone conversations, consent forms, medication order forms, and pathology reports was abstracted from Watson Clinic's medical records. These documents were used to find the following data points: prescription date, medication name and dosage, ordering provider, prior authorization date, funding approval date, date of when the patient started taking the drug, ECOG status, diagnosis, living situation, insurance, prescription coverage, specialty pharmacy used, co-pay, and any grants or additional funding the patient received.

Once the data was abstracted the patient population was narrowed down to only patients previously diagnosed with breast, prostate, melanoma, myeloma, or renal cell carcinoma.

The patient population was 82 patients; however, six of the patients were started on two oral chemotherapies in the time frame and were counted one time for each drug created the total study population of 88 encounters. A preliminary data analysis was conducted in order to find the time from prescription date to start date and the diagnosis for the population as a whole. This analysis revealed significant time differences resulting in further inspection of the barriers faced by patients starting oral chemotherapy. The population was then categorized by insurance company and by specialty pharmacy. Insurance information was examined to see what percent of patients were covered by each insurance company, the time from prescription date to the date of prior authorization, the average co-pay for each company and finally what percent of patients in each of the different companies received funding. Specialty pharmacy data was observed to determine the percent of patients that used each pharmacy, and how long each pharmacy took from prior authorization to shipping date.

RESULTS

PRESCRIPTION TO START DATE OF PATIENTS RECEIVING ORAL CHEMOTHERAPY

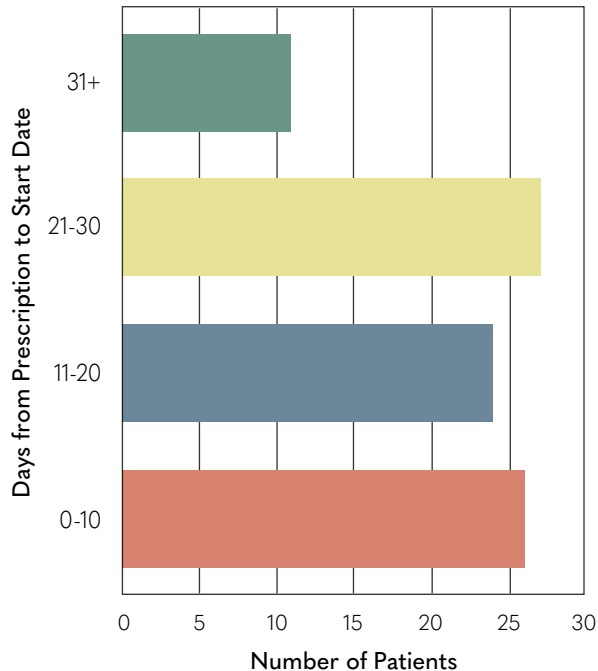


Figure 1: Out of the 88 total patients, 77 patients started their drug within 30 days after the prescription date, 26 of which were begun in the first 10 days. 24 patients, 27.3 percent, began their oral chemotherapy between days 11 and 20, and 27 patients, 30.7 percent, began between days 21 and 30. There were 11 patients, 12.5 percent, that began the drug over 30 days after the prescription date. The average amount of days from the prescription date to start date for all 88 patients was 18.89 days. The patients that took over 31 days were further investigated, two delayed for personal reasons, two because of other treatment and the last seven were time delays in the process of receiving the drug.

DIAGNOSIS OF PATIENTS RECEIVING ORAL CHEMOTHERAPY

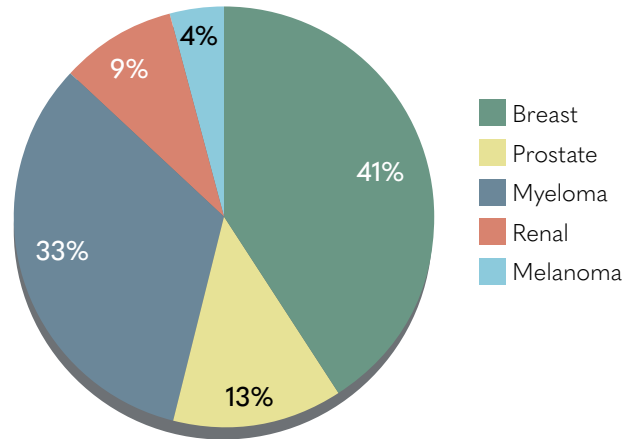


Figure 2: 74 percent of patients were diagnosed with either Breast, 41 percent, or Myeloma, 33 percent, and the other 26 percent of the patients were diagnosed with Renal Cell Carcinoma, nine percent, Melanoma, four percent, or Prostate cancer, 13 percent.

INSURANCE COMPANIES

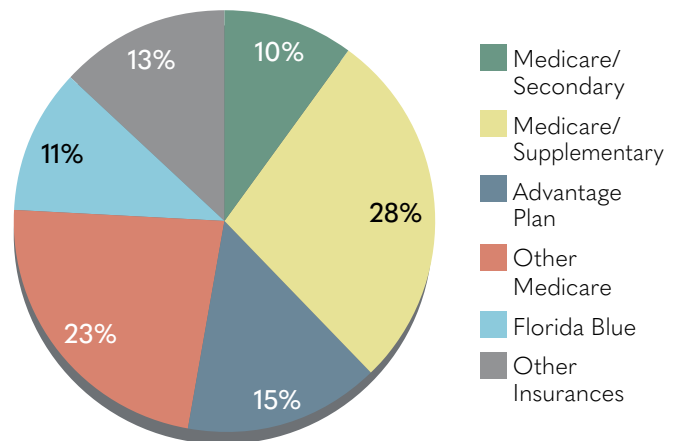
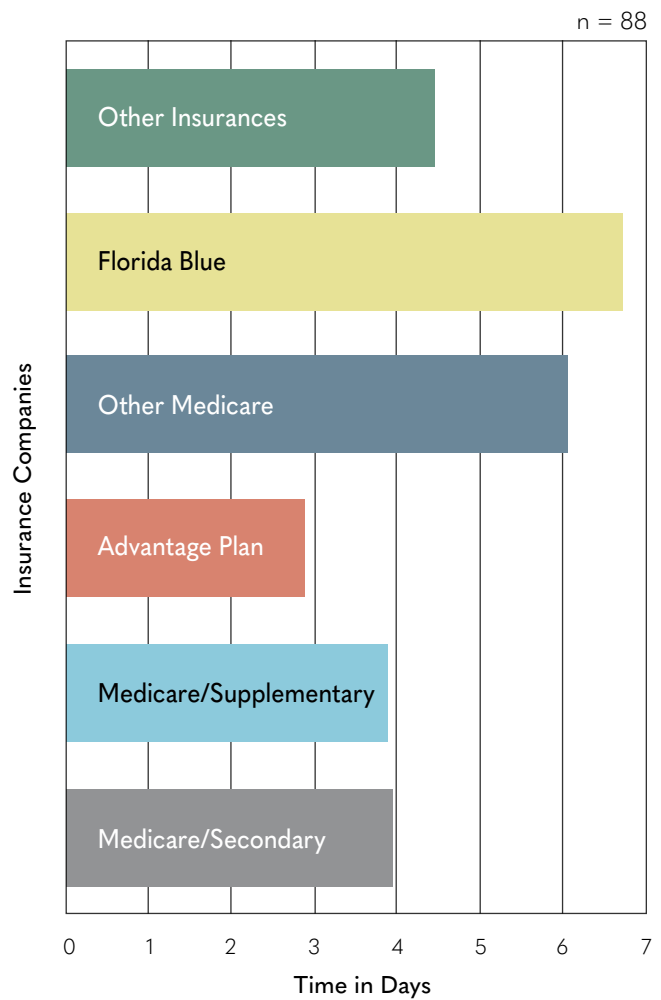


Figure 3: The data showed two companies that made up half of the patients' insurance, Medicare/Supplementary and Other Medicare companies. Medicare/Secondary, Advantage Plan, Florida Blue and Other Insurances provided for smaller portions of the population, with Medicare/Secondary contributing the smallest amount in the population at 10 percent and Advantage Plan the largest amount, providing for 15 percent of the patient population.



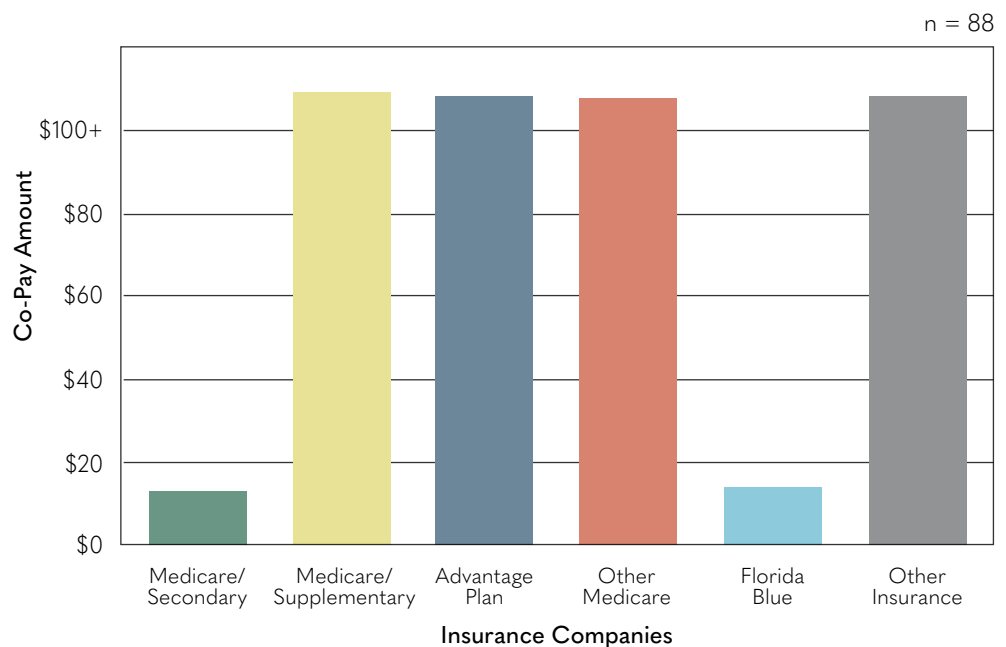
TIME FROM PRESCRIPTION DATE TO PRIOR AUTHORIZATION

Figure 4: Florida Blue had the longest time delay from prescription date to prior authorization, averaging 6.71 days, followed by Other Medicare insurances at 6.05 days. Advantage Plan had the least time from prescription to authorization, averaging 2.89 days. Medicare/Supplementary averaged at 3.88, Medicare/Secondary at 3.94 and Other Insurances at 4.44 days.



CO-PAY

Figure 5: Average Co-Pay for Each Insurance Company. Co-Pay amount over 100 indicates that the average co-pay was high. Medicare/Supplementary had an average co-pay of \$907 and Advantage Plan's average co-pay was \$886.65. Other Insurance's average co-pay was \$342.30, Other Medicare had the lowest of the high co-pay averages at \$317.00. Medicare/Secondary and Florida Blue were the only insurance companies that had co-pays that were less than \$100. Medicare/Secondary had an average co-pay of \$12. Florida Blue had an average co-pay of \$13.



PERCENTAGE OF PATIENTS THAT RECEIVED FUNDING FOR EACH INSURANCE COMPANY

n = 88

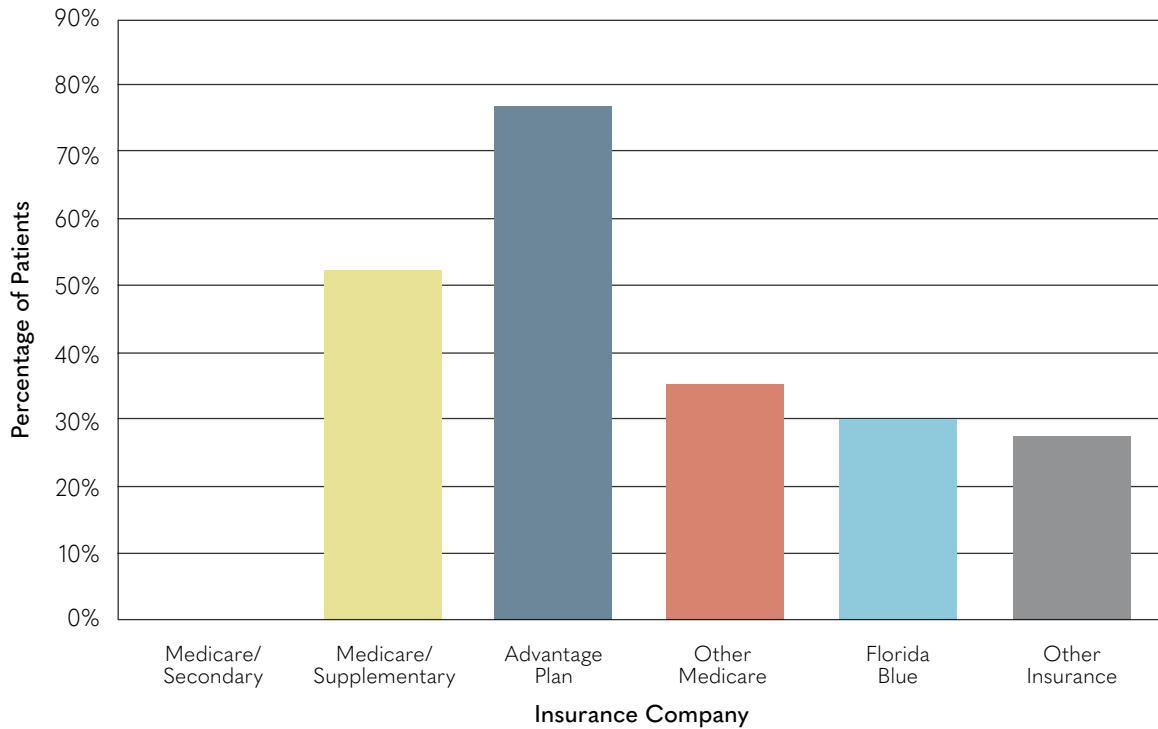


Figure 6: The percentage of patients that received funding was found for each insurance company. 52 percent of Medicare/Supplementary patients received funding to help pay for the oral chemotherapy. 76.9 percent of Advantage Plan, 35.0 percent of Other Medicare, 30 percent of Florida Blue and 27.3 percent of Other Insurance patients received funding. Medicare/Secondary was the only insurance that had no patients, zero percent, apply for or receive funding.

SPECIALTY PHARMACY

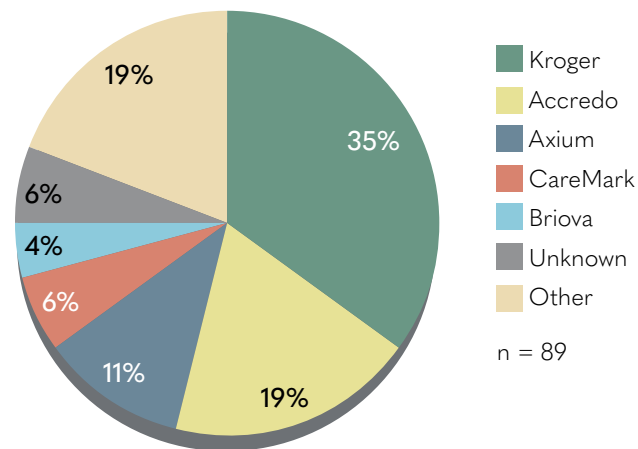


Figure 7: One patient used two different specialty pharmacies for the same oral chemotherapy producing a population of 89 patients. Kroger Pharmacy was used by 35 percent of the patients, 31 patients, in this population followed by Accredo and Other pharmacies which were used by 19 percent each or 17 patients. The pharmacy used by five patients or six percent of the patients was not able to be identified.

TIME FROM PRIOR AUTHORIZATION TO SHIPPING

n = 84

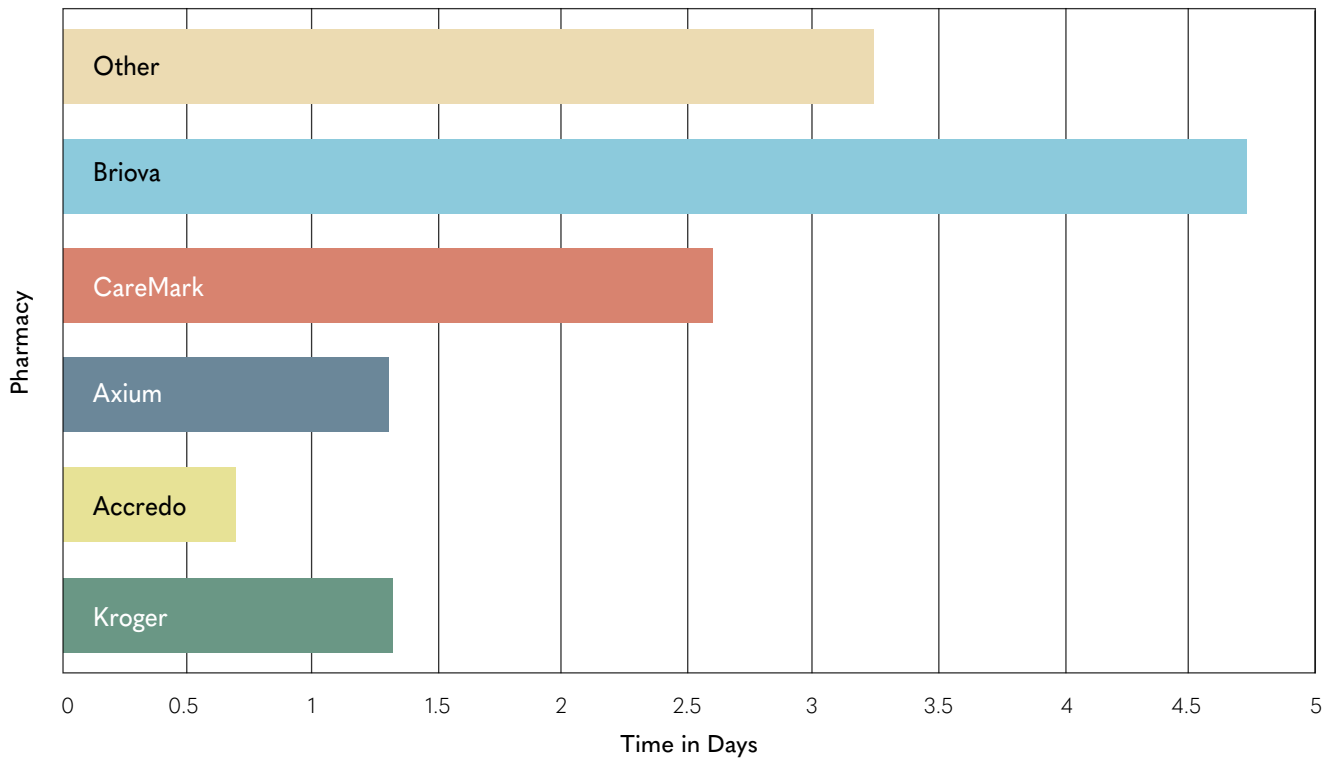


Figure 8. Accredo pharmacy took the least amount of time between prior authorization and shipment of the oral chemotherapy, averaging 0.69 days, whereas Briova took on average 4.75 days between prior authorization and shipment. Axiom and Kroger averaged the same time at 1.3 days. CareMark averaged 2.6 days and other pharmacies averaged 3.25 days from authorization to shipment. The patient population was 84 because there were five pharmacies that could not be identified.

DISCUSSION

Watson Clinic patients took an average of 18.89 days from prescription to start date. Of these days, 4.7 were from prescription date to prior authorization, followed by 1.7 days from prior authorization to shipping, and then 12.29 days from shipping to start date in which patients received funding. The results showed that patients faced the same barriers faced nationwide, including financial and time delays. Prior authorization created a time delay between the time that the specialty pharmacy received and was able to fill the prescription. Advantage Plan had the least amount of time between prescription and prior authorization, taking less than three days, compared to Florida Blue, which took over six days.

After prior authorization the pharmacies also had a time delay in how long it took for the prescription to be filled and shipped. The pharmacy with the least time delay was Accredo, which took less than a day to get the drug shipped after authorization, whereas Briova took over four days to ship the oral chemotherapy. Another barrier that was faced by 19.3% of the patients was prescription transfer from one pharmacy to another, either by request of the insurance company or the company providing funding to the patients, further delaying the shipment of the drug. Once the oral chemotherapy was shipped, patients took an average of 12 days to begin their oral chemotherapy.

Financial barriers were also faced by Watson Clinic patients, with almost half of them needing financial assistance to afford their oral chemotherapy. Co-pay was significantly more than \$100 (\$508-\$3,051) for 43 percent of the patients in the study, creating a significant financial barrier. Patients delayed starting the oral therapy in order to apply for funding to help cover out of pocket costs. Approximately 43.2 percent of patients received at least one form of financial assistance including grants, free trial vouchers, or receiving the drug free from a company.

Fox Chase Cancer Center in Philadelphia conducted a similar study consisting of 116 patients (149 total encounters) diagnosed with prostate and renal cell carcinoma. Those patients had an average of 14.5 days from prescription to start date and six days from prescription date to prior authorization. They also found that 59 percent of patients had a co-pay of over \$100, and that 54.2 percent received financial assistance. It was also noted that 32 percent of prescriptions were transferred from one pharmacy to another before being filled and shipped. (Geynisman, et al., 2018) Although there is a difference in the study population and the diagnoses that were evaluated, the results show that patients in both studies faced similar barriers in receiving the prescribed oral chemotherapy.

CONCLUSION

We have found that certain companies have a more streamlined process for being able to provide oral chemotherapy in a timely fashion, whereas some of the drug companies are still needing improved protocols. We feel that Accredo, Kroger, and Axium may be modeled by other providers to help our patients get their life-saving medications in a timely manner. Overall, our social workers do a great job providing patients with necessary medications, even those who need financial assistance. Patients who received funding took an average of three days after prior authorization to receive the needed funding. After identifying the barriers, there does not appear to be a significant impact we can make from the doctor's office perspective to improve the timeliness of starting oral chemotherapy.

WORKS CITED

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Triple-Negative Breast Cancer Compliance Study 2018

WATSON CLINIC CANCER & RESEARCH CENTER
PRINCIPAL INVESTIGATOR: SHALINI MULAPARTHI, MD
STUDENT RESEARCHER: STEFANI SHOREIBAH

PURPOSE

The Watson Clinic Cancer & Research Center's standards of care and protocol were measured with the National Comprehensive Cancer Network (NCCN) guidelines in assessing the surveillance and treatment of triple-negative breast cancer patients from 2015 to 2017.

PATIENTS AND METHODS

Watson Clinic Cancer Registry provided a list of the 64 total patients in this study, all of whom were diagnosed and treated for triple-negative breast cancer between January 1, 2015 and December 31, 2017. Patient data was abstracted from medical records and collected onto a spreadsheet to examine data points including demographics (age, weight, race/ethnicity), patient history (menopausal state, comorbidities, family history of cancer), diagnosis (clinical staging), treatment (chemotherapy, surgery, radiation), and follow-up evaluations (mammography, bone density scans, gynecological assessments, survival status). Analysis

of patient data gathered from these data points was utilized to assess Watson Clinic's standards of care and patterns of treatment protocol to the NCCN guidelines.

RESULTS

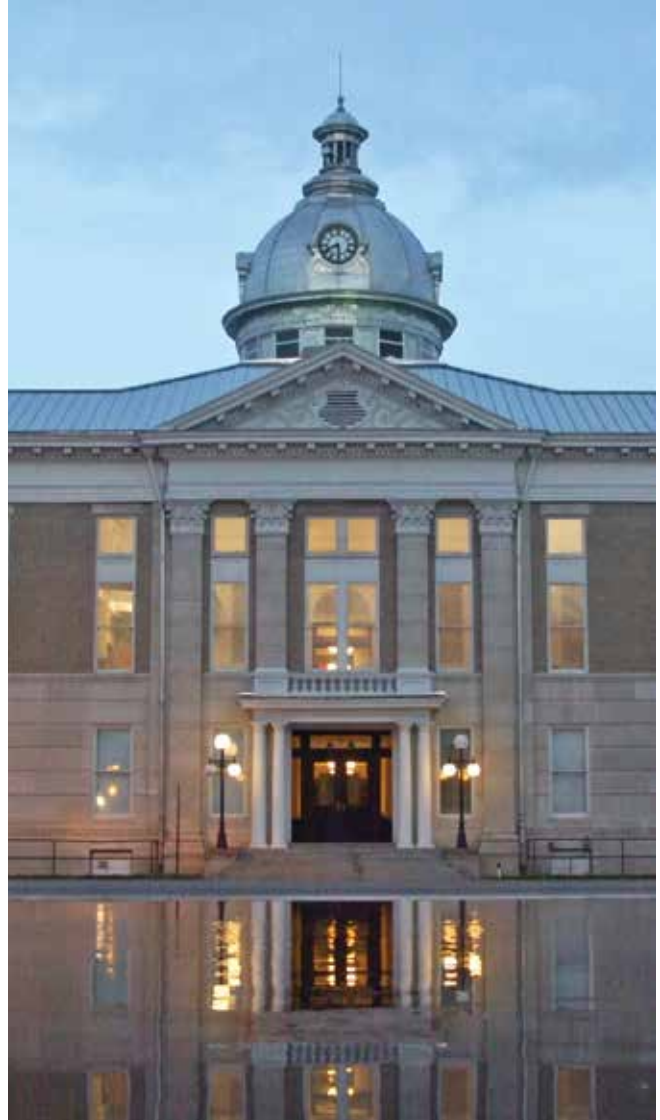
The survival status of the 64 patients in this study as of December 2017 shows 92 percent of patients still living, with the remaining eight percent of patients deceased from breast cancer-related causes. Patient survival status was confirmed through review of 2018 charts. Treatment records showed 78 percent of patients received chemotherapy, six percent of patients relocated to different facilities, five percent of patients declined treatment, and seven percent of patients were not advised chemotherapy due to ECOG performance status, extensive comorbidities, and/or advanced age. Of those patients stages I to IV, 70 percent received neoadjuvant chemotherapy and 30 percent received adjuvant chemotherapy. Surgical procedures including lumpectomies, mastectomies, and reconstruction were followed

by radiation treatment, with the exception of patients who received mastectomies that did not require radiation. Patients who received post-mastectomy radiation were stage III, indicated for cis criteria, and had positive lymph node status. In patient follow-up, 30 percent of patients received a bone density scan in surveillance evaluation, 63 percent of patients did not receive a bone density scan in surveillance evaluation, and seven percent of patients relocated to different facilities.

PATIENT DEMOGRAPHICS

Age Range	27-88
Age Mean	64
Age Median	66
# of Deceased Patients	5/64 (8%)

Table 1: Age at Diagnosis & Mortality Status. Mortality status recorded for all 64 triple-negative breast cancer (TNBC) patients, with eight percent of patients deceased and 92 percent of surviving patients at follow-up. The deaths of the five deceased patients were from breast cancer-related causes.



PATIENT WEIGHT

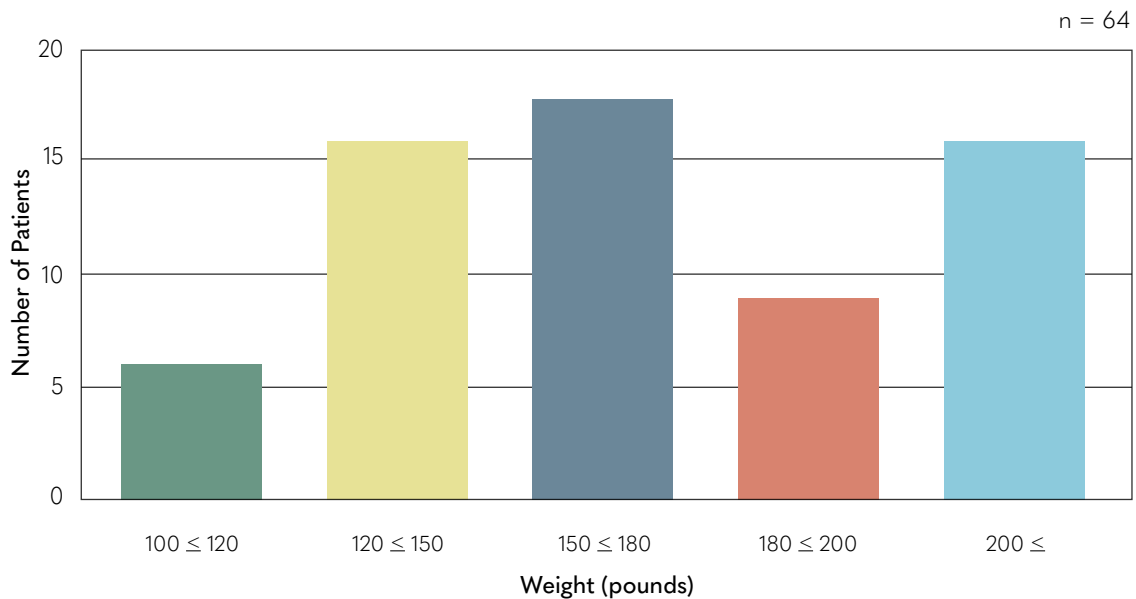


Figure 1: Patient weight recorded at time of TNBC diagnosis.

RACE/ETHNICITY

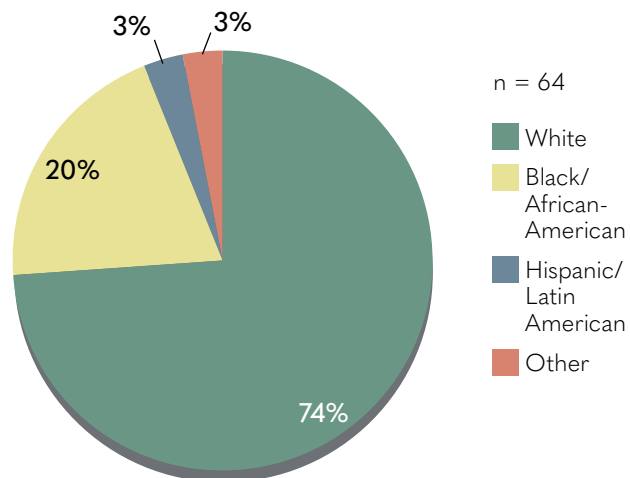


Figure 2: Race/ethnicity recorded for all 64 TNBC patients.

MENOPAUSAL STATE

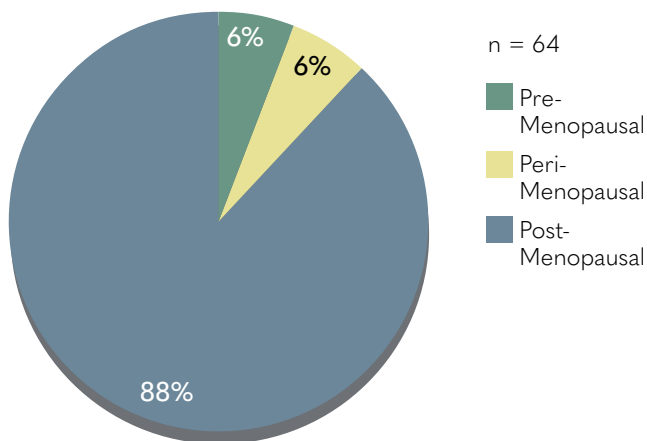


Figure 3: Menopausal state recorded for all 64 TNBC patients.

PATIENT COMORBIDITIES: OBESITY, DIABETES MELLITUS & OSTEOPOROSIS

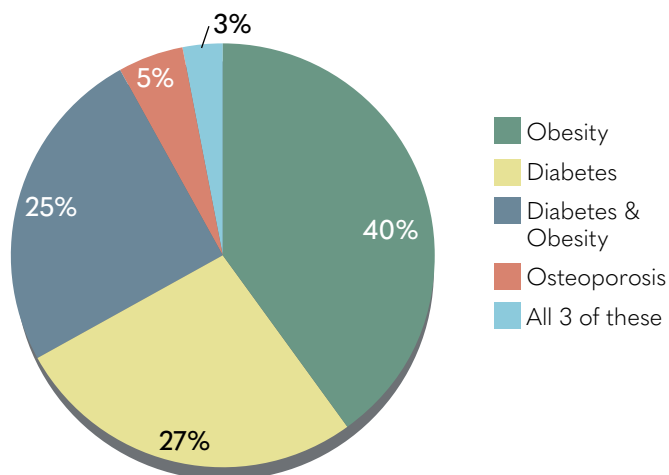


Figure 4: Comorbidities identified among TNBC patients. 40 out of 64 patients were found to have comorbidities of obesity, diabetes, osteoporosis, both obesity and diabetes, or all three of these.

PATIENT FAMILY HISTORY OF CANCER

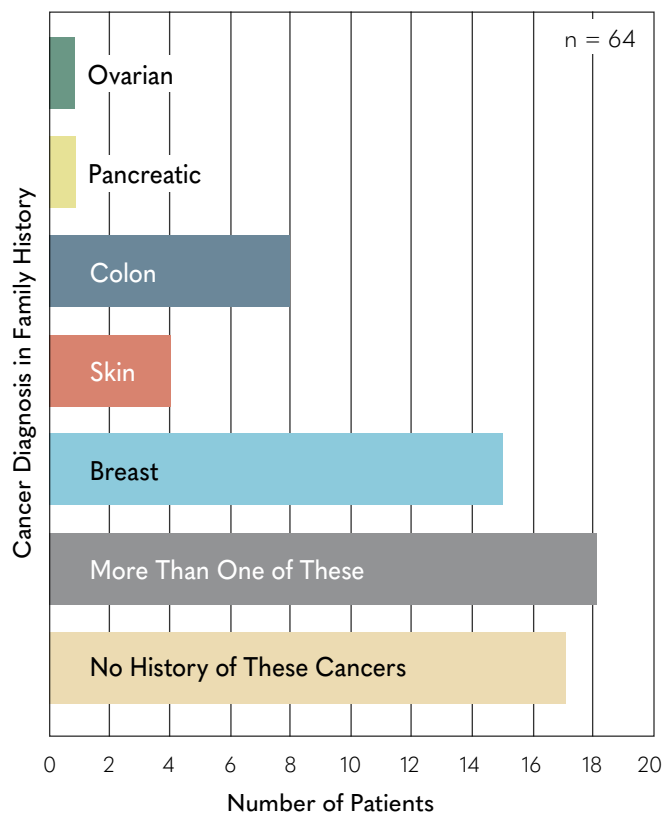


Figure 5: 47 out of 64 patients were found to have a family history of cancer. Diagnoses accounted for include colon cancer, skin cancer, breast cancer, pancreatic cancer, ovarian cancer, or more than one of these cancers in patient family history.



DIAGNOSIS

TRIPLE-NEGATIVE BREAST CANCER PATIENT STAGING

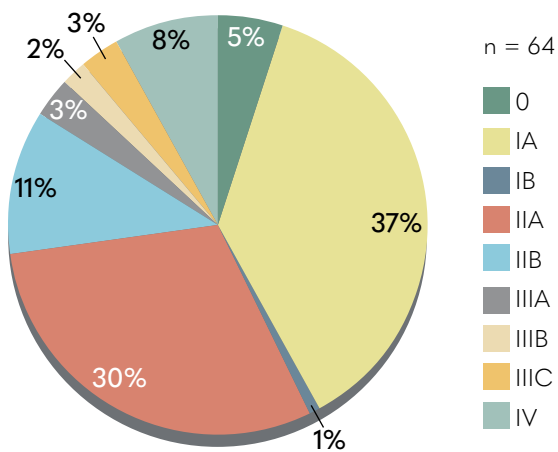


Figure 6. Table 2: Diagnostic Staging. TNBC staging was recorded for all 64 patients. Staging assessed from the American Joint Committee on Cancer (AJCC) 7th edition guidelines.

Stage	# of Patients	Percentage
0	3	5
IA	24	37
IB	1	1
IIA	19	30
IIB	7	11
IIIA	2	3
IIIB	1	2
IIIC	2	3
IV	5	8
Total	64	100

TREATMENT: CHEMOTHERAPY

PATIENT CHEMOTHERAPY STATUS

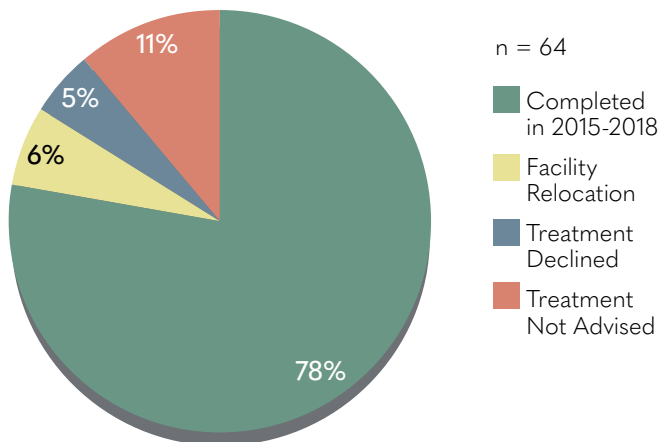


Figure 7. Table 3: Chemotherapy was completed by 50 out of 64 patients. Seven patients were not advised chemotherapy (from poor ECOG performance status scores, extensive comorbidities, and/or advanced age), three patients declined treatment, and four patients relocated to different facilities.

Chemotherapy Status	# of Patients	Percentage
Completed in 2015-2018	50	78
Facility Relocation	4	6
Patient Declination	3	5
Treatment Not Advised	7	11
Total	64	100

ADMINISTERED CHEMOTHERAPY TYPE

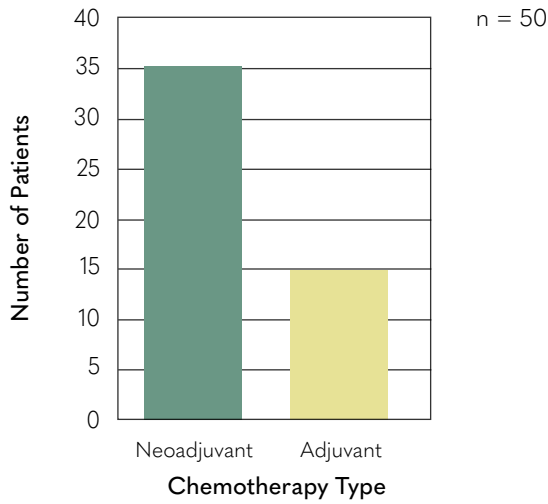
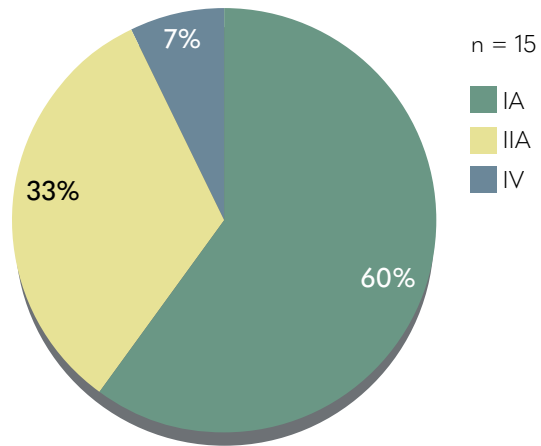
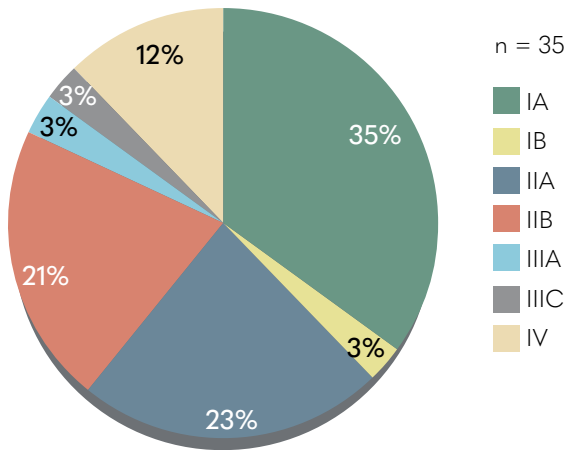


Figure 8: Chemotherapy was completed by 50 out of 64 patients from 2015 to 2018. Neoadjuvant chemotherapy was completed by 35 patients. Adjuvant chemotherapy was completed by 15 patients.

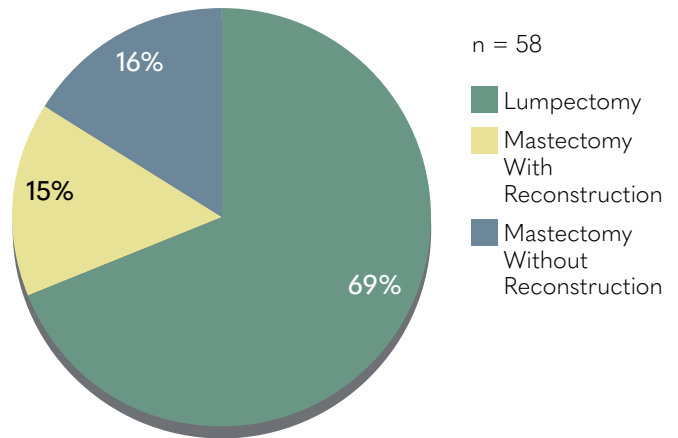
STAGING FOR PATIENTS WITH ADJUVANT CHEMOTHERAPY



STAGING FOR PATIENTS WITH NEOADJUVANT CHEMOTHERAPY



PATIENT SURGICAL TREATMENT



Surgical Treatment Plan	# of Patients	Percentage
Lumpectomy	40	69
Mastectomy with Reconstruction	9	15
Mastectomy without Reconstruction	9	16
Total	58	100

Figure 11. Table 4: 58 out of 64 patients underwent lumpectomy, mastectomy, and/or reconstruction surgical procedures. The six patients excluded from this figure did not have lumpectomies, mastectomies, or reconstruction performed due to death from breast cancer-related causes or patient facility relocation.



TREATMENT

SURGERY & RADIATION

Treatment Plan	# of Patients	Percentage
Lumpectomy With Radiation	40	63
Mastectomy With Radiation	5	7
Mastectomy Without Radiation	13	20
Radiation to other Areas of the Body (Stage IV)	3	5
No Radiation	3	5
Total	64	100

Figure 11. Table 5: Radiation treatment was given to 48 out of 64 patients. Patients who received a mastectomy followed by radiation were stage III, indicated for cis criteria, and had a positive lymph node status.

PATIENT FOLLOW-UP

MAMMOGRAPHY IN PATIENT FOLLOW-UP

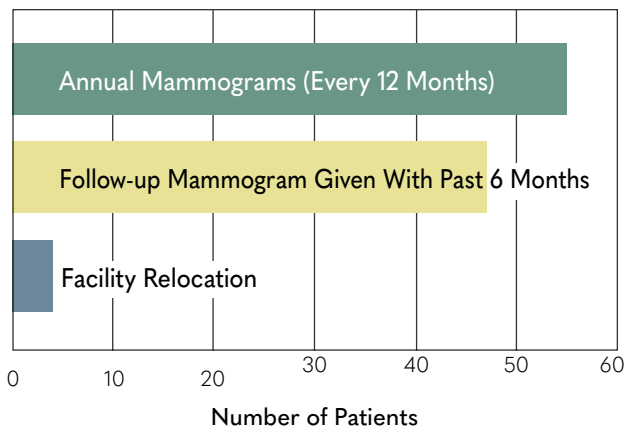


Figure 12: Mammography in patient follow-up was abstracted for surviving patients. Annual mammograms were given to 55 patients, 47 of whom received follow-up mammograms within the past six months. Four patients relocated to different facilities.

PATIENT BONE DENSITY SCAN IN FOLLOW-UP

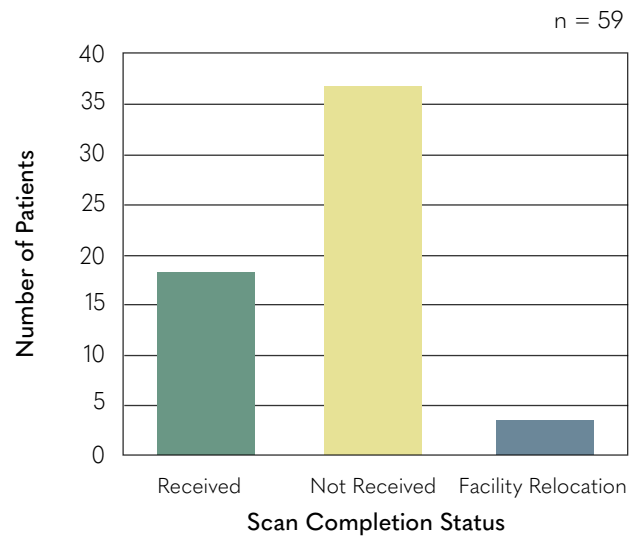


Figure 13: Bone density scan consistency in patient follow-up was abstracted for surviving patients.

Gynecological Assessment in Follow-up	# of Patients	Percentage
Within the Past 12 Months (Uterus Present)	13	22
Not Within the Past 12 Months (Uterus Present)	16	27
Not Within the Past 12 Months (Hysterectomy in Patient History)	26	44
Facility Relocation	4	7
Total	59	100

Table 6: A gynecological assessment within the past 12 months in patient follow-up was abstracted for surviving patients.

PATIENT FOLLOW-UP: SURVIVAL STATUS

MONTHS SURVIVED FROM DIAGNOSIS

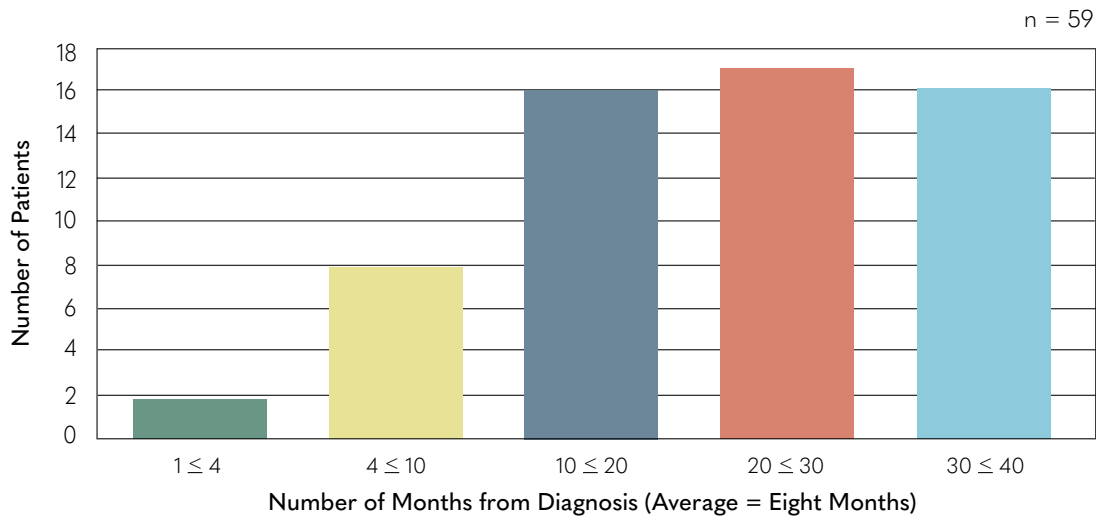


Figure 14: Patient Mortality Status. 59 surviving patients in total. Patients in this study have survived an average of 20 months from diagnosis date to December 2017

Deceased Patient	Region(s) of Metastasis	# of Months Survived from Diagnosis to Death
1	Lungs	7
2	Brain	4
3	Lungs, Liver	11
4	Brain, Pelvis	7
5	Brain, Liver	9

Table 7: Survival Duration of Deceased Patients. The survival duration of deceased patients was recorded in months from diagnosis date to date of death (avg. = eight months). The deaths of these five patients were from breast cancer-related causes.

CONCLUSION

This compliance study demonstrates the Watson Clinic Cancer & Research Center's overall adherence to the NCCN guidelines for treating triple-negative breast cancer patients. NCCN staging, chemotherapy, surgery, radiation, mammography, and gynecological assessment benchmarks were met. Among surviving patients, those who received a bone density scan in their surveillance follow-up versus those who did not presents a gap that allows for future consideration in this area of triple-negative breast cancer patient care.

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Aromatase Inhibitors (AIs) Study at Watson Clinic

PRINCIPAL INVESTIGATOR: NEEHARIKA SRIVASTAVA MAKANI, MD
STUDENT RESEARCHER: ANDREW K. MULVILLE

INTRODUCTION

Breast cancer is the most commonly diagnosed and the second most common cause of cancer death in women in the United States.¹ Hormone receptor positive tumors comprise approximately 70 percent of all breast cancers.² In post-menopausal women, the most effective endocrine or anti-hormonal therapy available for management of these tumors has been aromatase inhibitors (AIs).² The use of AIs has been shown to improve disease-free survival and is the standard of care in post menopausal patients with early stage (Stage 0, carcinoma in situ, Stage 1 & 2), hormone receptor positive breast cancer.³ Unfortunately, endocrine therapy does have a negative impact on the quality of life of patients and thus, patient compliance with this treatment has been problematic.³ Most patients diagnosed with early stage hormone receptor positive breast cancer, will need to be on anti-hormone or endocrine therapy for 5-10 years. According to a recent New England Journal of Medicine study, almost 79 percent of women remained compliant with anti-endocrine therapy after the first year of treatment without exceeding

a gap of 60 days. However, by the fifth year of therapy only 27 percent of women reported taking their endocrine therapy, without exceeding a 60-day gap.⁴ There are multiple known negative side-effects related to AI therapy, which lowers estrogen levels in the body. Depletion of estrogen in the body can diminish the quality of life of women by causing vaginal dryness, loss of sexual libido, increased breast swelling and tenderness, increased joint pain, increased bone loss which may lead to osteoporosis, worsening memory problems, increased hot flashes, mood swings, and other gastrointestinal issues such as gas or bloating. Due to the fact that patients require such extended courses of therapy (5-10 years of treatment) and that these side-effects can significantly diminish the quality of life, there are higher rates of non-compliance. The purpose of this study was to evaluate the effects of anti-hormonal therapy upon quality of life in post-menopausal women diagnosed with early stage, hormone receptor positive breast cancer. Data was collected in a prospective manner using validated and developed questionnaires the FACT-B, the FACT-B endocrine subscale (FACT-B-ES).

METHODOLOGY

Post menopausal women diagnosed from October 27, 2017 to July 11, 2018 with early stage breast cancer who were treated with aromatase inhibitors were asked to participate in the study. The informed consent and the FACT-B and FACT-B-ES patient questionnaires were obtained prior to the initiation of the first dose of hormonal therapy. The patient's electronic health record was reviewed and data was abstracted to determine demographic information and prior treatment interventions. Approximately 4-10 weeks after starting the anti-hormonal therapy, the patient completed the same FACT-B and FACT-B-ES patient questionnaires. Data from the FACT-B and FACT-B-ES questionnaires were analyzed using paired t-tests to determine if there were any statistically significant differences on quality of life prior to and within the first 10 weeks on therapy with aromatase inhibitors.

RESULTS

DEMOGRAPHICS

This study had a total of 26 patients (Table 1). The average and median age for the patients were 71 and 70, respectively (Table 1). The majority of patients in the study were Caucasian, with an ethnic distribution of 22 Caucasian, one Hispanic/Latino, and three African American patients (Table 1). The average body mass index (BMI) for the patients was 30.89 (Table 1).

Total Number of Patients	Age	Ethnicity	Body Mass Index (BMI)
26	Average	African American	Average
	71	3	30.89
	Median	Caucasian	Median
	70	22	29.90
		Hispanic/Latino	
		1	

Table 1: The total number, age, ethnicity, and body mass index of patients in the study.



Approximately, 46 percent, of the patients in the study were married (Figure 1). 96 percent of the patients obtained at least a high school or GED

degree and 42 percent obtained a bachelor's degree or higher (Figure 2).

MARITAL STATUS

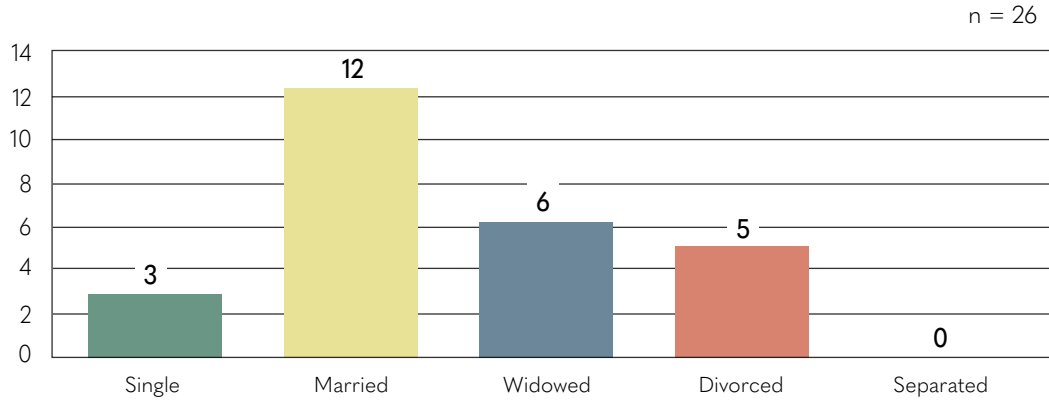


Figure 1: Marital status of patients in the study.

EDUCATION LEVEL

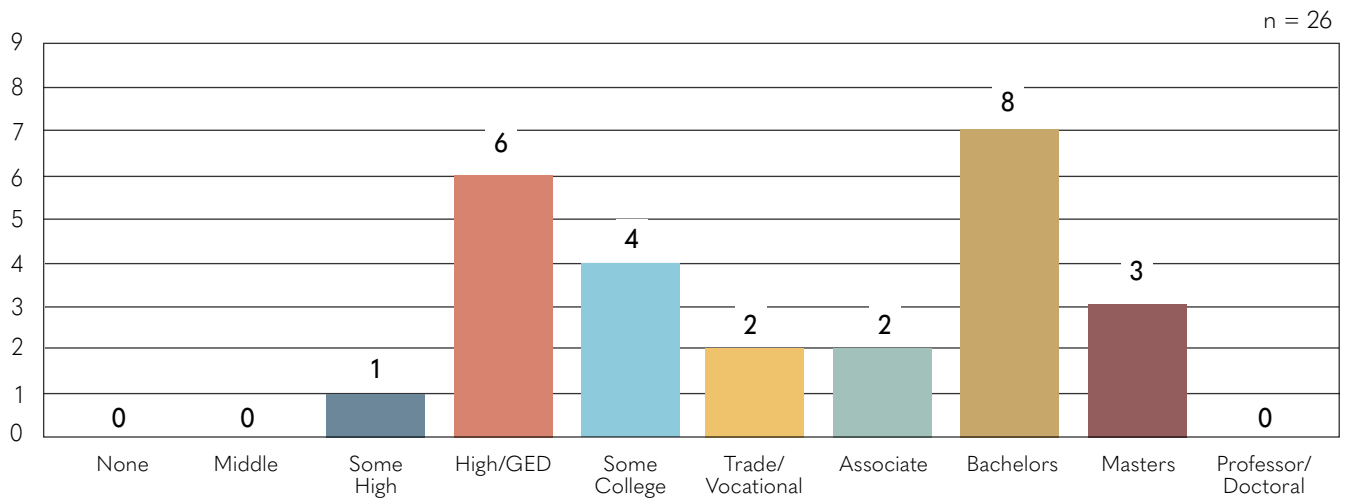


Figure 2: Education level of patients in the study.

All study patients had breast cancer that was hormone receptor positive with the histology of the cancers being the following: 81 percent of the patients had ductal carcinoma, 12 percent had lobular histology and seven percent had other (Figure 3).

HISTOLOGY

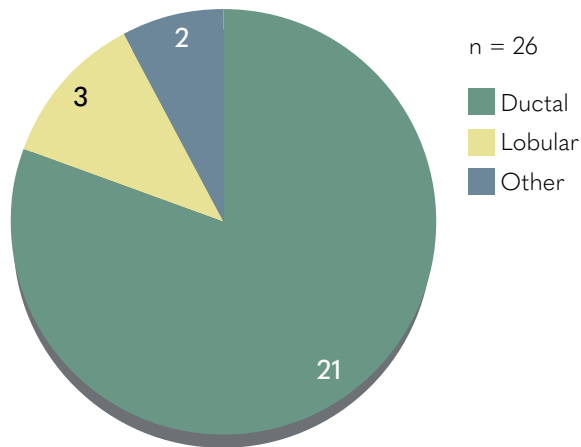


Figure 3: Histology of each patient's cancer.

The inclusion criteria for this prospective study included patients who had early stage breast cancer as defined by AJCC (stage 0-2, based on timing of diagnosis). 27 percent of patients had stage 0 (in-situ cancer), 50 percent of the patients had stage 1 cancer and 23 percent of patients were diagnosed with stage 2 breast cancer (Figure 4).

CANCER STAGING

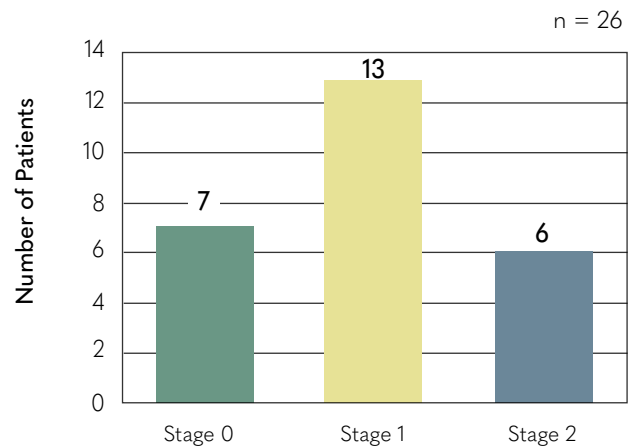


Figure 4: Number of patients with each stage of cancer included in the study.



In terms of treatment interventions that the patients received, four percent had chemotherapy, 77 percent received radiation, and all of the patients had surgery. Of the surgeries, 85 percent of patients had a lumpectomy while 15 percent had a mastectomy. In addition, 15 percent of patients had had a hysterectomy.

Baseline bone health was evaluated via a bone-density (DEXA scan) for some patients prior to initiation of AI therapy. One patient had known osteoporosis, five had osteopenia, and six had normal bone health. Data was unobtainable for 14 of the patients (Figure 5).

BONE HEALTH PRIOR TO TREATMENT

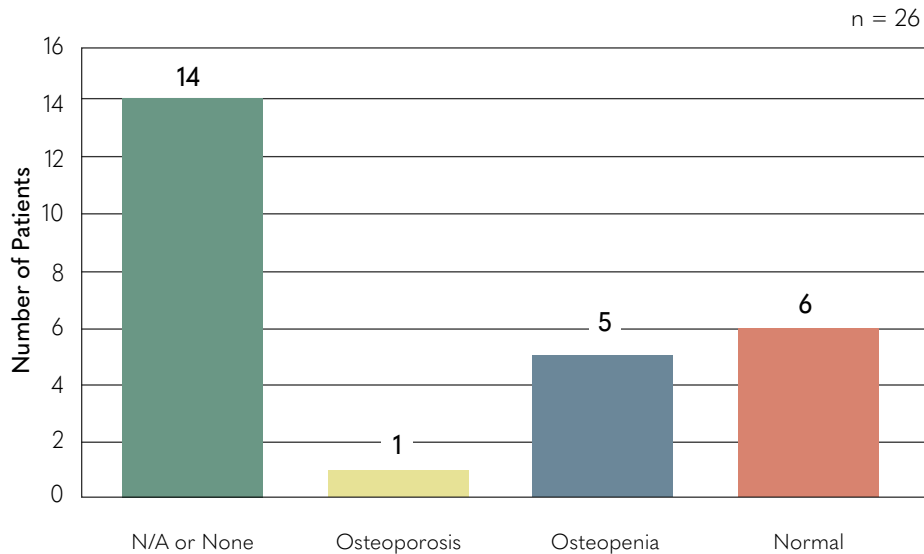


Figure 5: Bone health determined by the DEXA scan prior to AI treatment.

Prior to the study, 56 percent of patients regularly exercised (Figure 6).

NUMBER OF PATIENTS WHO REGULARLY EXERCISE

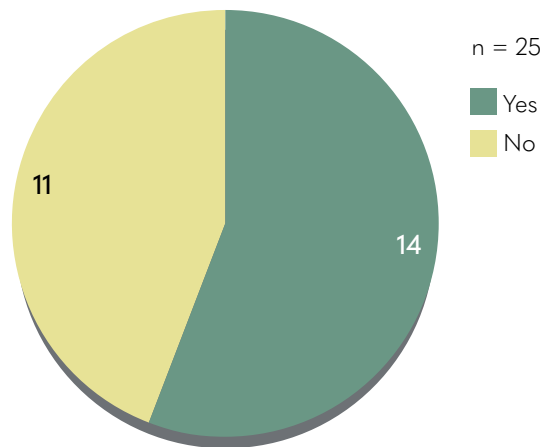


Figure 6: The number of patients who regularly exercised prior to AI treatment.

Assessing underlying depression and anxiety prior to starting AI therapy was obtained and 23 percent of patients reported being clinically diagnosed and treated for depression and/or anxiety.

Patients answered the Fact-B and Fact-B-ES questionnaires, which are both validated quality of life questionnaires used to study the functional assessment of cancer therapy on breast cancer patients. These questionnaires were administered prior to and again repeated 4-10 weeks starting AI therapy. Paired-t-test was used to analyze the data to determine if there were any statistically significant differences in the quality of life using a p-value of less than 0.05.

Fact-B and FACT-B-ES questionnaires have approximately 50 questions and is available online at: <http://www.facit.org/facitorg/questionnaires>.

THE RESULTS HIGHLIGHTED IN THIS PAPER DISCUSS THE STATISTICALLY SIGNIFICANT RESULTS.

From the Fact-B questionnaire, there were three parameters that were statistically significantly worse since starting the AI therapy.

In the study, patients felt bothered by the treatment's side effects significantly more after 4-10 weeks of treatment ($p=0.044$, $CI=0.95$, Table 2). They also were significantly less satisfied with their family communication about their illness ($p=0.031$, $CI=0.95$, Table 2). Patients also noted that they were sleeping significantly worse after starting AI therapy, ($p=0.001$, $CI=0.95$, Table 2).

	I am Bothered by Side Effects of Treatment	I am Satisfied With Family Communication About Illness	I am Sleeping Well
Before	0.38	3.77	2.92
After	0.69	3.31	2.23
P-Value	0.044	0.031	0.001
	Sig. More	Sig. Less	Sig. Less

Table 2: The average Fact-B responses from before and after 4-10 weeks of treatment.





FROM THE FACT-B-ES QUESTIONNAIRE, PATIENTS NOTED THE FOLLOWING.

After 4-10 weeks of treatment, patients had significantly more hot flashes on average ($p=0.030$, $CI=0.95$, Table 3) and more night sweats ($p=0.015$, $CI=0.95$, Table 3). Patients also felt significantly more bloated ($p=0.004$, $CI=0.95$, Table 3) after starting the AI therapy. Interestingly, patients

noted significantly less vaginal itching/irritation ($p=0.030$, $CI=0.95$, Table 3), breast sensitivity/tenderness ($p=0.006$, $CI=0.95$, Table 3), and joint pain ($p=0.008$, $CI=0.95$, Table 3) after starting the AI therapy.

	I Have Hot Flashes	I have Night Sweats	I Have Vaginal Itching/Irritation	I Feel Bloated	Breast Sensitivity/Tenderness	I Have Pain in my Joints
Before	1.23	1.04	0.31	.24	1.50	1.69
After	1.77	1.42	0.12	.65	.85	1.31
P-Value	0.030	0.015	0.030	0.004	0.006*	0.008*
	Sig. More	Sig. More	Sig. Less	Sig. More	Sig. Less	Sig. Less

Table 3 Table 2: The average Fact-B-ES responses from before and after 4-10 weeks of treatment.

DISCUSSION

Several preliminary conclusions can be drawn from this data. In the first 4-10 weeks, four (15 percent) of the patients stopped treatment. Three of these patients switched to a different AI medication or started a different class of endocrine therapy such as tamoxifen. Additionally, within a short period of time of starting the treatment, patients started to experience several negative side effects. Many of these side effects are detrimental to a patient's quality of life that could lead to non-compliance during AI therapy. Though most studies describe that chronic AI therapy leads to breast tenderness, worsening vaginal dryness and joint pain; our study shows that all three of these parameters improved while on AI therapy. This is most likely due to the cessation of radiation therapy. While patients are on radiation therapy there is an increase in breast swelling and tenderness and simply stopping radiation will lead to improvement of breast symptoms. Furthermore, chemotherapy treatments can lead to vaginal dryness and joint pain and thus, stopping chemotherapy will also initially lead to improvement of these symptoms. It is likely that with chronic AI therapy, patients will start to experience worsening breast tenderness, increased vaginal dryness and worsening joint pain.^{3,4}

By understanding and characterizing the negative side effects patients are experiencing while on AI therapy, we as healthcare providers can provide

better symptom management techniques to help patients cope with these side effects. This will help patients be more compliant with their AI therapy. Additionally, by providing other resources such as support groups or counseling sessions, patients can have better access to information and other cancer survivorship programs that directly address the concerns that arise while patients are on AI therapy. Furthermore, patients are encouraged to continue their therapy knowing that others may also be dealing with these side-effects but are getting the help needed to better cope with the side-effects.

Future studies include administering these two questionnaires every six months to monitor patients throughout their five years of AI therapy. This would help clinicians better understand the side-effect profile as it changes throughout the years of AI therapy on the body and the mind of patients. Additionally, results from this study would help women with early stage breast cancer be able to better advocate for other community resources. These resources could be used to help with access to exercise programs that focus on bone strengthening, easier access to sexual health like vaginal rejuvenation procedures, and even emotional support with breast cancer counseling sessions.

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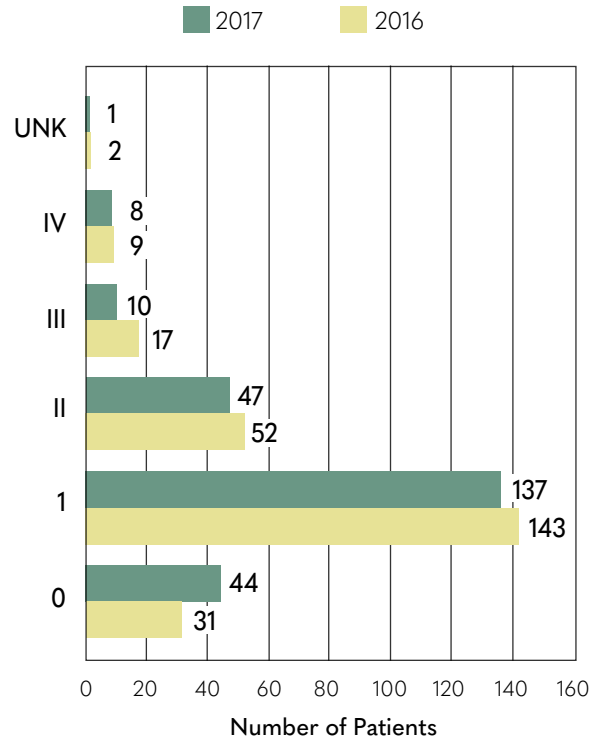
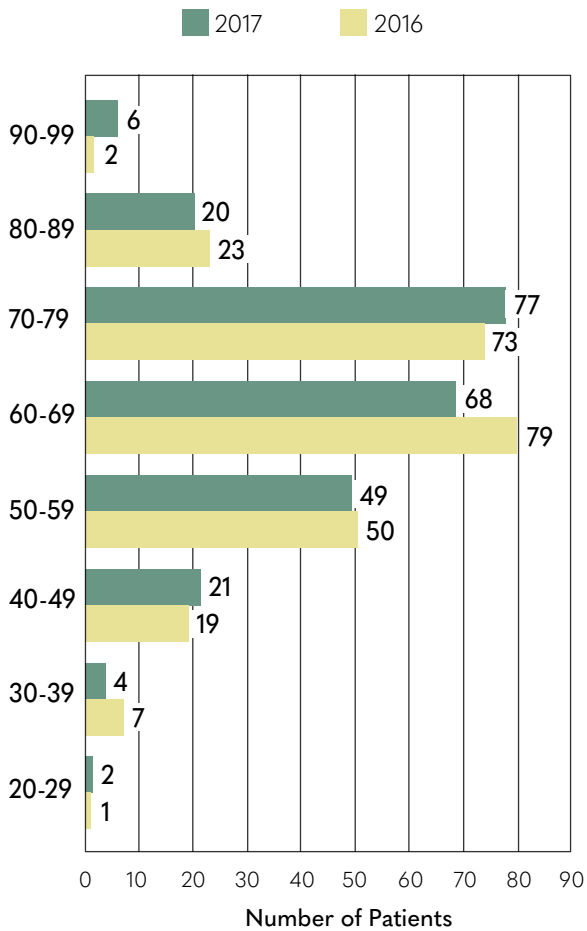
Cancer Registry Data Report 2018

NATIONAL CANCER INSTITUTE - SEER SURVEILLANCE, EPIDEMIOLOGY AND END RESULTS PROGRAM

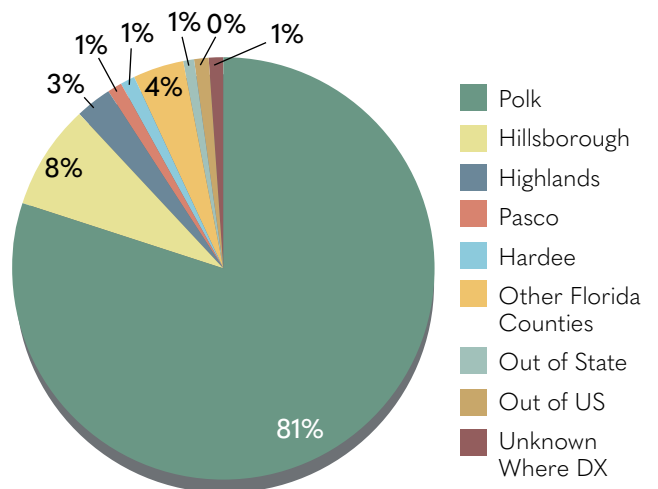
In 2018, it is estimated that there will be 266,120 new cases of female breast cancer and an estimated 40,920 people will die of this disease. Female breast cancer represents 15.3 percent of all new cancer cases in the U.S.

BREAST CANCER DATA YEARS 2016 AND 2017 GRAPHS COMPARING AGE AT DIAGNOSIS, AJCC STAGE AT DIAGNOSIS, AND GEOGRAPHICALLY WHERE OUR PATIENTS ARE FROM.

BREAST CANCER AJCC STAGING



DIAGNOSIS COUNTY CASES PERCENT ANALYTIC AND NON-ANALYTIC BREAST CANCERS 2016 AND 2017 DATA YEARS



A combined total of 501 analytic breast cancers diagnosed and treated at CRC and Watson Clinic Women's Center, 54 cases diagnosed were under the age of 50.

RESOURCES & INFORMATION ON CANCER

A Place For Her

727-447-1146 • www.aplaceforher.com

American Cancer Society (ACS)

800-227-2345 • www.cancer.org

American College of Surgeons (ACoS)

800-621-4111 • www.facs.org

American Institute for Cancer Research (AICR)

800-843-8114 • www.aicr.org

American Lung Association

www.lungassociation.org

Breast Cancer Foundation of Central Florida

417-862-3838 • www.bccf.org

CancerCare

800-813-HOPE • www.cancercare.org

Centers for Disease Control and Prevention (CDC)

www.cdc.gov

Central Florida Health Care Center

866-234-8534 • www.cfhconline.org

Chronic Disease Fund

877-968-7233 • www.cdfund.org

Citrus Connection Handy Bus

www.ridecitrus.com

Comfort Keepers

866-225-0320 • comfortkeepers.com

Commission on Cancer (CoC)

312-202-5009 • www.facs.org/cancer

Cornerstone Hospice

866-742-6655 • web.cshospice.org

Department of Children and Families

407-317-7000 • www.myflfamilies.com

Florida Cancer Data System (FCDS)

305-243-4600 • www.fcds.med.miami.edu

Florida Department of Health (FDH)

www.doh.state.fl.us

Good Shepherd Hospice

800-544-3280 • www.chaptershealth.org

Healthwell Foundation

800-675-8416 • www.healthwellfoundation.org

Lakeland Volunteers in Medicine

863-688-5846 • www.lvim.net

Leukemia & Lymphoma Society

800-955-4572 • www.leukemia-lymphoma.org

Lighthouse Ministries

863-687-4076 • www.lighthousemin.org

National Cancer Institute (NCI)

800-4CANCER • www.cancer.gov

Nurses Helping Hands Assisted Living

www.nurseshelpinghandsalf.com

Patient Access Network

866-316-7263 • www.panfoundation.org

Patient Advocate Foundation

800-532-5274 • www.patientadvocate.org

Patient Services, Inc.

800-366-7741 • www.patientservicesinc.org

Polk County Elderly Services

863-534-5320 • www.polk-county.net

Polk County Transport

www.polk-county.net

Social Security Administration

www.ssa.gov

Susan G. Komen

800-468-9273 • www.komen.org

Talbot House

863-687-8475 • www.talbothouse.org

United Way

2-1-1 or 863-648-1515 • www.uwcf.org

VITAS Hospice

863-583-7100 • www.vitas.com

Volunteers In Service to the Elderly (VISTE)

863-284-0828 • www.viste.org

We Care of Polk County

863-662-4227 • www.wecarecentralflorida.org



WATSON CLINIC^{LLP}
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 MOFFITT ONCOLOGY NETWORK MEMBER

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