Quality Improvement in Breast Cancer Project: Compliance With Antiresorptive Agents and Changing Patterns of Drug Use

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Abstract
The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute participated in NCCN’s Quality Improvement in Breast Cancer initiative. The Opportunities for Improvement (OFI) team elected to improve concordance with the NCCN Clinical Practice Guidelines in Oncology for Breast Cancer recommendation that all patients diagnosed with skeletal metastases receive bisphosphonates. Assembling a multidisciplinary team of clinicians, researchers, and administrative stakeholders, the OFI team followed Six Sigma’s approach to problem-solving known as DMAIC (define, measure, analyze, improve, and control). Baseline concordance was 79%, which was below the recommended target range. Initial analysis quickly revealed that 5 cases were concordant, resulting in a new baseline of 89%. The key root cause identified for the remaining gap was lack of documentation. The solution included education regarding documentation for existing staff, in addition to hard-wiring the material into new physician orientation, discussion of all patients with bone disease at tumor board meetings, and improved consistency with use of the new electronic medical record system. After implementation, the reported concordance was 92%, and the lack of documentation problem decreased from 11% in the baseline study to 6%. The team concluded that use of the NCCN Oncology Outcomes Database as an opportunity for clinical quality improvement initiatives not only is possible but also should be an essential element of any clinical program looking to continuously improve. (J Natl Compr Cancer Netw 2014;12[Suppl 1]:S33–S35)

The vision of the cancer program at The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute (OSUCCC) is, “To create a cancer-free world, one person, one discovery at a time.” The Opportunities for Improvement (OFI) program with NCCN allowed the institution to come one step closer to that vision in a project that touched all 3 parts of the mission: care, research, and education.

The Goal
The OFI team elected to improve concordance with the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Breast Cancer recommendation that all patients diagnosed with skeletal metastases receive bisphosphonates. The cancer program at OSUCCC uses a variety of tools for process improvement but is primarily committed to the Lean Six Sigma approach. As part of that approach, a multidisciplinary team was assembled that consisted of clinicians, researchers, and administrative stakeholders. The team then followed Six Sigma’s approach to problem solving known as DMAIC: define, measure, analyze, improve, and control. The team was facilitated by the Associate Executive Director of Quality.

Define
Baseline concordance with the NCCN Guidelines regarding bisphosphonates was 79%, which is below the recommended target range. The goal of the OFI team was to determine the root causes of the gap and implement solutions to improve performance on this measure.

Measure
Baseline data were collected from the NCCN Oncology Outcomes Database. The study cohort included all pa-
Patients with breast cancer meeting the guideline criteria presenting between July 2007 and March 2009 (21 months), resulting in 53 cases. Eleven of these were reported to be nonconcordant, which provided the baseline of 79%.

**Analyze**

Analysis of the nonconcordant cases involved a careful review of the medical and pharmacy records. This review quickly revealed that 5 cases originally noted as nonconcordant were concordant based on existing documentation but had not been coded correctly. This provided a new baseline of 89% concordance. At this point, the team considered whether the project needed to continue given that the new rate was within an “acceptable” range. However, the team decided to proceed, agreeing that improvement was possible and that the project would provide more understanding about the “art” of problem-solving in health care.

The remaining 6 nonconcordant cases showed no documentation of bisphosphonate use. Because members of the team were familiar with the cases, the determination was made that, at least in some cases, the clinician and patient discussed and considered bisphosphonate use. In these cases, the physician decided against prescribing bisphosphonates but did not include the discussion and decision in the progress note. The team theorized that behind the identified root cause—lack of documentation—were appropriate decisions based on clinical judgment involving patients for whom bisphosphonates were contraindicated.

In 2010, between the baseline study and implementation of action items, denosumab was added as an acceptable alternative to bisphosphates. For the purposes of this project, patients treated with denosumab were recorded as concordant.

**Improve**

First, the results and analysis were shared with the breast cancer disease-specific committee to increase awareness and gather ideas for improving the process. As is often the case with quality improvement projects, the solutions were multifold, and included the following:

- The primary focus was on education regarding documentation. This education was achieved through an in-service meeting on the topic for all stakeholders. Additionally, the topic was made a permanent part of new physician orientation.
- All cases involving patients with bone disease are now discussed at tumor board meetings. This discussion provides an additional opportunity for consideration and a reminder regarding documentation.
- The implementation of an electronic medical record system afforded a consistent platform for enhanced documentation and communication.

**Results**

The postimplementation cohort included all patients with breast cancer meeting the guideline criteria during a 21-month period, April 2011 to December 2012. Once again this resulted in 53 cases. The concordance reported for this period was 92%, compared with the initial baseline of 79% and the corrected baseline of 89%. Of the concordant cases, 84% had antiresorptive agents administered, and the remaining 16% had these agents “considered but not given” documented in the patient chart. Examples of the reasons given for nonconcordance included patient refusal, a life expectancy less than 3 months, and the presence of visceral disease with minimal bone involvement. Of the cases with antiresorptive agents administered, 71% involved zoledronic acid and 29% involved denosumab.

The 8% nonconcordant cases represented 4 patients. For 3 of these patients, antiresorptive agents were “considered but not given” but the discussion was not documented in the progress note. The remaining case involved a patient who is no longer in the system at OSUCCC and for whom follow-up information was not available. The “lack of documentation” problem decreased from 11% in the baseline study to 6% after implementation of improvements.

**Control**

The control phase of DMAIC is one of the most important because it is typical for improvements to fade over time. It is human nature to slip back to previous ways unless measures are put in place to make the
solutions permanent. Efforts to maintain high performance included:
- Monthly oversight in parallel with the American College of Surgeons’ Rapid Quality Reporting System;
- Regular and timely analysis of concordance data and nonconcordant cases;
- Continuing discussions at the tumor board; and
- Future plans to template the documentation in the electronic medical record system.

**Conclusions**

The OFI team concluded that the use of the NCCN Oncology Outcomes Database as an opportunity for clinical quality improvement initiatives not only is possible but also should be an essential element of any clinical program looking to continuously improve.