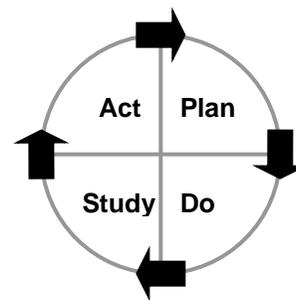


PeaceHealth United General Medical Center Cancer Committee Study on Quality – Standard 4.7 Bisphosphonate & Denosumab

Each year, based on category, the quality improvement coordinator, under the direction of the cancer committee, develops, analyzes, and documents the required studies that measure the quality of care and outcomes for patients with cancer.

The Cancer Committee will utilize the PDSA cycle which is shorthand for testing a change-by developing a plan to test the change (**Plan**), carrying out the test (**Do**), observing and learning from the consequences (**Study**), and determining what modifications should be made to the test (**Act**).



Focus / Problem Statement:

Missed opportunities have been noted for use of bisphosphonate and denosumab based on NCCN guidelines and recommended dosing guidelines for patients with breast cancer with metastasis, prostate cancer with metastasis and multiple myeloma.

As per the QOPI Measures Summary Report from the Fall of 2011, the private independent aggregate mean score for IV bisphosphonates or denosumab administered for breast cancer bone metastases was 78.58%.

Bisphosphonates are a class of drugs that prevent the loss of bone mass, used to treat osteoporosis and similar diseases. They are the most commonly prescribed drugs used to treat osteoporosis. They are called bisphosphonates because they have two phosphonate (PO(OH)₂) groups.

Denosumab is a fully human monoclonal antibody for the treatment of osteoporosis, treatment-induced bone loss, bone metastases, multiple myeloma, and giant cell tumor of bone.

NCCN guidelines for breast cancer state denosumab, zoledronic acid, or pamidronate should be given (category 1) in addition to chemotherapy or endocrine therapy if bone metastasis is present, expected survival is ≥ 3 months, and renal function is adequate. Patients should undergo a dental examination with preventative dentistry prior to initiation of this therapy. There are extensive data from randomized trials in support of the use of bisphosphonates for patients with metastatic disease to bone. Bisphosphonate treatment is associated with fewer skeletal-related events, fewer pathologic fractures, and less need for radiation therapy and surgery to treat bone pain.

In men with castrate resistant prostate cancer who have bone metastases, denosumab and zoledronic acid have been shown to prevent disease-related skeletal complications, which include fracture, spinal cord compression, or the need for surgery or radiation to bone.

For Multiple Myeloma patients, bisphosphonate, in addition to benefits for bone health, zoledronic acid reduced mortality by 16% and overall survival by 5.5 months.

Plan:

April - June 2015 Report:

- Oncology Clinical Manager to distribute NCCN guidelines for breast cancer with metastasis, prostate cancer with metastasis and multiple myeloma at Cancer Committee meeting for reference.
- Cancer Committee to determine compliance rate goal based on historical data (below) and on the on number of patients with diagnosis, number of patients meeting inclusion criteria and appropriate treatment received based on NCCN guidelines during the June 2015 meeting. **The goal is 90% adherence to guidelines, as per Committee recommendation in October 2015.**

- Continue study until outcome goal is sustained for 6 consecutive months or until implementation of Care Connect in May 2016 (whichever comes first).

October Report:

Inclusion criteria defined to include diagnosis of multiple myeloma first line treatment, prostate cancer with bone mets, or breast cancer with bone mets and exclusion criteria including SCr >3 or history/risk of osteonecrosis of the jaw, and life expectancy ≤ 3 months.

December Report:

NCCN Guidelines state the following criteria:

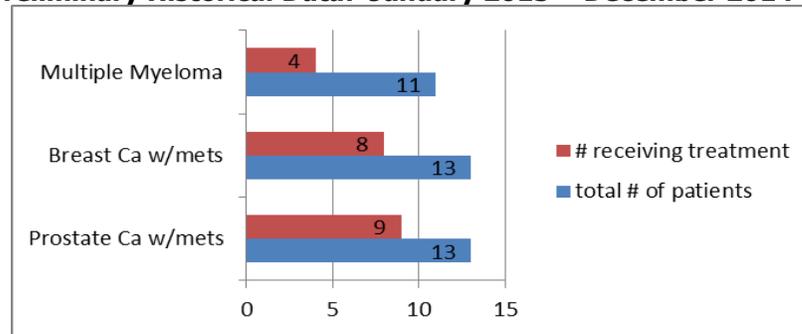
- Multiple Myeloma: Bisphosphonates (pamidronate and zoledronic acid) – All patients receiving primary myeloma therapy should be given bisphosphonate.
- Prostate Cancer: Consider bone antiresorptive therapy with denosumab or zoledronic acid if bone metastases present.
- Invasive Breast Cancer: Bone disease present – Add denosumab, zoledronic acid or pamidronate.

Do:

April - June 2015 Report:

- Oncology Clinical Manager to research if certain orders can be triggered based on diagnosis.
- Pharmacy to collect and present historical facility data from January 2013 – December 2014 to the Cancer Committee.

Preliminary Historical Data: January 2013 – December 2014



- Pharmacy to develop audit tool with inclusion criteria from NCCN guidelines.
- Pharmacy to develop physician tool including exclusion criteria.
- IDT to screen patients with appropriate diagnosis to determine if patient qualifies for this study based on NCCN guidelines.
- Pharmacy to begin real time audits in July 2015.

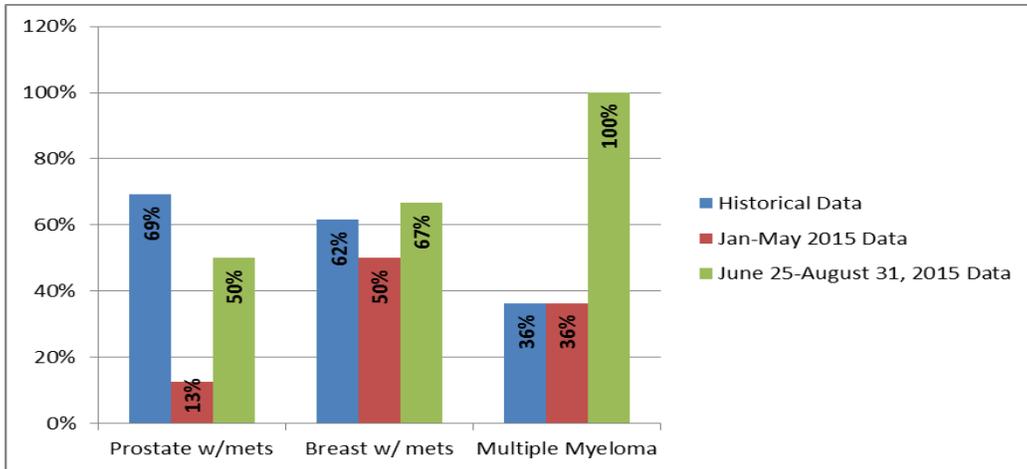
Study:

April – June 2015 Report:

- Study to compare real time audit results to the initial historical facility data from January 2013 – December 2014 and the national benchmark data, if available, to determine compliance.

October 2015 Report:

Data collection for January 2015 – August 31, 2015 was a challenge due to staff turn-over in Pharmacy. (*The goal is to have quarterly data available for the final report.*) Here is a snap shot of the data collected:



Patients Treated as per NCCN Guidelines that Qualified	Prostate w/mets	Breast w/ mets	Multiple Myeloma
Historical Data	9 out of 13	8 out of 13	4 out of 11
Jan-May 2015 Data	1 out of 8	2 out of 4	4 out of 11
June 25-August 31, 2015 Data	2 out of 4	2 out of 3	2 out of 2

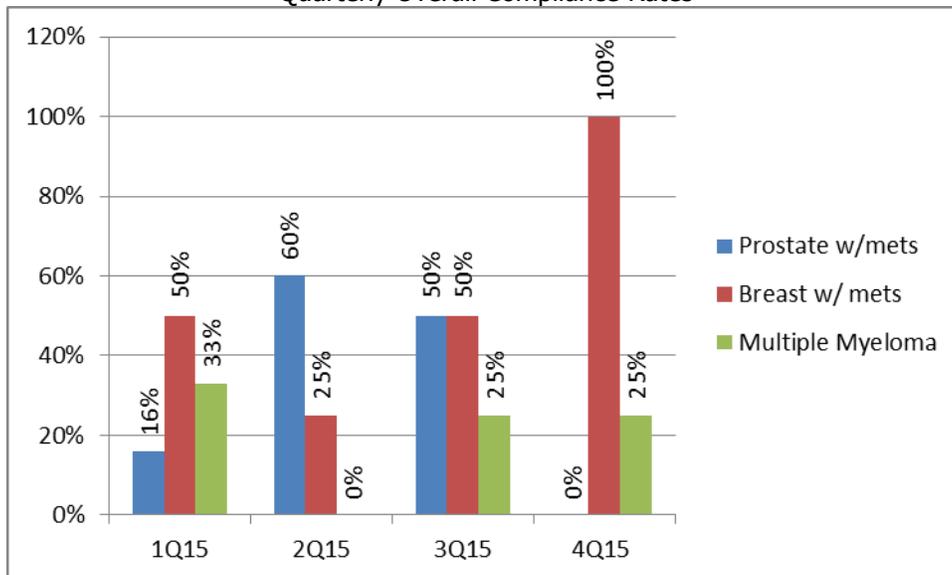
Patients diagnosed with both Prostate and Multiple Myeloma will be categorized by first diagnosis.

A vast improvement has been achieved for Multiple Myeloma patients. It appears that compliance is also improving for breast cancer patients with metastasis and prostate cancer patients with metastasis; however a trend has not yet been established.

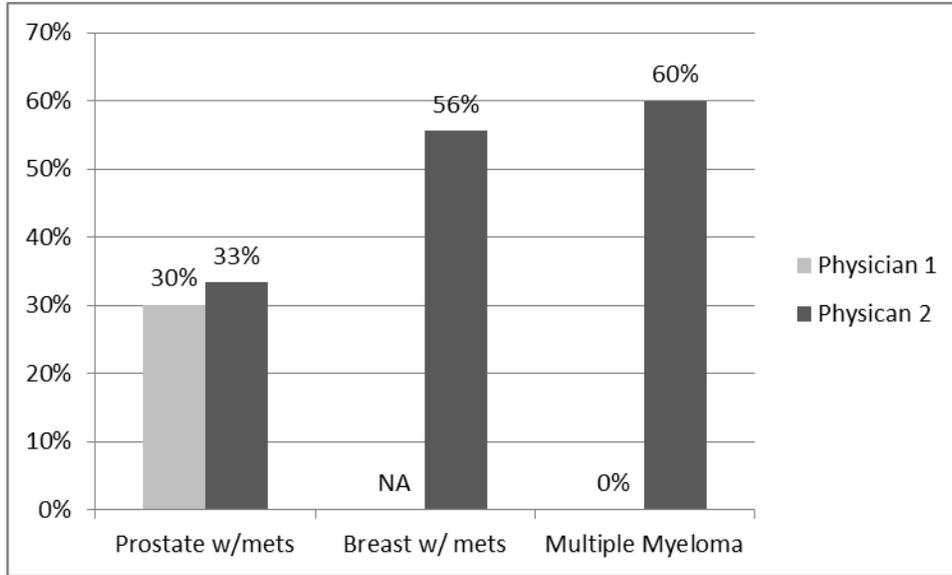
December 2015 Reports:

The screening tool for Pharmacy and Physicians has been completed and implemented on December 1.

Quarterly Overall Compliance Rates

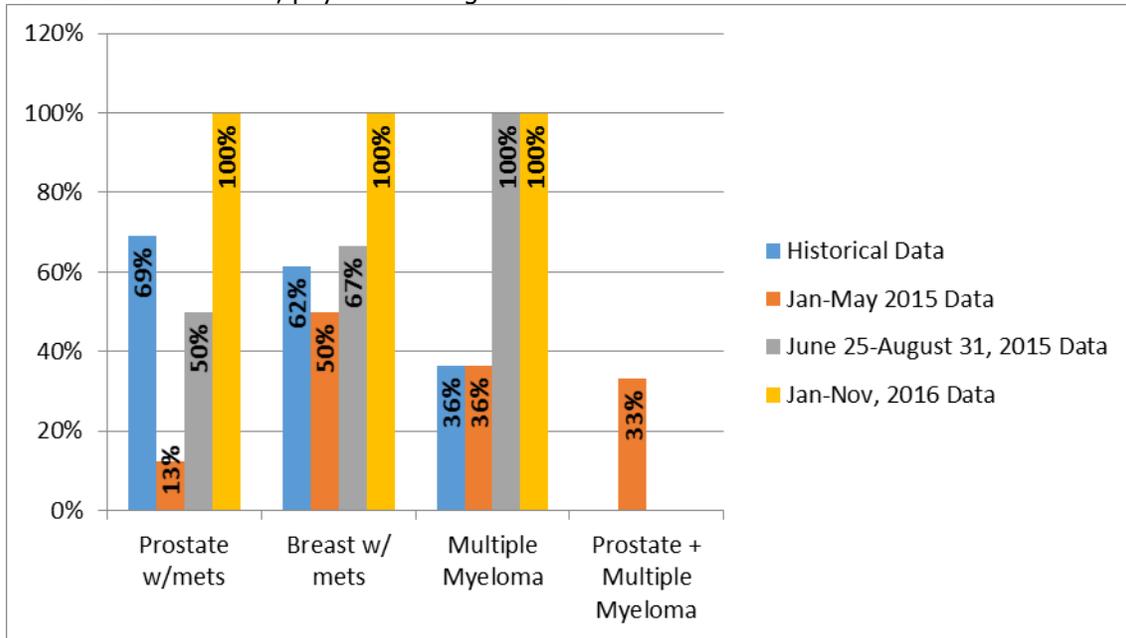


Year to Date Compliance Rates by Physician



December 2016 Report

It should be noted that due to electronic medical record system changes, data was not easily retrievable for the last quarter of 2015. In addition, physician changes occurred.



Act:

April – June 2015 Report:

- Discussion of outliers and non-compliance with physicians on a case by case basis in an effort to provide additional tools to ensure compliance.

October 2015 Report:

- Continued discussions regarding outliers and non-compliance with the physicians on a case by case basis will occur on a timely basis once the Pharmacy staffing vacancies are filled. In the meantime, this report has been shared with the physicians in an effort to improve compliance to the NCCN guidelines.
- Pharmacy is unable to develop physician tool including exclusion criteria because new forms are not allowed at this time due to the upcoming implementation of CareConnect; which will have indicators built into the system.
- Patients discussed during IDT with appropriate diagnosis will be reviewed to determine if they qualify for this study based on NCCN guidelines. Pharmacy to develop a checklist with inclusion criteria from NCCN guidelines. This checklist could then be applied to all new consults presented at interdisciplinary team meeting.

December 2015 Report:

- Recommendation (for Committee approval):
 - Continue this study through 2016.
 - Assign a Physician Champion to promote ownership and to provide physician input on process improvement plans.

December 2016 Report:

New physician practice has improved compliance scores to 100%.

Recommendation: To retire this study with the understanding that random audits will be conducted by Pharmacy Manager to ensure continued success. In the event that a trend of non-compliance is noted, a failure mode and effects analysis (FMEA) or a root cause analysis (RCA) will be conducted to ensure best practice becomes routine in nature. Results of FMEA or RCA would then be reported to this committee as applicable.