

Oncology: Prostate/Testis/Penis/Urethra

A Statewide Intervention Improves Appropriate Imaging in Localized Prostate Cancer

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Abbreviations and Acronyms

AUA = American Urological Association

BS = bone scan

CT = computerized tomography of abdomen and/or pelvis

EMR = electronic medical record

GS = Gleason score

MUSIC = Michigan Urological Surgery Improvement Collaborative

PSA = prostate specific antigen

Purpose: We implemented a statewide intervention to improve imaging utilization for the staging of patients with newly diagnosed prostate cancer.

Materials and Methods: MUSIC (Michigan Urological Surgery Improvement Collaborative) is a quality improvement collaborative comprising 42 diverse practices representing approximately 85% of the urologists in Michigan. MUSIC has developed imaging appropriateness criteria (prostate specific antigen greater than 20 ng/ml, Gleason score 7 or higher and clinical stage T3 or higher) which minimize unnecessary imaging with bone scan and computerized tomography. After baseline rates of radiographic staging were established in 2012 and 2013, we used multi-dimensional interventions to deploy these criteria in 2014. Imaging utilization was then remeasured in 2015 to evaluate for changes in practice patterns.

Results: A total of 10,554 newly diagnosed patients with prostate cancer were entered into the MUSIC registry from January 1, 2012 through December 31, 2013 and January 1, 2015 through December 31, 2015. Of these patients 7,442 (79%) and 7,312 (78%) met our criteria to avoid bone scan and computerized tomography imaging, respectively. The use of bone scan imaging when not indicated decreased from 11.0% at baseline to 6.5% after interventions ($p < 0.0001$). The use of computerized tomography when not indicated decreased from 14.7% at baseline to 7.7% after interventions ($p < 0.0001$). Variability among practices decreased substantially after the interventions as well. The use of recommended imaging remained stable during these periods.

Conclusions: An intervention aimed at appropriate use of imaging was associated with decreased use of bone scans and computerized tomography among men at low risk for metastases.

Accepted for publication October 28, 2016.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Supported by BCBSM (Blue Cross Blue Shield of Michigan) and the BCBSM Value Partnerships program (MUSIC).

* Financial interest and/or other relationship with BCBSM.

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Editor's Note: This article is the first of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1366 and 1367.

Key Words: prostatic neoplasms, neoplasm metastasis, bone neoplasms, diagnostic imaging, quality improvement

A large percentage of staging imaging studies may be unnecessary and without clinical benefits, resulting in substantial avoidable medical costs.¹ With the goal of reducing unnecessary testing, the Choosing Wisely® campaign, started in 2012 by ABIM (American Board of Internal Medicine®), partnered with AUA to develop 5 and later 10 recommendations for urologists for decreasing testing when not necessary.² Two of the Choosing Wisely recommendations are the elimination of imaging with BS and CT for staging men with newly diagnosed, low risk prostate cancer.

The importance of identifying metastases in men with newly diagnosed prostate cancer makes it necessary to find the balance between excessive imaging with a low likelihood of identification of metastases (overuse) vs not performing imaging when the risk of a positive study is substantively higher (underuse). There is evidence not only for pervasive overuse but also for substantial underuse.³⁻⁷

Appropriate imaging depends on the risk stratification of disease. Several clinical guidelines using different risk stratifications have addressed criteria for appropriate imaging.⁸ Previous analyses of various guidelines using MUSIC data and other relevant literature led us to develop MUSIC criteria for imaging (table 1). They are quite consistent with current AUA Best Practice recommendations and broader than those that address only patients at low risk.^{9,10}

Prior studies have demonstrated that imaging rates for men with low risk prostate cancer range between 20% and 40%, and there is wide variation among geographic regions.³⁻⁷ For men with intermediate risk disease, imaging recommendations vary and as a consequence use varies in this population.^{5,8} MUSIC provides a unique opportunity to study population based imaging utilization through a prospective database that includes patients from more than 85% of urologists in the state from diverse practices. The collaborative nature of MUSIC allows for the introduction of a multifaceted

intervention aimed at improving appropriate imaging use. Specific implementation strategies are necessary because the distribution of guidelines in isolation often have minimal impact on altering clinical practice.¹¹

To this end, over a 4-year period MUSIC collected baseline data, introduced several interventions to help practices adopt the newer recommendations and then remeasured imaging utilization rates.

MATERIALS AND METHODS

Study Population

MUSIC was established in 2011 as a BCBSM (Blue Cross Blue Shield of Michigan) funded consortium that now comprises 42 practices across Michigan, representing approximately 250 urologists. The goal of MUSIC is to improve the quality and cost efficiency of care for men with prostate cancer in Michigan. A clinical champion from each practice attends 3 collaborative-wide meetings per year and is charged with communication to other members of the practice. MUSIC quality improvement activities obtained exemption or approval from all local institutional review boards.

Trained clinical data abstractors review the medical records of patients undergoing a prostate biopsy or with a new diagnosis of prostate cancer from all participating physicians and enter standardized data elements into a web based registry. Data elements include age, PSA, biopsy date, number of cores taken and biopsy data, including number of cores, number of cores positive, percentage of each core positive, primary and secondary Gleason pattern, GS, clinical stage and imaging with BS or CT related to the staging of disease. BS or CT ordered by the treating physician was distinguished from studies obtained for reasons unrelated to the prostate cancer as well as staging tests ordered by other treating physicians, such as primary care, medical oncology and radiation oncology physicians.

BS or CT was interpreted as positive or negative based on the assessment of the treating physician and, in particular, if treatment was altered by the findings. In cases in which there was ambiguity about the interpretation of the scan, all medical records were reviewed by a senior urologist (JEM) at the MUSIC Coordinating Center and confirmed by the clinical champion. Magnetic resonance imaging data were not evaluated because of infrequent use in the study period and data collection was not yet optimized.

Intervention

The baseline period was calendar years 2012 to 2013. During this period, there were general discussions at MUSIC meetings about decreasing imaging with BS in patients at low risk based on the initial AUA Choosing Wisely recommendations² but no specific

Table 1. MUSIC criteria for imaging men with newly diagnosed prostate cancer

	Bone Scan	CT
PSA (ng/ml)	Greater than 20	Greater than 20
Gleason score	Greater than 8	Greater than 8
Clinical stage	Not applicable*	Greater than cT3

* Not used as clinical variable to determine need for bone scan.

recommendations were put forward. The MUSIC criteria for imaging were developed in 2013 and an implementation strategy was developed early in 2014.^{9,10} Calendar year 2014 was viewed as the transition period during which time implementation of the interventions occurred.

The interventions began with education of clinical champions by a power point presentation on MUSIC imaging criteria at the February 2014 collaborative-wide meeting, which was followed by open discussion. The imaging mantra that we proposed for ordering BS or CT was, "Do it when you should, don't when you shouldn't."

In spring 2014, we developed specific educational materials and toolkits with placards to be posted in the clinic for use by each practice. A slide presentation was developed for clinical champions to present to the rest of the practice. In addition, a script was developed for the urologist to use to educate a patient on the rationale for avoiding imaging when it was not necessary. Specifically noted were the low likelihood of a positive study and the risk of incidental, clinically insignificant findings on BS or CT, which often lead to additional imaging and occasionally invasive testing with a biopsy and the increased costs that the patient may bear.¹²

In spring and summer 2014, site visits were made to 32 practices throughout the state by MUSIC Coordinating Center personnel (DWS and AB). Semistructured interviews were used to gather context sensitive, qualitative data at the practice level and specifically determine how the imaging appropriateness criteria were disseminated and implemented in each practice. In summer and fall 2014, additional presentations were done by clinical champions to their colleagues in the practice and to support personnel. At the October 2014 collaborative-wide meeting, MUSIC criteria for imaging were distributed again and reviewed with the clinical champions, who in turn reinforced the criteria with their partners and staff. Throughout the year, clinical champions were encouraged to review and present imaging performance data of their practice and specifically interact with colleagues who demonstrated more high intensity imaging utilization. The post-intervention period for imaging data was calendar year 2015.

Primary Outcomes

The primary outcome was the use of BS and CT according to MUSIC imaging criteria before and after the quality improvement intervention. MUSIC established a consensus goal to have each individual practice order BS or CT in less than 10% of patients when the MUSIC criteria were not met, but to order imaging in 90% of patients when the criteria were met. Individual practice-to-practice variations in BS and CT use before and after the intervention period were identified.

Statistical Analysis

Descriptive statistics of categorical variables consist of frequencies and proportions. Means, medians and IQRs are reported for continuous variables. The chi-square and Mann-Whitney tests were used to compare the statistical significance of differences in proportions and medians, respectively. All statistical testing was performed with SAS®, version 9.0 at the 5% significance level.

RESULTS

Table 2 presents patient characteristics in the baseline and post-intervention groups. Although there were statistically significant differences in patient characteristics between the baseline and post-intervention groups, the differences were small and not clinically meaningful.

Utilization of both BS and CT in patients who did not meet MUSIC imaging criteria decreased significantly in the pre-intervention and post-intervention periods (fig. 1). From January 1, 2012 through December 31, 2013 and January 1, 2015 through December 31, 2015, 10,554 patients with newly diagnosed prostate cancer were entered into the MUSIC registry. Of these patients 79% (7,442 of 10,554) met our criteria to avoid BS imaging and 78% (7,312 of 10,554) met our criteria to avoid CT imaging. Clinical staging could not be determined in 53 patients, who were excluded from analysis.

In the pre-intervention groups from 2012 to 2013, among patients who met the criteria to avoid imaging with BS, 11% (394 of 3,583) still received BS. In the 2015 post-intervention period the use of BS decreased to 6.5% (250 of 3,859 patients) ($p < 0.0001$). Similarly, a baseline rate of imaging with CT decreased from 14.7% (520 of 3,531 patients) to 7.7% (291 of 3,781) after intervention ($p < 0.0001$). In 2015 improved utilization of MUSIC criteria for imaging saved men in Michigan from undergoing 147 and 223 unnecessary BSs and CTs, respectively.

In addition, variation in the imaging rate among practices decreased markedly between the baseline and post-intervention periods for both BS and CT

Table 2. Characteristics of patients with newly diagnosed prostate cancer stratified by intervention stage

	Baseline	Post-Intervention	p Value
Yrs	2012–2013	2015	
No. pts	4,517	5,019	–
Median age (range)	65 (28–99)	65 (19–100)	–
No. biopsy Gleason score sum (%):			
6 or Less	1,557 (34.5)	1,695 (33.8)	0.03
3 + 4	1,554 (34.4)	1,640 (32.7)	
4 + 3	622 (13.8)	700 (13.9)	
8–10	780 (17.3)	982 (19.6)	
No. ng/ml PSA (%):			
Less than 10	3,641 (81.1)	3,851 (77.2)	<0.0001
10–20	530 (11.8)	702 (14.1)	
Greater than 20	317 (7.1)	435 (8.7)	
No. clinical stage (%):			
T1/T2	4,408 (97.8)	4,825 (97.2)	0.04
T3/T4	98 (2.2)	141 (2.8)	
No. race (%):			
White	3,270 (83.5)	3,916 (82.2)	0.04
Black	532 (13.6)	731 (15.3)	
Other	113 (2.9)	118 (2.5)	
Pos cores (range):			
Median No.	3 (0–30)	4 (1–99)	<0.0001
Mean %	34.7 (1–100)	38.8 (1–100)	<0.0001

Imaging rates when not indicated by MUSIC criteria, Baseline (2012-2013) vs. Post-Intervention (2015)

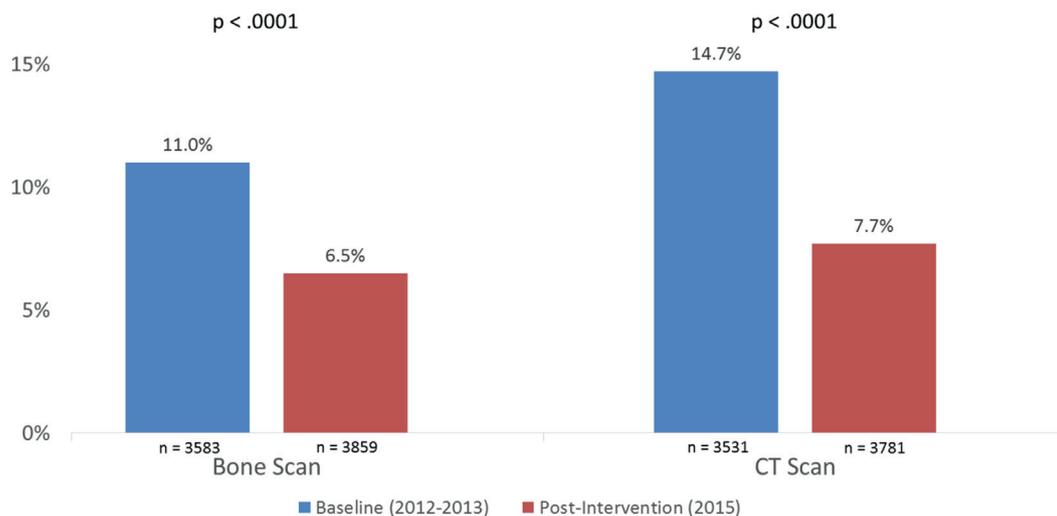


Figure 1. Staging BS and CT use before and after statewide quality improvement intervention among patients who did not meet MUSIC imaging appropriateness criteria.

(fig. 2). All practices that had utilization rates greater than 10% decreased use after interventions and no practice increased use. There was no discernible trend in type of practice and imaging use after intervention by practice size, academic affiliation or location. All types of practices improved.

When recommended, the use of BS imaging increased slightly from 81.6% at baseline to 82.8% after interventions ($p = 0.491$). When recommended, CT imaging remained stable at 74.6% at baseline and after interventions (fig. 3). The rate of positive studies when indicated was 16.7% and 15.4% for BS and CT at baseline, and 16.5% and 15.1%, respectively, after interventions.

Even after the intervention, some patients in whom BS or CT was not indicated by MUSIC criteria still received imaging. In this subset 250 patients underwent BS, which was positive for metastases in 4 (1.6%), and none were low risk. In 2 of the 250 patients (1.2%) the BS results were ambiguous and could not be confirmed. Similarly, 291 patients underwent CT when not recommended, of which 1 CT (0.3%) was positive for metastases.

DISCUSSION

Our data demonstrate successful implementation of imaging criteria that not only decreased the use of low value imaging in patients with newly diagnosed prostate cancer but reduced variation among practices in a population based, statewide

quality improvement collaborative. These changes in processes and subsequent imaging utilization were accomplished by a combination of clinical champion, practitioner and patient education, in-office tool kits, onsite visits by MUSIC coordinating center staff to individual practices, and repetitive presentation and reinforcement of individual, practice and collaborative-wide performance data.

Implementation science is a burgeoning discipline that is more complicated than often appreciated and a discipline with which most practitioners are unfamiliar. Our implementation strategy was straightforward, although labor intensive, but not as complex as other recently reported interventions that use combinations of education, informatics and financial incentives.¹³ Integrating prompts into an electronic medical record was not feasible due to the multitude of practices using different electronic medical records. MUSIC urologists receive no financial incentives, other than data management support, to participate in the quality improvement activities.

Target levels for collaborative-wide performance according to MUSIC criteria were somewhat arbitrarily set at less than 10% use when not indicated, and greater than 90% use when indicated. In general, performance targets greater than 0% or less than 100% use are necessary because there are always going to be unusual circumstances requiring clinical judgment, irrespective of guidelines. For example, in patients in whom imaging was not

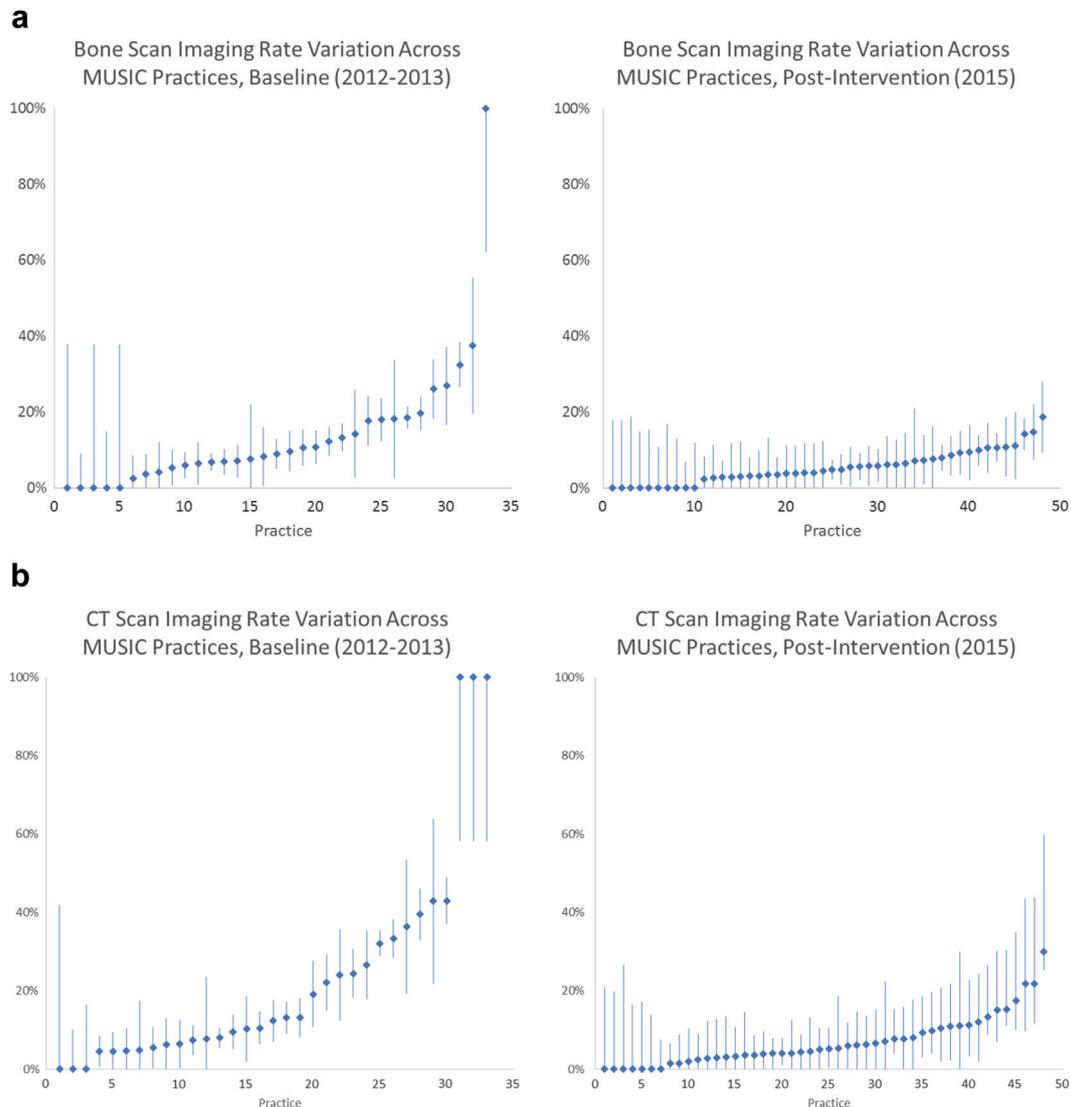


Figure 2. Variation in practice level use of staging imaging at baseline and after intervention for patients who did not meet MUSIC imaging appropriateness criteria. *a*, bone scans. *b*, CT.

indicated, BS or CT may be appropriate because of symptoms such as bone or abdominal pain, respectively. There may also be patients who have an extreme level of anxiety about metastases and, thus, imaging may be appropriate.

In addition, there are going to be patients in a marginal zone in which they may be just in or out of the criteria for imaging but have other clinical or pathological features that cause the urologist to be more or less concerned about metastases. For example, a patient with a single core of GS 4 + 4 but PSA below 10 ng/ml and low clinical stage may be viewed as being at lower risk for metastases and, thus, not need imaging. Conversely, a patient with GS 4 + 3 in 10 of 12 cores with PSA 18 ng/ml and CT2c clinical stage may technically not meet the criteria for imaging but certainly has worrisome

disease and imaging would be reasonable. Because a specific cut point for decision making in a guideline is only a representation of a continuum of risk and not an all or none phenomenon, marginal cases must be acknowledged.

MUSIC criteria proscribe that only about 20% to 30% of all patients with newly diagnosed prostate cancer need imaging. At the outset, practitioners were concerned that positive studies would be missed by performing fewer imaging studies. Additional education about the literature and our MUSIC data helped dispel this concern. The rate of positive BS or CT when indicated remained stable both at baseline and after interventions. The low rate of positive studies in the group that was imaged even when not recommended was also reassuring.

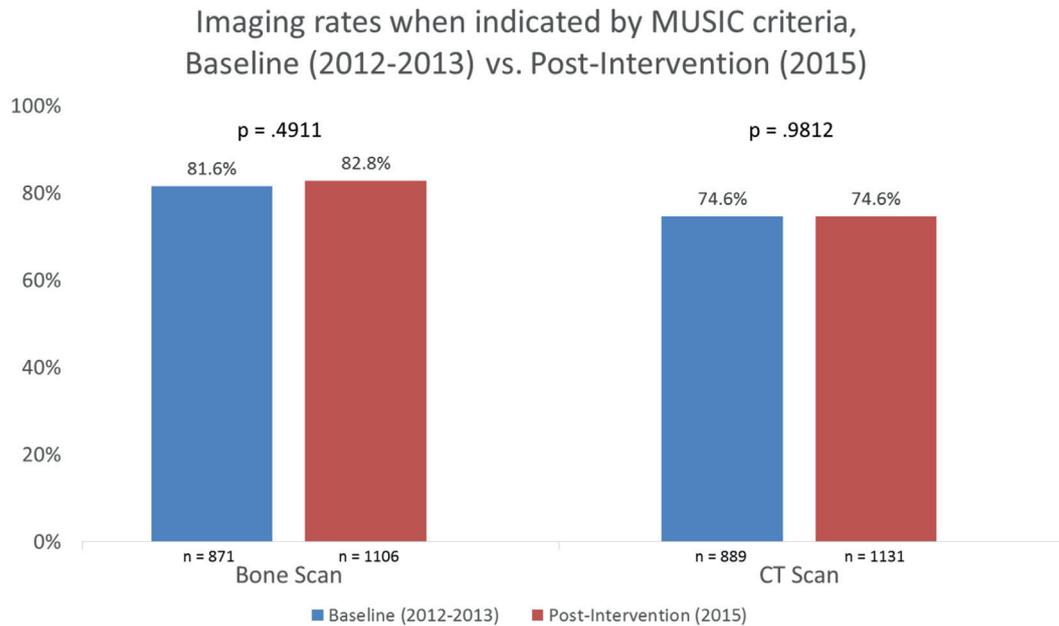


Figure 3. Use of staging BS and CT before and after statewide quality improvement intervention among patients who met MUSIC imaging appropriateness criteria.

While we decreased the use of nonrecommended imaging, we did not observe the so-called thermostat effect, in which all utilization, appropriate or not, is lowered.¹⁴ Our educational efforts on both appropriate and inappropriate imaging criteria may have decoupled the thermostat effect. Failure to substantially increase appropriate imaging may be partially due to the fact that clinicians may take into account other specific patient factors not included in the criteria, such as the number of cores involved, the amount of Gleason pattern 4 cancer or even the economic burden imposed on the patient by the imaging.

Practices that remained high users of imaging after the interventions were high for both BS and CT. This would imply that a practice philosophy toward more aggressive imaging in general drove utilization, rather than financial incentives because of ownership of CT facilities. Six practices remained higher users of CT after intervention and 3 had ownership interests in CT. However, there were many other practices with ownership of CT facilities that did not have high imaging rates, again suggesting that practice philosophy and not ownership are responsible for imaging rates.

Our study has several limitations. The imaging criteria could be the subject of debate but these criteria coincide well with current AUA Best Practice recommendations.⁹ It is feasible that some of the improvement in imaging utilization was due to existing time trends as a consequence of enhanced

publicity about the overuse of imaging. However, the Choosing Wisely Campaign² and other national performance measures have focused only on patients at low risk and not on the more expansive criteria adopted by MUSIC. Choosing Wisely BS criteria were only introduced in 2013 and CT criteria were introduced in 2015.

We also focused only on imaging ordered by urologists in MUSIC and not those ordered by primary care, radiation oncology or medical oncology physicians. We focused on urologists because they were the physicians whom we could influence through the collaborative. Clearly, additional efforts are necessary to educate additional specialties about better utilization of imaging.

Our findings have important implications for medical practice and quality of care initiatives. We have found that the infrastructure in a surgical quality improvement collaborative can effectively modulate imaging practices, improve care, decrease low yield imaging and, thus, improve value for payers.

CONCLUSIONS

An educational intervention by MUSIC in Michigan successfully enhanced the appropriate use of imaging in patients with newly diagnosed prostate cancer. These data confirm the ability of a regional quality improvement collaborative to improve the quality of care for patients with cancer at a population level.

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