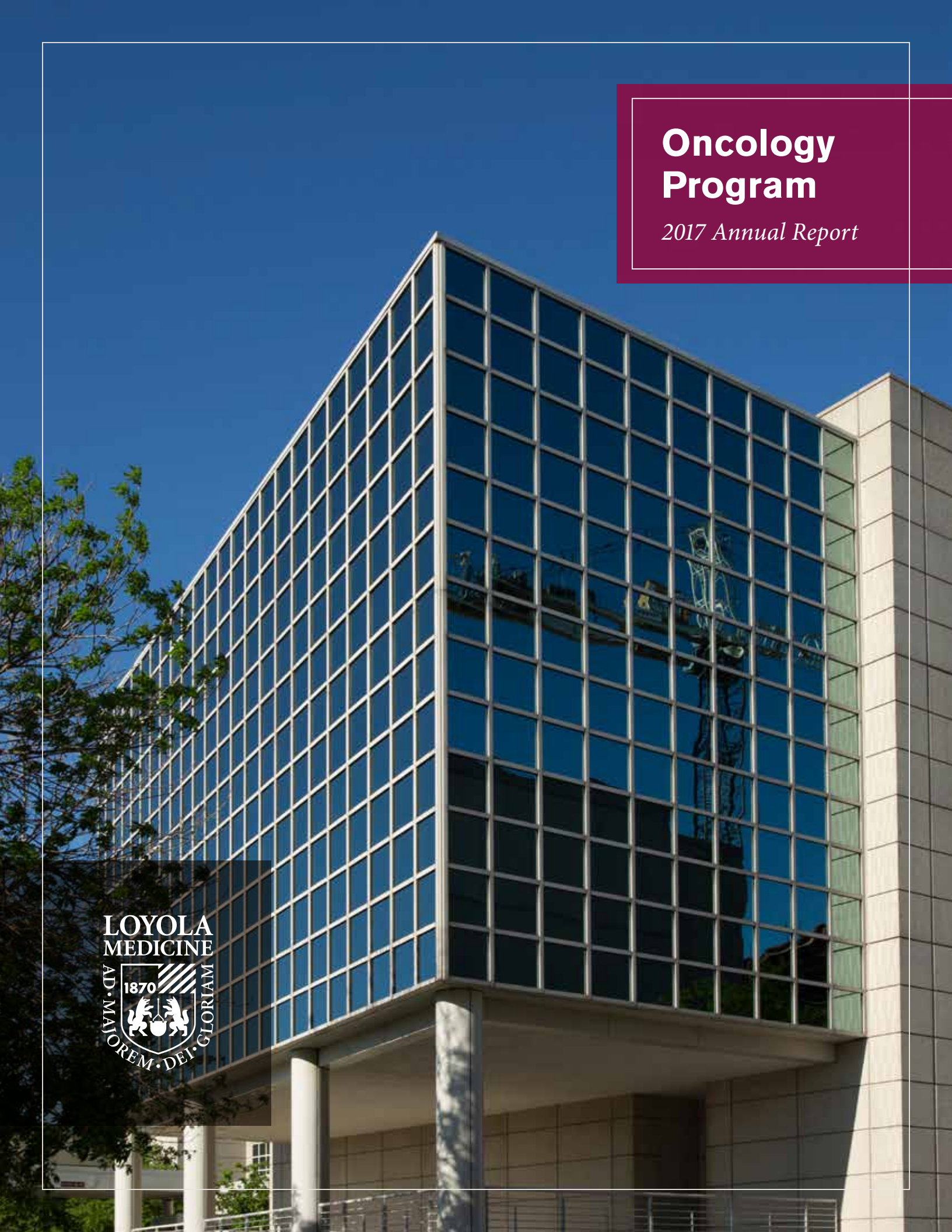

Oncology Program

2017 Annual Report

LOYOLA MEDICINE

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Mission Statement

Trinity Health Mission Statement

We serve in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit to improve the health of our communities, and to steward the resources entrusted to us.

Loyola Medicine is committed to excellence in patient care and the education of health professionals. We believe that our Catholic heritage and Jesuit traditions of ethical behavior, academic distinction and scientific research lead to new knowledge and advance our healing mission in the communities we serve. We believe that thoughtful stewardship, learning and constant reflection on experience improve all we do as we strive to provide the highest-quality healthcare.

We believe in God's presence in all our work. Through our care, concern, respect and cooperation, we demonstrate this belief to our patients and families, our students and each other. To fulfill our mission, we foster an environment that encourages innovations, embraces diversity, respects life and values human dignity. We are committed to going beyond the treatment of disease. We also treat the human spirit.

Brand Promise

The people of Loyola promise patients that we go beyond the illness to treat the whole person.

The Cardinal Bernardin Cancer Center is located on the east side of the campus and faces First Avenue. Parking is available in a parking lot in front of the building and valet parking is available at the entrance. A coffee bar is located just inside the building on the first floor. Named in honor of the late Archbishop of Chicago Joseph Cardinal Bernardin, the cancer center was the first free-standing facility in Illinois dedicated to cancer research, diagnosis, treatment and prevention. Loyola's cancer center contains all outpatient cancer care along with extensive research laboratories, offices and educational space. Many of the multidisciplinary clinics within the cancer center provide a one-visit, one-team approach, providing patients with a diagnosis and treatment plan in the same day. Patients can see their physician, have lab work done, undergo chemotherapy and have cancer care-related prescriptions filled, among many other services in the building.

Message from the Chairman

The year 2017 brought combined improvements to the wide array of cancer services available to patients of Loyola University Medical Center, American College of Surgeons Accredited Oncology Program. It is with great pleasure to offer my congratulations to the entire cancer team from administration to all clinical and volunteer staff in this institution to providing high-quality cancer care to our patients, meeting and exceeding the standards set by our cancer program.

This report provides an overview of the Program's organization of services and highlights a statistical summary in a narrative, tabular and graphic form of all cancer cases diagnosed and treated at Loyola University Medical Center.

Through our commitment and determination, the accomplishments of the oncology program are wholly dependent upon the tireless efforts of a team of caring professionals, without whom we could not strive to reach our goal in providing oncology service of highest caliber.

Palos designated Loyola as its exclusive academic partner, and Loyola committed to support the development of clinical and educational programs at Palos.

Celebrating the achievements of this relationship, they are working together to:

- Jointly expand access to specialty clinical services at Palos
- Improve quality of care
- Increase efficiency of services

On Palos' South Campus, plans have been developed and the state of Illinois Certificate of Need (CON) approved to build a facility that will house an advanced oncology center. This center will be staffed and supported by Loyola subspecialists in medical, surgical and radiation oncology.

Improved Access to Services, a one-call system has been established for the transfer of neurosurgery patients. Since Loyola provided a telestroke neurosciences consult service for Palos physicians, the capability of both teams to treat stroke and other neurologic diseases has greatly improved. Loyola's stroke specialists use a telemedicine robot to conduct patient exams remotely, in real time.

As an academic medical center, Loyola can offer the opportunity to enroll in clinical trials of experimental new drugs that are not available at most hospitals. These new treatments potentially can reduce side effects, prolong remissions, and in some cases cure cancers.

We also enhanced access to trauma transfer services by implementing the "auto-accept" policy to all requests. Now, all trauma transfer requests from Palos Hospital are managed efficiently.

In addition, subspecialty referrals from Palos physicians to Loyola are now expedited through the patient access center in the Loyola Medicine Preferral free app for iOS and Android smartphones. This mobile application offers an easy tool to refer patients to primary care providers and specialists. It supports better communication and a working relationship with the provider network and sends physician details to a patient by text message.

Loyola is providing access to robust and advanced educational programming to Palos physicians by teleconferencing grand rounds presentations. Palos physicians also have access to Loyola Medicine Continued Medical Education courses. Palos attending physicians attained academic and medical staff appointments at Loyola and have begun supervising medical students.

Palos Health offers continuity of care with Loyola Medicine thanks to connectivity through our common EMR, Epic. The Epic installation and the unique agreement between our organizations offers a better flow of information and allows providers to freely exchange and access information for patients under joint management.

Constantine Godellas, MD
Oncology Program Committee Chairman

Member List

The Cancer Committee membership is multidisciplinary, representing physicians from the diagnostic and treatment specialties and non-physicians from administrative and supportive services. The following list of Committee members in 2017 reflects the multidisciplinary nature of the Cancer Committee:

Member	Specialty
Constantine Godellas, MD Oncology Program Committee Chairman	Surgical Oncology
Gerard Abood, MD Oncology Program Cancer Liaison Physician	Surgical Oncology
Carol Bier-Laning, MD	Otolaryngology
Davide Bova, MD	Diagnostic Radiology
Violeta Dimovic, CTR	Manager, Oncology Data Management
Elisa Estrada	Oncology Data Management
Debbie Fager	ACS Representative
Kathleen Fujiu, RN, BA, BSN, MBA, OCN	Nurse Manager 6 West, Coordinator
Kathy Grego, RHIT, CTR	Oncology Data Management, Coordinator
Madelyn Dupee	Rehabilitation
Elizabeth Henry, MD	Hematology/Oncology
Kate Heraty	Genetic Counselor
Tess McCoo	Radiation Therapy, Director
Edward Melian, MD	Radiation Therapy
Angelique Mercier	Genetic Counselor
Stephanie Mills, RHIT	Oncology Data Management
Laura Morrell	Social Work, Cancer Center, Coordinator
Patricia Mumby, PhD	Professor, Psycho-Oncology
Gayle Payonk	Cancer Service Line, Oncology Support Ex Director
Ceil Petrowsky, RN MSN CCRC	Manager Cancer Clinical Trials Office
Maria Picken, MD, PhD	Professor of Pathology & Director of Renal Pathology
Mark Speyer, MD	Palliative Care
Sheryl Svoboda	Dietitian, Cancer Center
Peter Tortorice	Manager, Pharmacy Oncology

Prepared by: V. Dimovic, CTR

Oncology Services

All patients at the Cardinal Bernardin Cancer Center begin with a visit to one of the center's specialty or multidisciplinary clinics. There, the patient and family meet with the cancer specialist responsible for establishing an individual treatment plan and coordinating care. Within our unique multidisciplinary setting, a patient will meet with a team of cancer experts that may include surgeons, medical oncologists, radiation oncologists, radiologists, pathologists and plastic surgeons. These specialists work together to evaluate a patient's condition. During the same visit, patients might also meet with a nutritionist, nurse, social worker or other supportive staff.

Programs and Services

Below is a list of our programs and services for cancer care:

Art Therapy

Bone Marrow Transplantation

Breast Cancer

Breast Care

Breast Oncology Center

CAN-HELP Cancer Information Service

Cancer Genetics Evaluation Program

Cancer Risk Assessment & Prevention

Cancer-Pediatric Hematology & Oncology: Through our membership in the Children's Oncology Group, we participate in clinical trials and studies for pediatric conditions such as: (Leukemia, Lymphoma, Brain Tumors, Neuroblastoma, Wilm's Tumor, Rhabdomyosarcoma and Other Soft Tissue Sarcoma, Bone Malignancies)

Cancer Survivorship Program

Caregivers Class for Bone Marrow Transplant Patients

Centers for Fitness

Chaplain Services

Chemotherapy Classes

Clinical Research

Coleman Foundation Image Renewal Center

Gastroenterology Services

Gastrointestinal Oncology Center

Gynecologic Oncology Services

Head and Neck Oncology Clinic

Hematology Clinic

Hematology/Oncology Services

Home Care & Hospice

Image Renewal Center

Melanoma Clinic

Neuro-Oncology Clinic

Nutrition Services

Psychology Support Services

Radiation Oncology Services

Screening and Early Detection - Cancer

Skin Cancer and Mohs Micrographic Surgery Center

Speech Therapy

Surgical Oncology

Thoracic and Lung Oncology Program & Urologic Oncology Clinic

**click on bolded programs and services to view website page.*

Primary Site Table — 2017

The following table summarizes the primary sites by gender for 2017. The top five most frequent occurring cancers at Loyola University Medical Center in 2017 were: breast, lung, prostate, thyroid and colorectal.

TABLE: 1

Primary Site	Male	Female	Analytic	Non-analytic	Total
ALL SITES	**1239**	**1331**	**2302**	**268**	**2570**
Oral Cavity	**117**	**67**	**174**	**10**	**184**
Lip	2	0	2	0	2
Tongue	32	23	52	3	55
Oropharynx	3	0	3	0	3
Hypopharynx	3	2	4	1	5
Other	77	42	113	6	119
Digestive System	**238**	**156**	**366**	**28**	**394**
Esophagus	20	7	25	2	27
Stomach	26	17	42	1	43
Colon	36	28	54	10	64
Rectum	28	23	45	6	51
Anus/Anal Canal	1	5	5	1	6
Liver	66	31	68	2	70
Pancreas	42	28	67	2	70
Other	19	17	36	0	36
Respiratory System	**161**	**121**	**259**	**23**	**282**
Nasal/Sinus	12	2	13	2	14
Larynx	24	11	26	9	35
Lung/Bronc Small Cell	21	19	39	1	40
Lung/Bronc Non-Small Cell	95	82	166	11	177
Other	3	6	9	0	9
Blood & Bone					
Marrow	98	79	157	20	177
Leukemia	46	43	83	6	89
Multiple Myeloma	31	23	47	7	54
Other	21	13	27	7	34
Bone	**3**	**3**	**6**	**0**	**6**
Connective/Soft Tissue	**13**	**13**	**23**	**3**	**26**
Skin	**79**	**58**	**124**	**13**	**137**
Melanoma	66	50	105	11	116
Other	13	8	19	2	21

Primary Site	Male	Female	Analytic	Non-analytic	Total
Breast	**2**	**337**	**320**	**19**	**339**
Female Genital	**0**	**226**	**202**	**24**	**226**
Cervix Uteri	0	41	35	6	41
Corpus Uteri	0	109	106	3	109
Ovary	0	45	33	12	45
Vulva	0	25	22	3	25
Other	0	6	6	0	6
Male Genital	**203**	**0**	**180**	**23**	**203**
Prostate	187	0	168	19	187
Testis	7	0	4	3	7
Other	9	0	8	1	9
Urinary System	**109**	**45**	**116**	**38**	**154**
Bladder	58	27	63	22	85
Kidney/Renal	45	17	48	14	62
Other	6	1	5	2	7
Brain & CNS	**64**	**66**	**111**	**19**	**130**
Brain (Benign)	3	0	2	1	3
Brain (Malignant)	18	5	20	3	23
Other	43	61	89	15	104
Endocrine	**64**	**98**	**144**	**18**	**162**
Thyroid	40	81	112	9	121
Other	24	17	32	9	41
Lymphatic System	**68**	**45**	**88**	**25**	**113**
Hodgkin's Disease	10	5	10	5	15
Non-Hodgkin's	58	40	78	20	98
Unknown Primary	**13**	**6**	**16**	**3**	**19**
Other/Ill-Defined	**7**	**11**	**16**	**2**	**18**

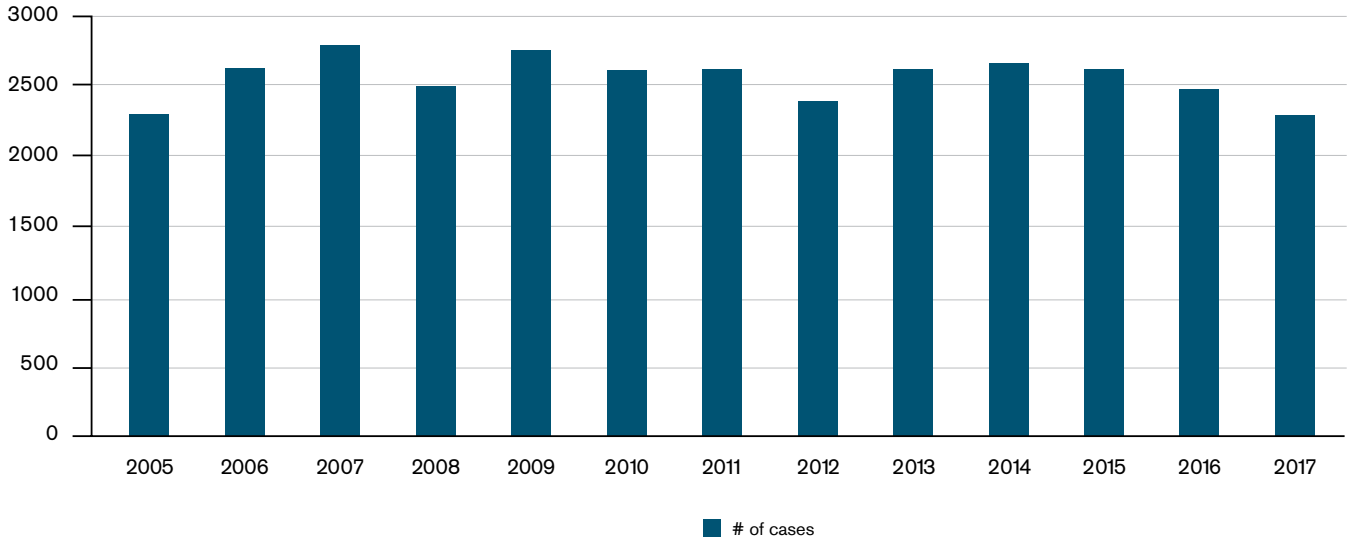
Analytic: A cases first diagnosed and/or receiving first course treatment at the facility, or diagnosed at autopsy.

Non-Analytic: Any case diagnosed at another facility and receiving all first course treatment at that facility, then seen at Loyola University Medical Center for subsequent treatment.

Data Analysis

GRAPH 1: INCIDENCE PER YEAR

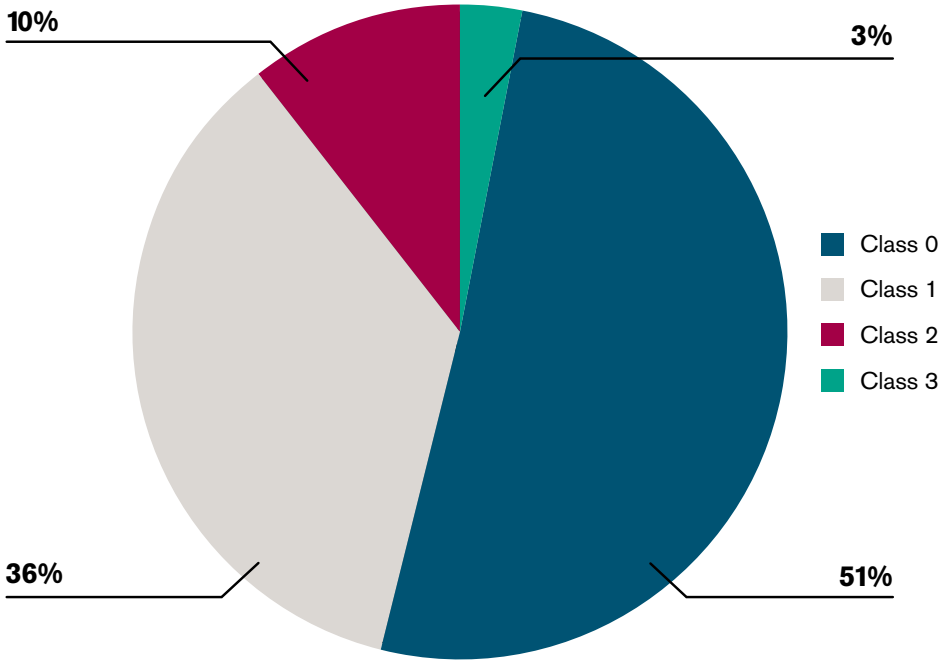
Data shows that the number of analytic cases diagnosed and treated at Loyola University Medical Center from 2005 through 2017.



In most of the 2017 cases, a total of 51 percent (1,308), patients received their initial diagnosis at LUMC; 36 percent (914) of patients were diagnosed elsewhere, but came in our facility to be treated; 3 percent (81) of patients were diagnosed at our facility and all their first course of therapy was done elsewhere; and 10 percent (267) of the patients came here for treatment of recurrent disease. (See Figure 1)

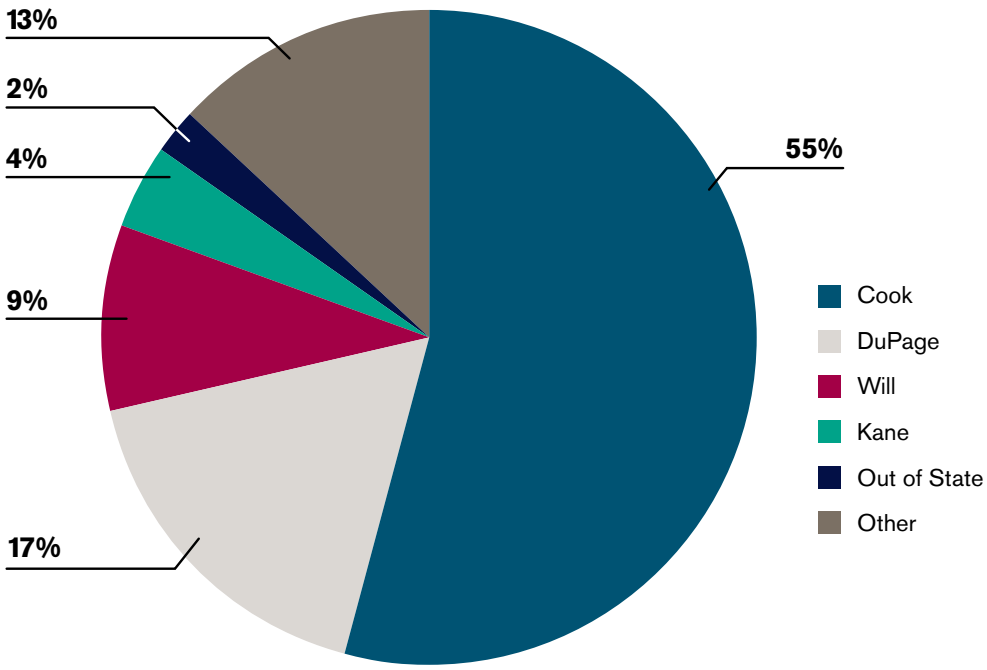
Total 2,916

FIGURE 1: CLASS OF CASE



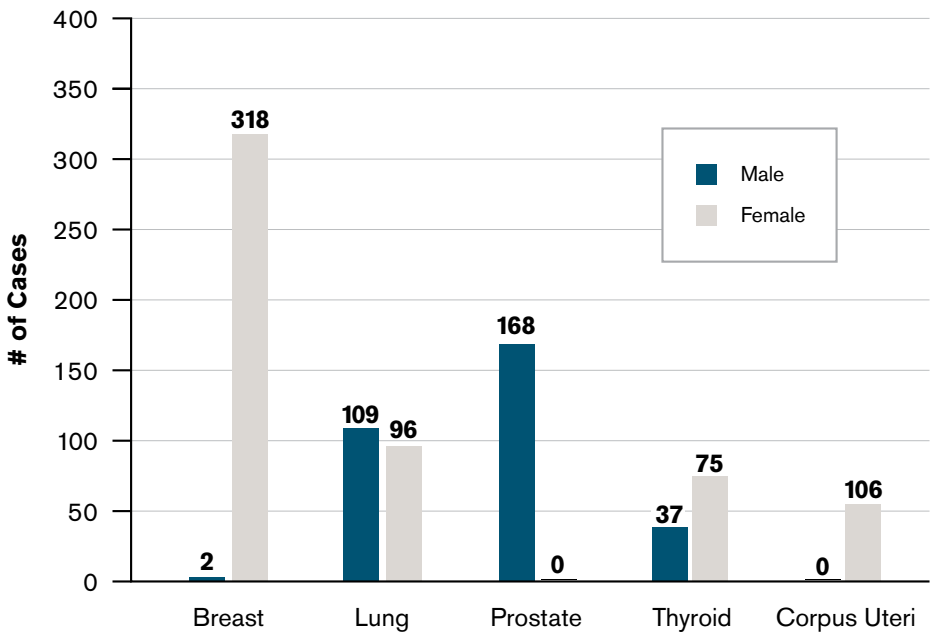
Most of the 2017 cases, 55 percent (1,469) of the patients were seen from Cook county, followed by 18 percent (463) from DuPage, 8 percent (206) from Will, and 4 percent (114) from Kane. Out-of-state cases accounted for 1 percent (80) and the remaining others accounted for 11 percent (284).

FIGURE 2: CASES BY DIAGNOSIS COUNTY



For all analytical cases, the most frequent site is Breast 35 percent (320). Next in frequency is the Lung with 23 percent (205), Prostate 18 percent (168), Thyroid with 12 percent (112) and finally Corpus Uteri with 12 percent (106). (See Graph 2)

GRAPH 2: FIVE MAJOR SITES



For new analytic cases 53 percent (1224) were female and 47 percent (1072) male. Graph 3 below shows that the diagnosis of cancer was most found in the 60-69 year range for males and females.

GRAPH 3: AGE BY SEX

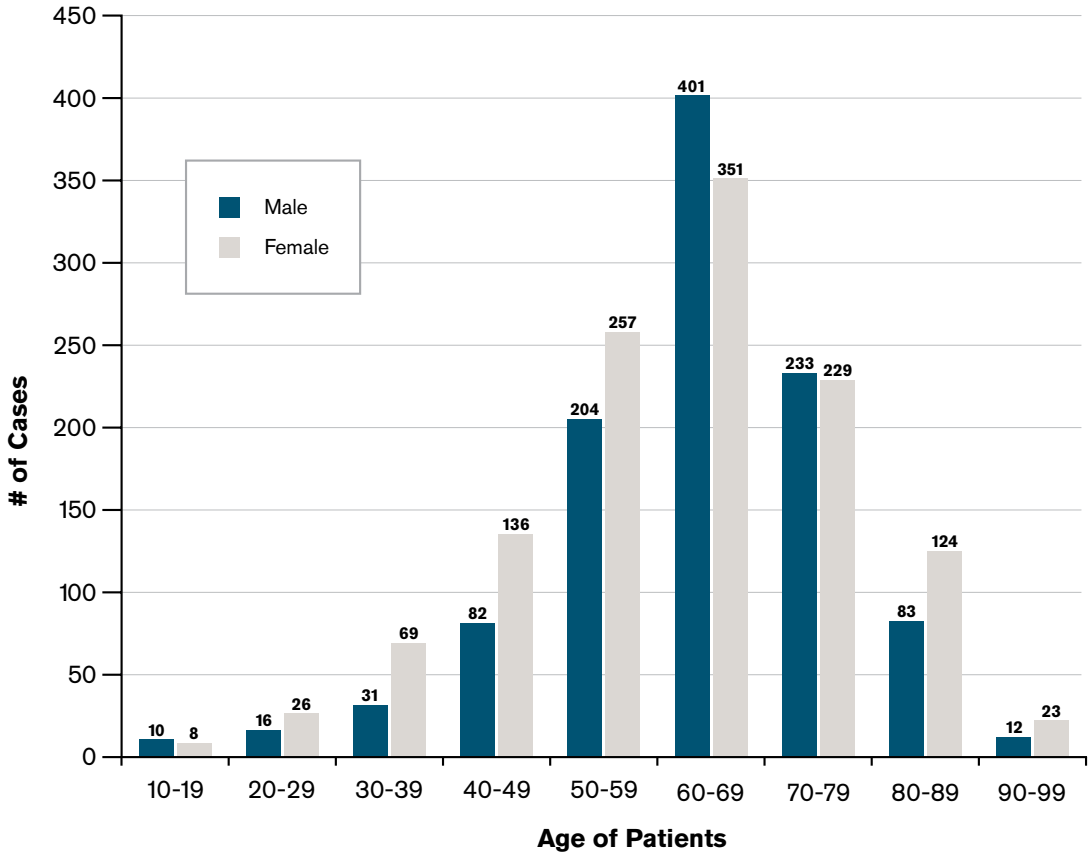
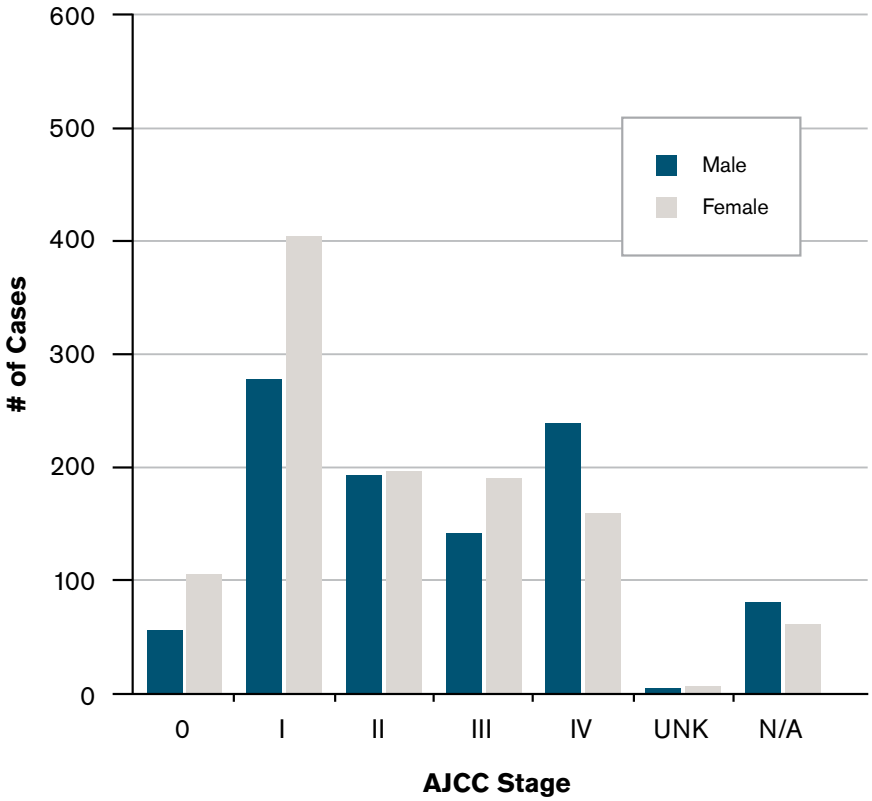


TABLE 2: AGE BY SEX

Age Range	Male	Female
10-19	10	8
20-29	16	26
30-39	31	69
40-49	82	136
50-59	204	257
60-69	401	351
70-79	233	229
80-89	83	124
90+	12	23
Total (2,548)	**1072**	**1224**

For all analytic combined staged cases: (143) were stage 0; (683) Stage I; (393) Stage II; (333) Stage III; (398) Stage IV, (94) Unknown Stage (10) and Non-applicable (342).

GRAPH 4: AJCC STAGE BY SEX



Cancer Incidence by Sex and Site with the State and National

The American Cancer Society National estimates for site and sex distribution for all races were used to compare the estimates with Loyola University Medical Center data and the state of Illinois Cancer Statistics. The numbers reported are percentages of the total cases by sex. For the male population as compared to both the state and the nation, we observed quite a high incidence of Kidney, Liver, Leukemia and Pancreas but a lower level of Prostate, Lung, and Colorectal.

For the female population as compared to the state and nation, we observed quite a high incidence of Corpus Uteri, Thyroid and Ovary, but a lower level of Breast, Lung and Colorectal.

TABLE 3: MALES

SITE	LUMC %(1,076) Year-2017	ILLINOIS % (33,888) Year-2015	NATIONAL % (836,150)* Year-2017
Prostate	15.6	22.6	19.3
Lung	10.1	14.2	13.9
Liver	5.8	2.2	3.5
Melanoma	5.5	4.8	6.2
Colorectal	4.9	9.8	8.5
Leukemia	4.0	3.1	4.3
Non-Hodgkin's	3.9	4.6	4.8
Pancreas	3.7	3.1	3.3
Thyroid	3.4	1.6	1.7
Bladder	3.3	6.9	7.2

**Estimated New Cancer Cases Year-2017*

TABLE 4: FEMALES

SITE	LUMC %(n=1,226)	ILLINOIS % (n=34,661)	NATIONAL% (n=852,630)
Breast	26.0	29.8	29.6
Corpus Uteri	8.6	6.8	7.2
Lung	7.8	13.4	12.4
Thyroid	6.1	4.7	4.9
Colorectal	3.8	8.4	6.2
Melanoma	3.8	3.8	4.1
Leukemia	3.3	2.3	3.0
Non-Hodgkin's	2.9	3.7	3.8
Cervix-Uteri	2.9	1.4	1.5
Ovary	2.7	2.6	2.6

Loyola University Medical Center

Patient Care Evaluation Study

Gerard Abood, MD
Cancer Liaison Physician
Cancer Program

Violeta Dimovic, CTR
Manager, Oncology Data
Cancer Program

Assessment and Evaluation of Treatment Planning of Pancreatic Cancer Patients

STANDARD 4.6

1. **Opportunity/Aim Statement:** To perform a study to assess whether pancreatic cancer patients are evaluated and treated according to evidence-based national treatment guidelines. The analysis will determine if the diagnostic evaluation is adequate and treatment plan is concordant with recognized guideline.
2. **Measurable Goal:** Measuring the proportion of pancreatic cancer patients treated according to recognized standards of care. Decision regarding the management and resection ability involves a multidisciplinary consultation in our high-volume center with reference to appropriate imaging findings.

Numerator: Whipple technique is considered for pancreatic cancer patients with Stage I and II cancers

Denominator:

Age at diagnosis

Patient comorbidities

Performance status

Present with jaundice

Location of the tumor (head)

Vitals Status is Alive

Goal or Target: To achieve a margin negative dissection for purposes of long-term survival.

Source of Goal or Target: Review of a single treatment (Whipple procedure) for a specific cancer site (Pancreas): NCCN

DO

Treatment plans reviewed by Dr. Abood for each of the patients and all recommendations were found to be concordant with NCCN guidelines.

STUDY

Results –January 1, 2015 - Dec 31, 2015

69 pancreatic cases identified

9 Surgical candidates (Whipple)

1 Stage 0

1 Stage IB

1 Stage IIA

5 Stage IIB

1 Stage IV

ANALYSIS: 9 PATIENTS HAD THE WHIPPLE PROCEDURE PERFORMED

Checklist	Met	Total	%
Received recommended treatment for stage	9	9	100%
# Lymph Nodes Removed	>12 8	9 No nodes removed In the Stage 4 (excluded)	100%
Post-Surgical Nutritional Consults	9	9	100%
Referral for Genetic Counseling	1	1	100%
CA-19 documented in EMR	6	9	67%
Specimen orientation and margin identification	9	9	100%

REFERRAL FOR GENETIC COUNSELING

A referral to genetic counseling for hereditary pancreatic cancer should be considered for individuals with a personal and/or family history that includes any of the following risk factors:

- Multiple cases of pancreatic cancer on the same side of the family
- A combination of related cancers on the same side of the family (e.g., pancreatic/breast/ovarian, pancreatic/melanoma, or pancreatic/colon/uterine/ovarian)
- Multiple related primary cancers in one individual (e.g. pancreatic/melanoma, pancreatic/breast)
- Ashkenazi Jewish ancestry and pancreatic cancer
- Pancreatic cancer and multiple and/or early onset gastrointestinal polyps including greater than 15 gastrointestinal polyps or greater than five hamartomatous polyps

CA 19-9 is a test that measures proteins shed by pancreatic cancer cells. The test is used as an aid in monitoring disease status in those patients having confirmed pancreatic cancer who have levels of serum or plasma CA 19-9 above the cutoff, at the time of diagnosis. Incorporating the CA 19-9 measurement is a key decision point to prospectively validate the findings and facilitate implementation.

In general, before surgery, the higher the CA19-9 level is, the larger the tumor is and the less chance that the tumor is resectable. For the purposes of evaluating treatment, a decreasing or stable CA19-9 level generally indicates an improved prognosis and an increasing level indicates the progression of disease.

High postoperative CA 19-9 levels have been associated with poor survival and may identify patients who should receive alternative systemic therapy or be entered into clinical trials evaluating new treatments for pancreatic cancer.

According to NCCN guidelines, based on the criteria defining resect ability status, assessment for all patients was appropriately defined.

Rx Type	# of Cases	%
Surgery/Chemotherapy	6	60
Surgery	3	30
Surgery/Chemotherapy/Radiation	1	10
Total Cases	**10**	**100%**

Histology was predominately adenocarcinoma and infiltrating duct ca.

Histology	Male	Female	Total
Adenocarcinoma	3	1	4
Carcinoid	1	0	1
Intraductal papillary-mucinous ca	0	1	1
Infiltrating duct ca	2	2	4
Total	**6**	**4**	**10**

1/10 (23 percent) was at the age of 27 years old.

BY AGE & SEX:

Age	Male	Female
20-27	1	0
50-59	0	2
60-69	2	2
70-79	3	0
Total	**6**	**4**

ACT

Will continue to review cases quarterly to ensure that all eligible patients' surgical treatment decisions are appropriately selected and if nutritional psychosocial and genetic counseling was offered.

CONCLUSION

Pancreatic cancer is most often diagnosed in the later stages of disease. This is due to the location of the pancreas deep in the body and symptoms do not usually occur until the cancer has spread. If signs and symptoms appear in a patient, physicians will use those signs in combination with other clinical tests and exams to determine if the cause is pancreatic cancer.

Symptoms that can occur as a result of pancreatic cancer include: jaundice, yellowing of the eyes and skin; back or abdominal pain; weight and appetite loss; diabetes; and digestive problems.

When examining a patient suspected of having pancreatic cancer, physicians will use one or a combination of different tests. Physical exams will look for masses or fluid buildup as well as to check for jaundice. CT Scans, PET Scans, MRI and Ultrasound are all types of imaging that can be used to help physicians diagnose and stage a cancer if present.

Although it is a common surgery for pancreatic cancer, the Whipple procedure is a complicated surgery that requires a great deal of skill to perform. Our surgical oncologists have extensive experience in performing Whipple procedures.

Our multidisciplinary care includes accurate, timely and consistent staging, stage-specific treatment plans, and multidisciplinary treatment groups are comprised of specialized surgeons, medical oncologists, radiation oncologists, radiologists, histopathologists, palliative care specialists, dietitians and nurse specialists.

TREATMENT OPTIONS FOR PANCREATIC CANCER

Stage	Treatment Options
Stage I and stage II pancreatic cancer	Surgery/ radical pancreatic resection, including: ▪ Whipple procedure (pancreaticoduodenal resection) ▪ Total pancreatectomy when necessary for adequate margins ▪ Distal pancreatectomy for tumors of the body and tail of the pancreas
	Postoperative therapy (chemotherapy with or without chemoradiation therapy)
	Postoperative chemotherapy: Gemcitabine and capecitabine/Gemcitabine and erlotinib/Gemcitabine and erlotinib with or without 5-FU/capecitabine-based chemoradiation
Stage III pancreatic cancer	Palliation Surgery
	Chemoradiation therapy
	Chemotherapy
Stage IV pancreatic cancer	Palliative Therapy
	Chemotherapy
Recurrent pancreatic cancer	Palliative Therapy
	Chemotherapy

Loyola University Medical Center

Quality Study 2017

Hospital-acquired Clostridium Difficile (*C. Diff*)

PROJECT PURPOSE

According to the Center for Disease Control, Clostridium Difficile (*C. Diff*) causes nearly half a million infections among patients per year with approximately two-thirds of the infections occurring at an inpatient healthcare facility. Clostridium difficile, or *C. Diff* for short, can be a very aggressive intestinal bug. Each year, this rod-shaped bacterium infects roughly 500,000 people in the U.S., sending more than 347,000 to the hospital for treatment. In extreme cases, C. difficile infection can be fatal, with estimates of *C. Diff*-associated death ranging from 14,000 to 30,000 annually. C. difficile infection costs the U.S. $1 billion each year. Once affected, patients are at high risk for relapse despite treatment. Amongst patients who contract CDI, hematopoietic stem cell transplant (HSCT) recipients represent an especially vulnerable population due to prolonged hospital stays, frequent readmissions and immunosuppression. The risk of CDI in HSCT recipients is well described and estimated incidence ranges 7.5 percent – 17 percent.[1] Less is known about risk factors for development of recurrent CDI in the HSCT population. To date, several studies have identified potential risk factors but with inconsistent results.[3]

The goal of our study is to characterize the risk of CDI recurrence and associated risk factors to inform future infection prevention strategies and promote antibiotic stewardship. The *C. Diff* Quality Study Improvement Project was initiated to reduce the prevalence of hospital-associated *C. Diff* in the Oncology service line at Loyola University Medical Center. As of August 31, 2016, the oncology service line had 131 complications from Sept 2015 – Aug 2016 and of those, 28 were *C. Diff* cases.

AIM

The aim of this project is to decrease the number of hospital-acquired *C. Diff* cases to 0 and to characterize the risk of CDI recurrence and associated risk factors to inform future prevention strategies and promote antibiotic stewardship in the hematopoietic stem cell transplants recipients population.

OBJECTIVE

- To identify the incidence and severity of recurrent CDI at our institution
- To identify whether vancomycin as first line treatment is associated with shorter duration of antibiotics and fewer incidences of recurrent CDI when compared to metronidazole
- To identify any potential risk factors of initial CDI among bone marrow transplant recipients and risk of development of recurrent CDI

Will conduct a single institution retrospective analysis that were documented with positive CDI at least six months before autologous or allogenic bone marrow transplant and up to two years post transplant from 2012-2017.

SCOPE

Incidence and risk factors for recurrent Clostridium Difficile infection in hematopoietic stem cell transplant recipients, single institution experience

PROCESS MEASURES

SCHEDULE

Deliverable/ Milestone	Date
Project Start Date: Kickoff meeting, Brainstorming session	August 1, 2016 - November 1, 2016
Deliverable One: Baseline data of cell phone use obtained	December 1, 2016
Deliverable Two: Development of intervention(s)	March 1, 2017
Deliverable Three: Implementation plan developed and initiated	June 1, 2017
Project End Date: Implementation to be completed	TBA
Look Back Date	March 1, 2017

OUTCOME MEASURES

OUTCOME MEASURES

Measure	Current	Target
Number of hospital-acquired *C. Diff* cases (Oncology—All Other)	4 (Sept 2015 – Aug 2016)	0
Number of hospital-acquired *C. Diff* cases	11 (Sept 2015 – Aug 2016)	0
Number of hospital-acquired *C. Diff* cases	8 (Sept 2015 – Aug 2016)	0
Number of hospital-acquired *C. Diff* cases	5 (Sept 2015 – Aug 2016)	0

Oncology Service Line had 131 complications from September 2015-August 2016, and of those, 28 were *C. Diff* cases.

PROCESS MEASURES

PROCESS MEASURES

Measure	Current	Target
% Compliance with Hand Washing Protocol (6 West)	100% (Sept 2016)	100%
% Compliance with Hand Washing Protocol (6 South)	40% (Sept 2016)	100%
% Compliance with Hand Washing Protocol (6 North)	67% (Sept 2016)	100%
% Compliance with Hand Washing Protocol (6 East)	67% (Sept 2016)	100%

Most Likely Causes:

- Semi-private rooms
- Significant traffic in/out of patient rooms
- Patient transportation to other departments
- Lack of caregiver awareness
- Infection control practices

Potential Solutions and Data Needed for Evaluation:

- Use of bleach wipes to "high touch" areas and equipment leaving the room
- Handwashing only with soap and water; use of alcohol gel not effective
- Increase caregiver awareness – staff education
- Increase number of private rooms
- Monitor rates if infection

Outcome Measure:

UHC complication #MS-9 Hospital-acquired *C. Diff* June 2016-May 2017 (Baseline)=27

Process Measures:

* # of *C. Diff* Ordering Issues 7/23/17-8/26/17 (Baseline) = 31 (21 related to serial ordering and 10 related to patients on laxative with 48 hours)
* 6th Floor Compliance with *C. Diff* Nursing Protocol May 2017 (Baseline) = North 1/3, 33 percent, East 1/4, 25 percent, South 0/4, 0 percent, West 6/11, 55 percent

Changes:

The team improved hospital-acquired Clostridium difficile (*C. Diff*) rates on the 6th floor by implementing key strategies for preventing infection transmission. These strategies focused on hand hygiene, contact precautions and environmental cleaning.

Improving prevention bundle components:

- Educate clinicians on appropriate hand-hygiene practices to prevent spread of infection.
- Provide patient and family information guide to prevent *C. Diff* infections
- Reinforce strict adherence to hospital hand-hygiene policy and environmental cleaning.
- Directly observe hand-hygiene practices per C. difficile prevention bundle
- Signage on doors for use of bleach wipes and handwashing with soap and water
- Discuss infection rates at unit meetings
- Signage on gel dispensers to stop and use soap and water
- Review overall antimicrobial stewardship program in order to optimize the use of the right drug, for the right purpose, at the right dose, and for the right duration in an effort to promote judicious use of the antimicrobial agent

Conducted a retrospective single institutional analysis on 103 patients that were documented with positive CDI (from stool PCR toxin A/B) at least six months before autologous or allogeneic bone marrow transplant and up to two years post-transplant from 2012-2017.

Incidence and risk factors for recurrent Clostridium Difficile infection in hematopoietic stem cell transplant recipients: a single institution experience

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Introduction:

Clostridium difficile infection (CDI) is a leading cause of hospital-acquired infection and is increasingly recognized as a community-acquired infection as well. Once affected, patients are at high risk for relapse despite treatment. Amongst patients who contract CDI, hematopoietic stem cell transplant (HSCT) recipients represent an especially vulnerable population due to prolonged hospital stays, frequent readmissions and immunosuppression. The risk of CDI in HSCT recipients is well described and estimated incidence ranges 7.5 percent – 17 percent. Less is known about risk factors for development of recurrent CDI in the HSCT population. To date, several studies have identified potential risk factors but with inconsistent results. The goal of our study is to characterize the risk of CDI recurrence and associated risk factors to inform future infection prevention strategies and promote antibiotic stewardship.

Objective:

- To identify the incidence and severity of recurrent CDI at our institution
- To identify whether vancomycin as first line treatment is associated with shorter duration of antibiotics and fewer incidences of recurrent CDI when compared to metronidazole
- To identify any potential risk factors of initial CDI among bone marrow transplant recipients and risk of development of recurrent CDI

Methods:

We conducted a single institution retrospective analysis of 103 patients that were documented with positive CDI (from stool PCR toxin A/B) at least six months before autologous or allogeneic bone marrow transplant and up to two years post-transplant from 2012-2017. Recurrent CDI was defined if a patient had a repeat positive CDI stool PCR after the first appropriately treated episode (after 14 days) with oral vancomycin or metronidazole. Data was also collected on HSCT characteristics and other one-hundred day infectious complications which will be reported in a separate study. Study data were collected and managed using REDCAP electronic data capture tools hosted at Loyola University Medical Center.[2] Statistical methods: rates of CDI recurrence were compared with chi-square tests or Fisher's exact tests as appropriate. Analysis were performed in SAS9.4(Cary, NC)

TABLE 1: PATIENT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

	Number Patients	n (%) with recurrent CDI	p-value
Underlying malignncy			
Myelodysplastic syndrome	11	6 (54.5)	
Leukemia	42	8 (19.0)	
Lymphoma	25	8 (32.0)	
Multiple Myeloma	18	3 (16.7)	0.17
Aplastic anemia	2	1 (50.0)	
Myelogibrosis	2	0 (0.0)	
Amyloid	2	0 (0.0)	
Prior chemotherapy regimens			
Cytotoxic	87	21 (24.1)	0.76
Targeted	5	2 (40.0)	0.60
Small molecule inhibitors	28	5 (17.9)	0.44
Biologics	9	2 (22.2)	0.99
BMT type			
Autologous	36	8 (22.2)	
Allogeneic matched related	21	4 (19.0)	0.66
Allogeneic matched unrelated	24	6 (25.0)	
Allogeneic cord blood	23	8 (34.8)	
Conditioning			
Myeloablative	53	11 (20.8)	0.66
Nonmyeloablative	45	11 (24.4)	
Total body irradiation for conditioning	**41**	**10 (24.4)**	**0.98**
GVHD present	**17**	**6 (27.9)**	**0.54**

TABLE 3: CDI LABORATORY VALUES AND TREATMENT CHARACTERISTICS

	# Patients	n (%) with recurrent CDI	p-value
White blood cells			
Neutropenia	40	7 (17.5)	
WBC< 15,000	52	16 (30.8)	0.35
WBC< 15,000	12	3 (25.0	
Baseline creatinine			
<0.5	7	2 (28.6)	
0.5-1	82	21 (25.6)	
1-1.5	8	1 (12.5)	0.82
1.5-2	5	1 (20.0)	
>2	2	1 50.0)	
Creatinine indicating AKI	**5**	**1 (20.0)**	**0.99**
Albumin			
<2	4	1 (25.0)	
2-2.9	55	15 (27.3)	0.88
3-3.9	42	9 (21.4)	
≥ 4	1	0 (0.0)	
Hypotension			
None	91	22 (24.2)	
Fluid-responsivehypotension	9	4 (44.4)	0.35
Pressor requirement	3	0 (0.0)	
Ileus	**2**	**1 (50.0)**	**0.44**
Treatment			
PO Metronidazole	72	17 (22.7)	0.38
IV Metronidazole	6	2 (33.3)	0.63
PO Vancomycin	20	7 (35.0)	0.25
Metronidazole converted to PO Vancomycin	10	3 (30.0)	0.70

Results and Conclusions:

CDI affected 11 percent of HSCT recipients from 2012-2017 (N=974). We report data on 104 patients with documented CDI. Of these, 44 (42 percent) developed first CDI within 100 days of HSCT. Recurrent CDI occurred in 24 patients (23 percent), with 21/24 (88 percent) of recurrences occurring within the first three months of index CDI. A quarter of patients (7/24) were treated for more than two CDI episodes in less than six months after their first documented recurrence. We did not observe significant impact on CDI recurrence from type of HSCT, conditioning regimen, or use of prior therapeutic antibiotics. There was a trend towards higher rates of recurrent CDI in patients who had prior carbapenem use (p=0.070) in first 100d after SCT, CDI treatment duration >2wk (p=0.065), and in patients with GI graft versus host disease (GVHD) (p=0.074). The risk of having recurrent CDI is 23 percent and our study demonstrated no impact from antecedent antibiotic use or transplant type. There was a trend towards increased CDI recurrence in patients with prior carbapenem exposure, longer CDI treatment duration, concurrent statin use and GI GVHD. Further investigations are warranted in this population.

The growing problem of C. difficile emphasizes the need for better diagnostics, meticulous attention to infection prevention and improved methods to manage both antibiotics and the disease. Implementing evidence-based interventions and increasing public awareness can decrease the incidence.

The goal of an antibacterial stewardship program is to optimize the use of the right drug, for the right purpose, at the right dose, and for the right duration in an effort to promote judicious use of the antimicrobial agent.

This includes:

- Precautions for duration of diarrhea
- Hand hygiene in compliance with CDC/WHO guidelines
- Cleaning and disinfection of equipment and environment
- Laboratory-based alert system for immediate notification of positive test results
- Educate about *C. Diff*; housekeeping, administration, patients, families

Next Steps:

- Provide education to environmental services personnel, executive level leadership and others, including at least the following: risk factors for *C. Diff*, transmission, local epidemiology, patient outcomes, treatment, hand hygiene, contact precautions, management of multidrug-resistant organisms and individual job responsibilities.
- Identify and implement methods for education and training of personnel that allow immersive experiences that enhance critical thinking and decision-making skills, including simulation experiences.
- Continue to provide education to patients and their families regarding *C. Diff.*
- Provide education and assist patients with performance of hand hygiene as an approach to preventing acquisition of pathogens.
- Continue to perform a *C. Diff* risk assessment as a basis for a comprehensive and multidisciplinary intervention.
- Standardize care processes and practices using bundles, checklists, protocols, and guidelines. Empower staff to report process defects to appropriate personnel as a means of facilitating rapid intervention and identification of barriers. Assign accountability for adherence to specific departments or functions.
- Continue to measure both process and outcomes on a regular basis.
- Provide monitoring data in various formats so it can be posted and broadly disseminated.

References:

1) Chopra T, Chandrasekar P, Salimnia H, et al. Recent Epidemiology of Clostridium Difficile Infection during hematopoietic stem cell transplantation; Clinical Transplant. 2011; 25:E82-87

2) Harris PA et al, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr; 42(2):377-81

3) Mani S, Rybicki L, Jagadeesh D, and Mossad SB. Risk factors for recurrent Clostridium difficile infection in allogeneic hematopoietic cell transplant recipients.

Bone Marrow Transplantation; 2016; 51:713-717.

Glossary of Terms

Accession: The addition of new cancer cases to the Oncology Registry. Each patient is assigned a separate and permanent number.

ACOS: American College of Surgeons

ACS: American Cancer Society

Class of Case: The class of case divides cases recorded in the database of the facility into categories of analytic and non-analytic. Analytic data includes cases diagnosed at the accessioning facility and/or administration of any of the first course of treatment after the *registry's reference date. Non-analytic cases are first diagnosed and receive all of first course of therapy at another institution, or are diagnosed at autopsy or by death certificate only. Non-analytic cases are not usually included in routine treatment or survival statistics. Based on category, the cancer program selects cases to be used by their facility or to be reported to the central registry, as well as, the National Cancer Data Base (NCDB).

Analytic: A case first diagnosed and/or receiving first course treatment at that facility or diagnosed at autopsy.

Non-analytic: Any case diagnosed at another facility and receiving all of first course treatment at that facility, then seen at Loyola University Medical Center for subsequent treatment.

Class 0 Diagnosis at accessioning facility and the entire first course of treatment was performed elsewhere or the decision not to treat was made at another facility.

> Patients who elect to be treated elsewhere.

> Patients who are referred elsewhere for treatment for any reason. For example, lack of special equipment; proximity of a patient's residence; financial, social or rehabilitative considerations

Class 1	Diagnosis at the accessioning facility, and all or part of the first course of treatment was performed at the accessioning facility.
	Patients diagnosed at the accessioning facility whose treatment plan is either not to treat or watchful waiting.
	Patients diagnosed at the accessioning facility who refuse treatment.
	Patients diagnosed at the accessioning facility who are not treatable or who were given palliative care only due to age, advanced disease, or other medical conditions.
	Patients diagnosed at the accessioning facility for whom it is unknown whether treatment was recommended or administered.
	Patients diagnosed at the accessioning facility for whom treatment was recommended, but it is unknown whether it was administered.
	Patients diagnosed at a staff physician's office who receive their first course of treatment at the accessioning facility. "Staff physician" refers to any medical staff with admitting privileges at the accessioning facility.
	Patients diagnosed at the accessioning facility who received all or part of their first course of treatment in a staff physician's office.
Class 2	Diagnosis elsewhere, and all or part of the first course of treatment was performed at the accessioning facility.
	Patient provided palliative care in lieu of first course treatment, or as part of the first course of treatment, at the accessioning facility.
Class 3	Diagnosis and all of first course treatment done elsewhere.
	Patient treated or managed at the accessioning facility, but first course of treatment information is unknown.
	Patient for whom the accessioning facility developed a treatment plan or provided "second opinion" services, but the diagnosis and treatment was provided elsewhere.
	Patient treated for a recurrence or progression for a previously diagnosed malignancy.

References

Illinois Cancer Facts & Figures

American Cancer Society, Incidence 2015

AJCC Manual for Staging

Seventh Edition

National Cancer Database

American College of Surgeons, Commission on Cancer

Electronic Registry Systems

Cancer Data Management Database Systems 2015

College of American Pathologists

www.cap.org CAP Cancer Protocols

NCCN Guidelines in Oncology-v.3.2016

National Comprehensive Cancer Network, 2016

National Cancer Facts & Figures, ACS

American Cancer Society, Inc., Surveillance Research, CDC, 2015

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