A Strategy for Changing Adherence to National Guidelines for Decreasing Laboratory Testing for Early Breast Cancer Patients

Laura A. Hill, MD; Choua A. Vang, BS; Colin R. Kennedy, MD; Jared H. Linebarger, MD; Leah L. Dietrich, MD; Benjamin M. Parsons, DO; Joy L. Hennessy, RN; Lonna M. Theede, RN; Laura K. VanderLei, PA-C; Luis D. Ramirez, MPH; Andrew J. Ernst, BS; Jeffrey Landercasper, MD

ABSTRACT

Introduction: Past studies indicate delays in adoption of consensus-based guideline updates. In June 2016, the National Comprehensive Cancer Network changed its guidelines from routine testing to omission of ordering complete blood cell count (CBC) and liver function tests (LFT) in patients with early breast cancer. In response, we developed an implementation strategy to discontinue our historical practice of routine ordering of these tests in asymptomatic patients.

Methods: The ordering of CBC and LFT for clinical stage I-IIIA breast cancer patients was audited in 2016. In June 2016, we utilized the levers of the National Quality Strategy implementation methodology to enact a system-wide change to omit routine ordering. To measure the plan's effectiveness, guideline compliance for ordering was tracked continually.

Results: Of 92 patients with early stage cancer in 2016, the overall rate of compliance with guidelines for ordering a CBC and LFT was 82% (88/107) and 87% (93/107), respectively. Segregated by the pre- and post-guideline change time period, the compliance rates for ordering a CBC and LFT were 78% and 87% ($P = 0.076$).

Conclusion: In contrast to historical reports of delays in adoption of new evidence-based guideline changes, we were able to quickly change provider practice during the transition from routine ordering to omission of ordering screening blood tests in newly diagnosed patients with early breast cancer.

INTRODUCTION

In patients with newly diagnosed breast cancer, routine blood testing to screen for metastatic disease increases cost but does not improve detection.[1] Specifically, ordering complete blood cell count (CBC) and liver function tests (LFT) add a charge but seldom add value to a patient encounter. Recognizing this, the National Comprehensive Cancer Network (Network) updated its breast cancer care guidelines in 2016 to recommend against routine screening blood tests in patients presenting without symptoms.[2] By doing so, its past recommendation was reversed to not order these tests in patients presenting with early clinical stages of breast cancer. As such, the Network aligned itself with multiple other oncology stakeholders to reduce practices of care that were "overutilized."[3-6]

Our breast center previously has demonstrated high in-house compliance with guidelines for diagnostic evaluation and treatment of patients with breast cancer.[7,8] To maintain compliance, our aim with the initiative described herein was to measure compliance with guidelines for ordering CBC and LFT before and after the calendar date when the guidelines transitioned from routine to unnecessary. To aid this effort, we used the levers endorsed by the Agency for Healthcare Research and Quality in its National Quality Strategy to accelerate our rate of adoption of guideline changes.[9,10]

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Author Affiliations: Department of Medical Education (Hill, Kennedy), Department of Medical Research (Vang, Ramirez, Ernst, Landercasper), Gundersen Medical Foundation, La Crosse, Wis; Department of General Surgery (Linebarger, VanderLei), Department of Medical Oncology (Dietrich, Parsons), Norma J. Vinger Center for Breast Care (Linebarger, Hennessy, Theede, VanderLei, Landercasper), Gundersen Health System, La Crosse, Wis.

Corresponding Author: Jeffrey Landercasper, MD, Gundersen Medical Foundation, 1900 South Ave, Mailstop C03-006B, La Crosse, WI 54601; phone 608.775.5695; fax 608.775.1565; email jlanderc@gundersenhealth.org.

METHODS

Institutional Review Board approval was obtained from the Gundersen Clinic Human Subjects Committee/Institutional Review Board to review our patient registry and electronic medical records for guideline compliance.

In 2013, Proctor et al—for the purpose of clarity, reproducibility, and testing—proposed guidelines for reporting 7 dimensions of an implementation strategy.[11] Insofar as possible, the description of our implementation strategy is compliant with these recommendations.

Compliance Culture

The study was performed in an interdisciplinary breast center accredited by the National Accreditation Program for Breast Centers. Since 2009, our compliance with guidelines for breast cancer care has been audited during "real time" patient contact by use of an electronic synoptic template embedded within our electronic medical record.[7,8] Trained abstractors entered this data into a patient registry. Furthermore, as patients were presented at tumor board, their providers or other tumor board members described whether their care plan was compliant with guidelines. Deviations prompted discussion. When applicable, guidelines and Consensus Statements, including but not limited to those of the American Society of Clinical Oncology, the Society of Surgical Oncology, the American College of Radiology, the American Society for Therapeutic Radiology and Oncology, and the American Society of Breast Surgeons, were also cited during discussions in real time during an interdisciplinary clinic in which all specialists saw the patient in the same geographic location on the same day. Additionally, one of two breast nurse navigators met with every patient. In doing so, they aided our compliance culture because historically these navigators were up-to-date with recommendations for diagnostic testing and treatment. The navigators were always encouraged to speak up whenever they recognized guideline deviations, including those related to preoperative testing.

Patients and Outcome Measurements

Breast cancer patients with early stage breast cancer [Clinical Stage I, II, and IIIA (T3N1M0)] presenting from January 1, 2016 through December 31, 2016 were identified. Patients were excluded from review if they were diagnosed during June, the month of the change in the guidelines ("washout" period) or if they presented with signs or symptoms suggestive of metastatic disease, stage greater than IIIA, prior history of breast cancer, recurrent breast cancer, or a recent nonbreast cancer diagnosis. Frequency of ordering CBC and LFTs (overall and per provider), subsequent testing prompted by abnormal results, and overall compliance with guidelines were entered into an Excel spreadsheet. If the patient underwent neoadjuvant chemotherapy, then ordering the CBC and LFTs was considered guideline compliant. In order to assess hospital charges and patient cost for laboratory testing, all patient charges were converted to Medicare equivalent dollars.

Institutional Setting

Gundersen is part of a physician-led, not-for-profit integrated health care system serving 19 counties in Wisconsin, Iowa, and Minnesota (estimated population > 500,000). The main facility is a 325-bed regional referral hospital with attached outpatient clinical space, located in a city with a population of about 50,000. The system includes 30 regional clinics and 5 rural hospitals. A comprehensive interdisciplinary breast center is housed on the primary clinic campus, but also provides outreach diagnostic breast imaging at 5 rural sites. Weekly breast cancer tumor boards are held on the main campus and patients under the care of rural surgeons are presented as requested. The system is fully integrated with an electronic medical record that is consistent between the primary hospital and all branch clinics. The medical center supports more than 10 residency training programs and has been designated the Western Academic Campus of the University of Wisconsin (UW) School of Medicine and Public Health. About half of all UW medical students have 1 or more rotations at our institution.

At the main campus, approximately 200 new patients receive a diagnosis of breast cancer each year. During the study period, patient care and "privileges" to order blood tests were provided by 4 fellowship-trained breast radiologists, 6 medical oncologists, 4 radiation oncologists, and 2 surgeons. As part of our institutional policy to comply with the Standards of the National Accreditation Program for Breast Centers, at least 1 representative from all these service lines was required to attend all tumor boards and forward any new guideline or breast center policy change to their respective departments.

Implementation Strategy

The study implementation strategy to change ordering of blood tests utilized the levers of the National Quality Strategy.[9,10] Beginning at the time of changes in the guideline (June 1, 2016), the planned levers included those described below.

This strategy was implemented entirely by the authors without formal involvement by nonmedical quality improvement staff. After study completion, the results were shared with the Quality Department, the Cancer Committee, the National Accreditation Program for Breast Centers site reviewer, and each in-house breast cancer provider of care.

1) Learning and Technical Assistance – PowerPoint presentations were delivered at 2-month intervals beginning June 2016 by a surgical resident-in-training (LH), a medical student (CK), and the principal investigator (JL). During these presentations, changes in breast cancer guidelines for testing were cited. In addition, the general topic of testing appropriateness, as recommended by the American Board of Internal Medicine's Choosing Wisely® campaign, was presented along with examples from the literature as overutilization of testing in breast cancer care.[3-6] Furthermore, a concurrent National Cancer Institute-funded Wisconsin quality initiative that aimed to add value to breast cancer care by decreasing unnecessary testing was discussed.[12] Other presentations were delivered on June 3, 2016 and July 28, 2016. Each of these included measurement and feedback as discussed below. Lastly, the guideline changes for testing were cited during numerous individual patient presentations at weekly tumor boards for

Table. Patient Characteristics Pre- and Post-Change in National Comprehensive Cancer Network Guidelines for Ordering CBC and LFTs

Variable	Pre-Guideline Change n = 40	Post-Guideline Change n = 52	*P* Value
Mean age, years	63.8 ± 15.3	61.9 ± 11.8	0.519
Sex, n (%)			0.999
Female	38 (95)	50 (96)	
Male	2 (5)	2 (4)	
Stage, n (%)			0.071
0	1 (3)	0	
1A	31 (78)	30 (58)	
2A	7 (18)	16 (31)	
2B	1 (3)	6 (12)	

Abbreviations: CBC, complete blood cell count; LFT, liver function test.

3 months following the date of the guideline change. The tumor board audience included but was not limited to physicians, residents/fellows-in-training, medical students, associate providers, and support staff (breast nurse navigators, oncology nurses, medical assistants, and research associates).

2) Measurement and Feedback – After initial implementation of our improvement strategy, an academic researcher (AV) audited the patient's electronic medical record for guideline compliance at both the individual ordering provider level and in the aggregate. With these results, we provided peer performance comparisons (benchmarking) with full transparency to providers and tumor board attendees by disclosing individual ordering provider performance compared to others. These presentations were performed on October 7, 2016 and January 20, 2017.

3) Certification, Accreditation, and Regulation – For educational presentations, we developed specific questions that would qualify for continuing medical education credits.

4) Innovation and Diffusion (of quality improvement strategies) – After introduction of the project described here, there was uniform agreement by tumor board participants with the concept of creating a program to rapidly comply with the updated guidelines, consistent with our recognition of the importance of a day-to-day local quality culture.

5) Workforce Development – Existing within our health care system was a structure in which department chairs, service line directors, and nonphysician administrative leaders had already undertaken education regarding health care quality improvement science as described by the Institute for Healthcare Improvement.[13]

6) Consumer Incentives and Benefits Designs – Information fact sheets containing information on the guidelines were created for patient education at their initial appointment. In these, patients would be encouraged to discuss lab testing and imaging with their provider, as recommended in the Choosing Wisely campaign.[3-6]

7) Payment – To reward and incentivize providers, a plan was discussed to reward them for high guideline compliance with gift certificates to local restaurants.

8) Health Information Technology – Modifications to our existing electronic medical record synoptic documentation template for new breast cancer patients were completed. This included a prompt that would alert providers not to order preoperative CBC and LFTs for patients with early stage I-IIIA breast cancer. If labs were ordered for these patients, a prompt would require documentation of the necessity.

Performance Transparency and Provider Feedback

After initiation of our interventions and a washout period of 1 month (June 2016), we collected, compared, and presented prospective data over the next 6 months (July 1, 2016 through December 31, 2016) to the tumor board. As with our retrospective collection, we looked at overall and per provider compliance with guideline changes, indications for laboratory testing when ordered, and further testing/findings if there were abnormal test results.

Analysis

Analyses included simple frequencies and comparisons of guideline compliance before and after our implementation strategy. We also looked for associations between provider, patient age and stage with guideline compliance by univariate analyses (Fisher's exact test). A P value < 0.05 was considered significant. Trend analyses of guideline compliance overall and by provider at monthly intervals, univariate analyses of test charges by provider, and multivariate analysis of provider and patient characteristics were not appropriate due to small sample sizes. There were 2 patients for which no charge data were available so these patients were excluded from charge analyses. No a priori benchmark (target goal) was established before the date of the implementation strategy, but there was recognition that 100% compliance with breast cancer guidelines was not an appropriate benchmark.[14]

RESULTS

One hundred seven patients presented with early stage breast cancer; 15 patients presented during the June washout period. Overall, 96% (103/107) were female and 4% (4/107) were male. Mean age was 62.8 ± 13.6 years. Distribution of patient age, sex and stages before and after the date of guideline changes were similar (Table).

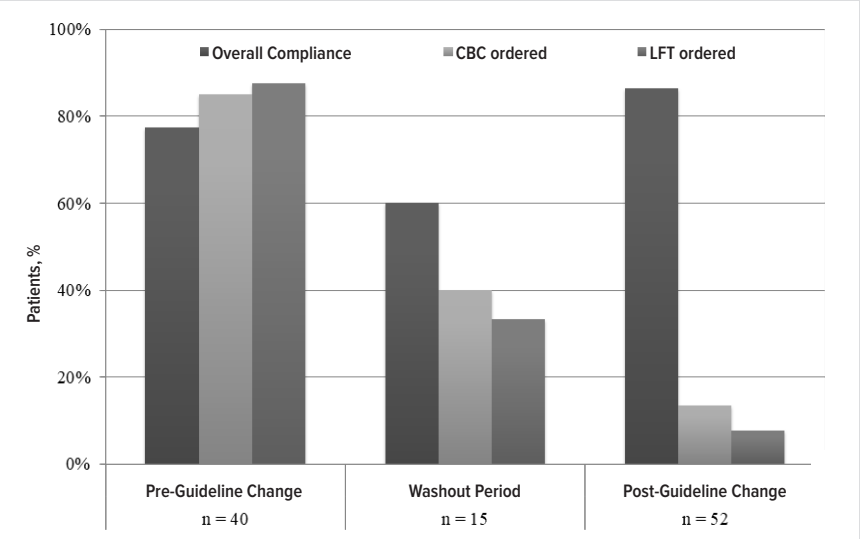
The overall compliance during the entire study time period for ordering a CBC and LFT was 82% (88/107) and 87% (93/107), respectively. Compliance stratified by the pre- and post-guideline change time periods is shown in the Figure. The compliance rate for ordering an individual CBC, stratified by the pre- and post-guideline change time periods, was 85% (34/40) and 87% (45/52) [$P = 0.834$]; for LFT, it was 88% (35/40) and 92% (48/52) [$P = 0.495$]. The mean charge per patient was $97.65 in the pre-guideline period versus $16.96 in the post-guideline period.

Tumor board attendance after the implementation strategy date averaged 14 providers (range 10-19). All tumor boards had at least 1 representative present from each service line that ordered blood tests.

National Quality Strategy Lever Implementation

Levers 1 through 5 described previously were implemented without difficulty. Levers 6 (consumer incentive) and 7 (provider financial incentive) were deemed unnecessary because measured compliance remained high during all audits. Lever 8 (an electronic ordering prompt to recommend against testing) was not available until near the study completion date and therefore did not contribute to guideline compliance.

Figure. Compliance With National Comprehensive Cancer Network Guidelines Over Time



Abbreviations: CBC, complete blood cell count; LFT, liver function test.

DISCUSSION

The evidence for unacceptable variability in the overall quality and cost of health care in the United States is indisputable.[15] In the population of patients with cancer, variability of care also exists as well as evidence of overutilization of tests and treatments. These have been well documented in seminal publications generated by the National Academy of Medicine (formerly the Institute of Medicine), the American Society of Clinical Oncology and others.[3,16-18] Recent examples include delays in the adoption of better diagnostic methods, such as needle biopsy instead of an open surgical biopsy for the diagnosis of breast cancer, and delays in omitting therapies, when safe, such as offering patients omission of postlumpectomy radiation after breast conserving surgery if they receive oral anti-estrogen treatment and are otherwise similar to the patients enrolled in the CALGB 9343 randomized trial.[19,20] Variability of care has even been documented within the participating institutions that constitute the National Comprehensive Cancer Network.[21]

Along with variability, there is increasing recognition of overutilization of care.[3-5,18] For example, Simos et al documented that noncompliant and unnecessary systemic imaging to screen for metastatic disease was performed in nearly 80% of early stage breast cancer patients in Ontario, Canada between 2007 and 2012, and in 2017 identified that over one-third of asymptomatic clinical Stage II breast cancer patients had receipt of chest computed tomography, non compliant with guidelines.[22] As a result of many similar studies, more than 100 professional organizations, including oncology societies, have submitted lists of costly tests and procedures that may not be necessary for optimal patient care.[3-6,22] Such is now the case, for routine ordering of CBC and LFT in patients with early breast cancer.

The National Comprehensive Cancer Network has been a leader in addressing the concerns of overutilization of care by creating evidence- and consensus-based guidelines to improve care and to limit delays in adoption of best practices.[23-25] The efficacy of using its guidelines to improve care has been documented in numerous publications that used compliance with their guidelines as a measure of the quality of care.[25,26]

Despite a robust literature describing delays in the adoption of new evidence- and consensus-based medicine, quick adoption of new changes in guidelines was identified in the in-house audits described here. Guideline compliance has long been part of the established safety and best-practice culture within our institution, as demonstrated by our efforts to monitor compliance with them for more than a decade.[7,8] This is aided by a highly integrated health care system with weekly multidisciplinary clinics and conferences.

Reproducibility

Replicating our findings of rapid adoption of guideline changes could be challenging in less integrated health care systems. For example, we have a physical infrastructure outside of tumor board that promotes ease of interdisciplinary communication as guidelines change. With this structure, all subspecialists and nurse navigators can see the patient concurrently or sequentially (in the same examination room) during breast cancer clinic. Before or after examinations, the entire team can then meet in an adjacent conference room to discuss the patient findings and care guidelines. We also have interoperability of electronic medical records and funding for academic research assistants to audit performance metrics. In the absence of such infrastructure, we would encourage care providers in less integrated systems to utilize real or virtual interdisciplinary tumor boards as a forum to update

providers on guideline changes. Even without interoperability of medical records, electronic synoptic templates can be harmonized between different providers, allowing less burdensome performance tracking.[7] Lastly, implementation strategies that use the National Quality Strategy levers are available to all health care systems.

Study Strengths and Limitations

Our institution has a history of high breast cancer guideline compliance.[7,8] A strength described here is the demonstration that we were able to rapidly achieve guideline deimplementation. By de-escalating the prior routine ordering of preoperative CBC and LFT, we maintained high compliance. As such, we provide support for all providers to adopt continuous quality improvement strategies as a methodology to deliver uninterrupted high quality patient care.[27]

A limitation of our study is that the small sample size and the structure of our breast center limit the generalizability of our findings to other settings.

CONCLUSION

A planned implementation strategy using 7 levers of the National Quality Strategy was successfully executed, resulting in consistently high and sustainable guideline compliance. We believe this format can lead to timely implementation of new evidence-based guidelines at other institutions as well.

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